

UTI ENDPOINTS CLASSIFICATION AND ADJUDICATION FORM

ID NUMBER:							
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FORM CODE: ADJ
VERSION: A 10/23/07

Contact
Occasion

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SEQ #

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Instructions: This form is to be completed by each assigned Endpoints Committee reviewer for every Study Adjudication Packet, documenting the review and adjudication of Study Endpoints.

A. MCID Number

1. Primary MCID Number associated with adjudication packet:

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BLIND_MCID

B. FEVER

2. Was there a documented fever of at least 100.4°F or 38°C, measured anywhere on the body either at home or at a medical facility?..... Y

N → Go to Item 6

ADA2

3. Was there a documented fever of at least 100.4° F or 38°C, **within 24 hours** of a (positive) urine collection? Y

N → Go to Item 6

ADA3

4. Measurement source of fever (occurring within 24 hours)?

Home..... H

During medical visit..... M

Both (home and during medical visit) B

ADA4

5. Data source of fever (within 24 hours) report:

MCN form..... N

MCA form..... A

Both MCN and MCA B

ADA5

C. SYMPTOMS

6. Was there documentation of UTI symptoms occurring with this event (list below)?..... Y

N → Go to Item 9

ADA6

7. Was there documentation of UTI symptoms occurring **within 24 hours** of a (positive) urine collection? Y

N → Go to Item 9

ADA7

8. For each of the symptoms listed below, indicate whether there is documentation of occurrence occurring **within 24 hrs** of the urine culture, and indicate the source of the report. Select one answer for each column (Y=yes, N=no, U=unknown, X=does not apply).

Symptoms Documented within 24 hrs of Urine Culture Collection

1. MCN

2. MCA Parent Complaint

3. MCA Medical Findings

a. Suprapubic, abdominal, or flank pain or tenderness

ADA8A1

Y N U

Y N U

ADA8A2

Y N U

ADA8A3

b. Urinary urgency, frequency, hesitancy

ADA8B1

Y N U

Y N U

ADA8B2

Y N U

ADA8B3

c. Dysuria

ADA8C1

Y N U

Y N U

ADA8C2

Y N U

ADA8C3

d. Foul smelling urine

ADA8D1

Y N U

Y N U

ADA8D2

Y N U

ADA8D3

e. Failure to thrive (<= 4 months old)

ADA8E1

Y N U X

Y N U X

ADA8E2

Y N U X

ADA8E3

f. Dehydration (<= 4 months old)

ADA8F1

Y N U X

Y N U X

ADA8F2

Y N U X

ADA8F3

g. Hypothermia (<= 4 months old)

ADA8G1

Y N U X

Y N U X

ADA8G2

Y N U X

ADA8G3

ID NUMBER:							
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D. PYURIA

9. Was urine tested for pyuria? Y N → **Go to Item 12** **ADA9**

10. Date of urine sample for pyuria assessment (mm/dd/yyyy):

 /

 /

ADA10

11. Pyuria results:

Positive Leukocyte Esterase (≥ trace) L

Positive WBC count (≥ 10 WBC/mm³ or ≥ 5 WBC/hpf) W **ADA11**

Both (positive leukocyte and WBC) B

No pyuria present N

E. CULTURE

12. Was a urine culture performed? Y N → **Go to Item 15** **ADA12**

13. Date of urine culture sample collection (mm/dd/yyyy):

 /

 /

ADA13

14. Positive culture based on study requirements Y N U **ADA14**

- Single primary organism, (neither lactobacillus nor candida)
- ≥ 50,000 CFU/ml (catheterized or suprapubic) OR
- ≥ 100,000 CFU/ml (clean-voided Specimen)
- Single contaminating organism present < 5,000 cfu/ml

At the 11/13/07 Steering Committee meeting it was decided to change the cutpoint from < 5,000 cfu/ml to < 10,000 cfu/ml

F. ADMINISTRATIVE INFORMATION

15. Endpoint Assessment Result:

Definite study UTI D

Persistent UTI (a treated study UTI, never resolved) P → **Go to Item 17**

Not a study UTI, possibly a clinical UTI C → **Go to Item 17** **ADA15**

No study UTI, not a clinical UTI N → **Go to Item 17**

16. What kind of study UTI occurred:

Febrile UTI (FUTI) F **ADA16**

Symptomatic Non-febrile UTI (SUTI) S

17. Comments: Y N **ADA17**

18. Date of endpoint review/adjudication (mm/dd/yyyy):

 /

 /

ADA18

19. Method of data collection (circle one):

Computer C **ADA19**

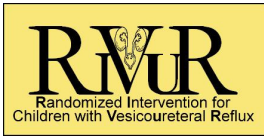
Paper P

20. Endpoint Reviewer's initials (if adjudication, record initials of all participants): a.

b.

c.

BLIND_STAFF_ID



ADVERSE EVENTS FORM

ID NUMBER:							
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FORM CODE: AEF
VERSION: B 10/12/09

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instructions: This form is to be completed for all study medication side effects, adverse events, or serious adverse events reported during the study. If item 14 is 'Y' and item 17 is 'C, D, or E' then complete MEDWATCH form FDA 3500A.

A. SIDE EFFECTS AND (SERIOUS) ADVERSE EVENTS

1. Onset date of side effect/(serious) adverse event (mm/dd/yyyy):.....

/

/

AEF1

2a. [PC] Diagnosis or symptom: _____ AEF2A

2b. [PC] Costart Preferred Term: _____ AEF2B

3. How often did your child have the [problem] since our last study contact (mm/dd/yyyy)? (*Read responses, circle one.*)

Rarely R
Sometimes S
Often O
Not Applicable N

AEF3

AEF2C - COSTART
CODE Value entered
into the DMS based
on what was entered
in item AEF2B

4. How much did the [problem] affect your child's activities? (*Read responses, circle one.*)

None N
A little L
A lot A

AEF4

5. When your child had the [problem], was it (*read responses, circle one*):

Mild M
Moderate D
Severe S
Not Applicable N

AEF5

6. Overall, how much did the [problem] bother your child? (*Read responses, circle one.*)

None N
A little L
A lot A

AEF6

7. Do you think the [problem] was caused by the study medication? (*Read responses, circle one.*)

No N → Go to Item 9
Yes Y
Don't know D → Go to Item 9

AEF7

ID NUMBER:							
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FORM CODE: AEF
VERSION: B 10/12/09

Contact Occasion		
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SEQ #		
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Line Number		
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Participant Name: _____

8. Overall, how much of a problem has this medication side effect been for your child? (*Read responses, circle one.*)

Not a problem N
Mild problem M
Moderate problem D
Severe problem S

AEF8

AEFA9

9 a. Did you seek any medical care for this [problem]? Y → **Complete MCN/MCA** N → **Go to Item 11**

b. Where did the medical care take place?

Emergency room visit E
Hospitalization H
Both emergency room and hospitalization B
Other O
If other, specify _____

AEFB9B

10. [PC] Record assigned MCID #: _____

BLIND_MCID

NOTE: Report the MCID # found on the MCN and MCA forms that correspond to this [problem].

11. [PC] How severe was the side effect/(serious) adverse event? (Circle one.)

Note: Refer to QxQ for standardized criteria on severity.

Mild M
Moderate D
Severe S
Life-threatening L
Death E

AEF11

12. [PC] Study action taken:

Yes

No

a. None Y
b. Treated at RIVUR clinic Y
c. Referred Y
d. Study drug temporary discontinued Y
e. Study drug permanently discontinued Y
f. Medical intervention Y
g. Surgical intervention Y
h. Hospitalization Y
i. Other Y

Go to Item 13

N AEF12A
N AEF12B
N AEF12C
N AEF12D
N AEF12E
N AEF12F
N AEF12G
N AEF12H
N AEF12I

If other, specify _____

13. [PC] Does this [problem] fit the definition of an SAE? Y

N → **Go to Item 22** AEF13

B. SERIOUS ADVERSE EVENT

14. [PC] Was this an unexpected serious adverse event? Y

N AEF14

ID NUMBER:							
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FORM CODE: AEF
VERSION: B 10/12/09

Contact Occasion		
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SEQ #		
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Line Number		
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Participant Name: _____

15. **[PC]** Describe more fully the serious adverse event: Y **AEF15**

16. **[PC]** Category of SAE:

- | | | | |
|--|---|---|---------------|
| a. Death | Y | N | AEF16A |
| b. Immediately life-threatening..... | Y | N | AEF16B |
| c. Persistent / significant disability / incapacity..... | Y | N | AEF16C |
| d. Hospitalization / prolonged hospitalization | Y | N | AEF16D |
| e. Serious as assessed by the Investigator | Y | N | AEF16E |
| f. Laboratory toxicity..... | Y | N | AEF16F |
| g. Other | Y | N | AEF16G |

If other, specify: _____

17. **[PC]** Relationship of serious adverse event to study medication (*circle one*):

- | | | |
|-----------------------------|---|--------------|
| Definitely unrelated..... | A | |
| Unlikely to be related..... | B | |
| Possibly related | C | AEF17 |
| Probably related | D | |
| Definitely related..... | E | |

18. **[PC]** Relationship of serious adverse event to study research (*circle one*):

- | | | |
|-----------------------------|---|--------------|
| Definitely unrelated..... | A | |
| Unlikely to be related..... | B | |
| Possibly related | C | AEF18 |
| Probably related | D | |
| Definitely related..... | E | |

19. **[PC]** Outcome of event at time of reporting (*circle one*):

- | | | |
|-------------------------------------|---|------------------------|
| Resolved | A | |
| Recovered with minor sequelae..... | B | |
| Recovered with major sequelae..... | C | AEF19 |
| Condition still present | D | → Go to Item 21 |
| Condition continues to worsen | E | → Go to Item 21 |
| Patient died | F | |

20. **[PC]** Date of event resolution or death (mm/dd/yyyy): **AEF20**

FORM CODE: AEF
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Contact
OccasionSEQ #

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Participant Name:

Line
Number

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21. **[PC]** SAE reviewed and authorized by (name of investigator):

[illegible]

22. Date of data collection (mm/dd/yyyy): / / AEF22

23. Method of data collection (*circle one*):

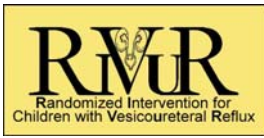
Computer C

Paper P

24. Recorder's initials:

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BLIND STAFF ID



ADVERSE EVENTS FORM

ID NUMBER:							
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FORM CODE: AEF
VERSION: A 10/24/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instructions: This form is to be completed for all study medication side effects and serious adverse events reported during the study. If item 14 is 'Y' and item 17 is 'C, D, or E' then complete MEDWATCH form FDA 3500A.

A. SIDE EFFECTS AND SERIOUS ADVERSE EVENTS

1. Onset date of side effect/serious adverse event (mm/dd/yyyy):

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 /

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 /

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--	--

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AEF1

2a. **[PC]** Diagnosis or symptom: _____ **AEF2A**

2b. **[PC]** Costart Preferred Term: _____ **AEF2B**

3. How often did your child have the [problem] since our last study contact (mm/dd/yyyy)? (Read responses, circle one.)

Rarely R
Sometimes S
Often O
Not Applicable N

AEF3

**AEF2C - COSTART
CODE Value entered
into the DMS based
on what was entered
in item AEF2B**

4. How much did the [problem] affect your child's activities? (Read responses, circle one.)

None N
A little L
A lot A

AEF4

5. When your child had the [problem], was it (read responses, circle one):

Mild M
Moderate D
Severe S
Not Applicable N

AEF5

6. Overall, how much did the [problem] bother your child? (Read responses, circle one.)

None N
A little L
A lot A

AEF6

7. Do you think the [problem] was caused by the study medication? (Read responses, circle one.)

No N
Yes Y
Don't know D

→ **Go to Item 9**

AEF7

→ **Go to Item 9**

ID NUMBER:							
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FORM CODE: AEF
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Contact
Occasion

--	--

SEQ #

--	--

Line
Number

--	--

Participant Name: _____

8. Overall, how much of a problem has this medication side effect been for your child? (*Read responses, circle one.*)

Not a problem N
Mild problem M
Moderate problem D
Severe problem S

AEF8

9. Did you seek any medical care for this [problem]? Y → **Complete MCN** N → **Go to Item 11** AEF9

10. [PC] Record assigned MCID #: BLIND_MCID

NOTE: Report the MCID # found on the MCN and MCA forms that correspond to this [problem].

11. [PC] How severe was the side effect/serious adverse event? (Circle one.)

Note: Refer to QxQ for standardized criteria on severity.

Mild M
Moderate D
Severe S
Life-threatening L
Death E

AEF11

12. [PC] Study action taken:

Yes

No

a. None Y → **Go to Item 13**
b. Treated at RIVUR clinic Y
c. Referred Y
d. Study drug temporary discontinued Y
e. Study drug permanently discontinued Y
f. Medical intervention Y
g. Surgical intervention Y
h. Hospitalization Y
i. Other Y

N AEF12A
N AEF12B
N AEF12C
N AEF12D
N AEF12E
N AEF12F
N AEF12G
N AEF12H
N AEF12I

If other, specify _____

13. [PC] Does this [problem] fit the definition of an SAE? Y N → **Go to Item 22** AEF13

B. SERIOUS ADVERSE EVENT

14. [PC] Was this an unexpected serious adverse event? Y N AEF14

15. [PC] Describe more fully the serious adverse event: Y AEF15

ID NUMBER:							
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FORM CODE: AEF
VERSION: A 10/24/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

16. [PC] Category of SAE:

- | | | | |
|---|---|---|--------|
| a. Death | Y | N | AEF16A |
| b. Immediately life-threatening..... | Y | N | AEF16B |
| c. Persistent / significant disability / incapacity | Y | N | AEF16C |
| d. Hospitalization / prolonged hospitalization | Y | N | AEF16D |
| e. Serious as assessed by the Investigator | Y | N | AEF16E |
| f. Laboratory toxicity | Y | N | AEF16F |
| g. Other | Y | N | AEF16G |
- If other, specify: _____

17. [PC] Relationship of serious adverse event to study medication (*circle one*):

- | | | |
|------------------------------|---|-------|
| Definitely unrelated..... | A | |
| Unlikely to be related | B | |
| Possibly related | C | AEF17 |
| Probably related | D | |
| Definitely related..... | E | |

18. [PC] Relationship of serious adverse event to study research (*circle one*):

- | | | |
|------------------------------|---|-------|
| Definitely unrelated..... | A | |
| Unlikely to be related | B | |
| Possibly related | C | AEF18 |
| Probably related | D | |
| Definitely related..... | E | |

19. [PC] Outcome of event at time of reporting (*circle one*):

- | | | |
|-------------------------------------|---|---------------|
| Resolved | A | |
| Recovered with minor sequelae..... | B | |
| Recovered with major sequelae..... | C | AEF19 |
| Condition still present | D | Go to Item 21 |
| Condition continues to worsen | E | Go to Item 21 |
| Patient died | F | |

20. [PC] Date of event resolution or death (mm/dd/yyyy):

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 /

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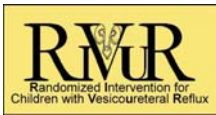
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AEF20

21. [PC] SAE reviewed and authorized by (name of investigator):

	BLIND_AUTHORITY
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BASELINE DEMOGRAPHIC FORM

ID NUMBER:						
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FORM CODE: BDF
VERSION: A 01/26/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is completed during baseline data collection, based on parent/guardian response. Y, N, U, R indicates Yes, No, Unknown, Refused.

A. ETHNICITY / RACE

1. Is your child of Hispanic ethnicity (origin)? Y N U R BDFA1
2. Which of the following best describes your child's race? (Answer each.)
- | | | | | | |
|--|---|---|---|---|--|
| a. White | Y | N | U | R | BDFA2A |
| b. Black or African-American | Y | N | U | R | BDFA2B |
| c. Asian | Y | N | U | R | BDFA2C |
| d. Native Hawaiian or Other Pacific Islander | Y | N | U | R | BDFA2D |
| e. American Indian or Alaska Native | Y | N | U | R | BDFA2E |
| f. Other | Y | N | U | R | BDFA2F |
1. If other, please specify: _____ BDFA2F1

See
additional
derived race
variables in
derv_nikkk1

B. HOME / EDUCATION / OCCUPATION

3. How many days per week does your child live in the **primary** household, the home in which your child lives most of the time? ☐ BDFA3
4. What is the number of adults (aged 18 years or older) living in the primary household? ☐ BDFA4
5. What is the number of children (aged less than 18 years) living in the primary household? ☐ BDFA5
- 6a. What is the highest level of education completed by the primary care-giver? (Circle one.) BDFA6A
- | | |
|---|---|
| Less than high school | A |
| Some high school | B |
| High School diploma/GED | C |
| Some college or 2-year degree/certificate | D |
| College graduate | E |
| Post-graduate | F |
| Refused | G |
| Unknown | H |
- 6b. What is the primary care-giver's sex? M F BDFA6B

ID NUMBER:							
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FORM CODE: BDF
VERSION: A 01/26/07

Contact
Occasion

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SEQ #

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7a. What is the highest level of education completed by the secondary care-giver?
(Circle one.)

BDFA7A

- Less than high school A
- Some high school B
- High School diploma/GED C
- Some college or 2-year degree/certificate D
- College graduate E
- Post-graduate F
- Refused G
- Unknown H
- No secondary care-giver I →

Go to Item 8

7b. What is the secondary care-giver's sex? M

F

BDFA7B

C. RESOURCE INFORMATION

8. What is the current total annual income in your child's primary household? (Use BDF Response Card #1.)

BDFA8

- Under \$13,500 A
- \$13,500 – 23,499 B
- \$23,500 – 33,499 C
- \$33,500 – 57,999 D
- \$58,000 – 99,999 E
- \$100,000 – 149,999 F
- \$150,000 and above G
- Don't know H
- Refused I

9. What medical insurance does your child currently have? (Answer each.)

- | | | | | | |
|---|---|---|---|---|---------------|
| a. Commercial insurance | Y | N | U | R | BDFA9A |
| b. Tricare (formerly CHAMPUS) | Y | N | U | R | BDFA9B |
| c. Medicaid or other state-promoted program | Y | N | U | R | BDFA9C |
| d. No insurance | Y | N | U | R | BDFA9D |
| e. Other | Y | N | U | R | BDFA9E |
1. If other, please specify: _____ **BDFA9E1**

10. Is your child's primary household currently receiving public assistance (include WIC, food stamps, SSI)? (Circle one.)

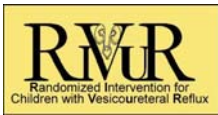
Y

N

U

R

BDFA10



BASELINE MEDICAL HISTORY FORM

ID NUMBER:						
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FORM CODE: BMH
VERSION: A 01/25/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form should be completed during the child's baseline clinic visit with input from the parent(s)/guardian.

A. NATAL HISTORY

1. Was your child ever breastfed? Y N → **Go to Item 4** **BMHA1**
2. What age did you add formula or other foods to your child's diet
(months)?

--	--

BMHA2
(99=current breastfed only)
3. What age did your child stop breastfeeding (months)?

--	--

BMHA3
(99=current breastfed)

B. MEDICATION HISTORY

4. How many times in the past 6 months has your child been
prescribed antibiotics for illnesses such as ear infections,
bronchitis, and other respiratory tract infections?

--	--

BMHA4
5. Has your child ever been prescribed a prophylactic antibiotic that
was taken longer than 3 months? Y N **BMHA5**
6. Is your child currently taking any prescription or over-the-counter
medications, including anti-microbials? Y → **Complete CMF** N **BMHA6**

C. VOIDING HISTORY

7. Has your child been toilet-trained for urine during the day (out of
diapers and pull-ups, wearing underwear)? Y N → **Go to Item 9** **BMHA7**
8. How old was your child when he/she began urinating in the toilet or
potty by him/herself during the day (months)?

--	--

BMHA8

D. BOWEL HISTORY

9. Has your child been toilet-trained for bowel movements? Y N → **Go to Item 12** **BMHA9**

ID NUMBER:						
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FORM CODE: BMH
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SEQ #

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10. How old was your child when he/she began defecating in the toilet or potty by him/herself (months)?

--	--

BMHA10
11. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool? Y N **BMHA11**
12. During the last 2 months, how many bowel movements did your child have per week on average?

--	--

BMHA12
13. Does your child have a history of constipation? Y N **BMHA13**
14. Has your child ever been treated for constipation? Y N **BMHA14**

E. FAMILIAL MEDICAL HISTORY

15. Does your child have any blood relatives with any of the following medical conditions?
(Circle one for each family category. An X response indicates not applicable.)

	1. Full or Half-Siblings				2. Parents			3. Grandparents		
a. Recurrent childhood UTIs	Y	N	U	X	BMHA15A1	Y	N	U	BMHA15A2	Y N U BMHA15A3
b. Vesicoureteral reflux	Y	N	U	X	BMHA15B1	Y	N	U	BMHA15B2	Y N U BMHA15B3
c. Hypertension	Y	N	U	X	BMHA15C1	Y	N	U	BMHA15C2	Y N U BMHA15C3
d. Chronic kidney disease	Y	N	U	X	BMHA15D1	Y	N	U	BMHA15D2	Y N U BMHA15D3
e. Dialysis treatment	Y	N	U	X	BMHA15E1	Y	N	U	BMHA15E2	Y N U BMHA15E3
f. Kidney transplant	Y	N	U	X	BMHA15F1	Y	N	U	BMHA15F2	Y N U BMHA15F3

F. ADMINISTRATIVE INFORMATION

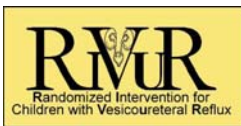
16. [PC] Date of data collection (mm/dd/yyyy):

		/			/				
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BMHA16
17. [PC] Method of data collection (circle one):
Computer C **BMHA17**
Paper P
18. [PC] Interviewer's initials:

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BLIND_STAFF_ID



Blood Specimen Results Form

ID NUMBER:							
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FORM CODE: BSR
VERSION: A 06/28/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form from medical records abstraction to report on all local laboratory results at baseline and end-of-study, or at any time during the study when a blood specimen is drawn.

A. BLOOD COUNT (CBC)

1. Are CBC test results available?

BSRA1

Yes Y

No, sample inadequate I → **Do Item 2, then go to Item 7**

No, other reason O

a. If other, specify: _____

→ **Go to Item 7**

BSRA1A

2. Date CBC sample drawn (mm/dd/yyyy):

		/			/				
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BSRA2

3. White blood cell count (WBC) (countx10⁹/L)

		.	
--	--	---	--

BSRA3

4. Hemoglobin (Hgb) (g/dL)

		.	
--	--	---	--

BSRA4

5. Hematocrit (Hct) (%)

		.	
--	--	---	--

BSRA5

6. Platelet count (countx10⁹/L)

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BSRA6

B. METABOLIC / ELECTROLYTE RESULTS

7. Are metabolic/electrolyte test results available?

BSRA7

Yes Y

No, electrolytes not required at this contact C → **Go to Item 15**

No, sample inadequate I → **Do Item 8, then go to Item 15**

No, other reason O

a. If other, specify: _____

→ **Go to Item 15**

BSRA7A

8. Date metabolic/electrolyte blood drawn (mm/dd/yyyy):

		/			/				
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BSRA8

9. BUN (mg/dL)

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BSRA9

10. Creatinine (mg/dL)

	.	
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BSRA10

11. Sodium (mmol/L)

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BSRA11

12. Potassium (mmol/L)

	.	
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BSRA12

ID NUMBER:							
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FORM CODE: BSR
VERSION: A 06/28/07

Contact
Occasion

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SEQ #

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13. Chloride (mmol/L)

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BSRA13

14. Carbon dioxide (mmol/L)

		.	
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BSRA14

C. ADMINISTRATIVE INFORMATION

15. Date of data collection (mm/dd/yyyy):

		/			/				
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BSRA15

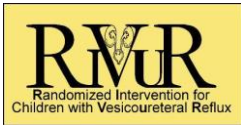
16. Method of data collection (*circle one*):

Computer C
Paper P **BSRA16**

17. Recorder's initials:

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BLIND_STAFF_ID



CENTRAL LAB BLOOD RESULTS FORM

ID NUMBER:						
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FORM CODE: CLR
VERSION: B 04/14/10

Contact
Occasion

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SEQ #

0	0
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Instructions: Central lab personnel will complete this form from central lab blood specimens.

A. SPECIMEN DESCRIPTION

1. Date sample drawn at site (mm/dd/yyyy):

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CLRB1
2. Indicate the appearance of the serum:
- No hemolysis 0
- Pink (slight hemolysis) 1 **CLRB2**
- Red/light red (moderate hemolysis) 2
- Dark red (gross hemolysis) 3

B. CYSTATIN-C RESULTS

3. Are cystatin C results available?
- Yes Y **CLRB3**
- No N
- If N, please specify reason: _____ → **Go to Item 6**
4. Date of cystatin C analysis (mm/dd/yyyy):

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CLRB4
5. Cystatin C (mg/L)

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CLRB5

C. CREATININE RESULTS

6. Are serum creatinine results available?
- Yes Y **CLRB6**
- No N
- If N, please specify reason: _____ → **Go to Item 9**
7. Date of serum creatinine analysis (mm/dd/yyyy):

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 /

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CLRB7
8. Serum creatinine (mg/dL)

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 .

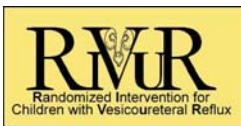
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CLRB8

D. HIGH SENSITIVITY C REACTIVE PROTEIN (hs-CRP) RESULTS

9. Are hs-C reactive protein results available?
- Yes Y **CLRB9**
- No N
- If N, please specify reason: _____ → **Go to Item 12**



Concomitant Medication Form

ID NUMBER:							
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FORM CODE: CMF
VERSION: B 07/18/08

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy):

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CMF1
2. Method of data collection (circle one):
Computer C **CMF2**
Paper P
3. a. Recorder's initials:

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BLIND_STAFF_ID
b. Is contact considered a 'Missed Contact'? Y → **Exit form** N **CMFB3B**

B. CONCOMITANT MEDICATION USE

4. Is the child currently taking medication (baseline), or, have there been any changes in their medication use since the last contact? Y N → **Exit form** **CMF4**

CMF5B - CMF28B (DMS only): Medication Preferred Name selected from list using the Master Drug Data Base v2 from Medi-Span

CMF5C - CMF28C (DMS only): Medication Code

	Medication	Date Start	E. Date Stop <i>If continuing use 00/00/0000</i>	F. Reason Medication Taken
5.	CMF5A	CMF5D ___ / ___ / 20__	CMF5E ___ / ___ / 20__	CMFB5F
6.	CMF6A	CMF6D ___ / ___ / 20__	CMF6E ___ / ___ / 20__	CMFB6F
7.	CMF7A	CMF7D ___ / ___ / 20__	CMF7E ___ / ___ / 20__	CMFB7F
8.	CMF8A	CMF8D ___ / ___ / 20__	CMF8E ___ / ___ / 20__	CMFB8F
9.	CMF9A	CMF9D ___ / ___ / 20__	CMF9E ___ / ___ / 20__	CMFB9F
10.	CMF10A	CMF10D ___ / ___ / 20__	CMF10E ___ / ___ / 20__	CMFB10F
11.	CMF11A	CMF11D ___ / ___ / 20__	CMF11E ___ / ___ / 20__	CMFB11F

ID NUMBER:							
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FORM CODE: CMF
VERSION: B 07/18/08

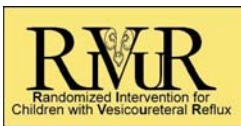
Contact
Occasion

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SEQ #

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	A. Medication	D. Date Start	E. Date Stop <i>If continuing use 00/00/0000</i>	F. Reason Medication Taken
12.	CMF12A	CMF12D ___ / ___ / 20__	CMF12E ___ / ___ / 20__	CMFB12F
13.	CMF13A	CMF13D ___ / ___ / 20__	CMF13E ___ / ___ / 20__	CMFB13F
14.	CMF14A	CMF14D ___ / ___ / 20__	CMF14E ___ / ___ / 20__	CMFB14F
15.	CMF15A	CMF15D ___ / ___ / 20__	CMF15E ___ / ___ / 20__	CMFB15F
16.	CMF16A	CMF16D ___ / ___ / 20__	CMF16E ___ / ___ / 20__	CMFB16F
17.	CMF17A	CMF17D ___ / ___ / 20__	CMF17E ___ / ___ / 20__	CMFB17F
18.	CMF18A	CMF18D ___ / ___ / 20__	CMF18E ___ / ___ / 20__	CMFB18F
19.	CMF19A	CMF19D ___ / ___ / 20__	CMF19E ___ / ___ / 20__	CMFB19F
20.	CMF20A	CMF20D ___ / ___ / 20__	CMF20E ___ / ___ / 20__	CMFB20F
21.	CMF21A	CMF21D ___ / ___ / 20__	CMF21E ___ / ___ / 20__	CMFB21F
22.	CMF22A	CMF22D ___ / ___ / 20__	CMF22E ___ / ___ / 20__	CMFB22F
23.	CMF23A	CMF23D ___ / ___ / 20__	CMF23E ___ / ___ / 20__	CMFB23F
24.	CMF24A	CMF24D ___ / ___ / 20__	CMF24E ___ / ___ / 20__	CMFB24F
25.	CMF25A	CMF25D ___ / ___ / 20__	CMF25E ___ / ___ / 20__	CMFB25F
26.	CMF26A	CMF26D ___ / ___ / 20__	CMF26E ___ / ___ / 20__	CMFB26F
27.	CMF27A	CMF27D ___ / ___ / 20__	CMF27E ___ / ___ / 20__	CMFB27F
28.	CMF28A	CMF28D ___ / ___ / 20__	CMF28E ___ / ___ / 20__	CMFB28F



Concomitant Medication Form

ID NUMBER:							
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FORM CODE: CMF
VERSION: A 11/27/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy): _____

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CMF1
2. Method of data collection (circle one):
Computer C **CMF2**
Paper..... P
3. Recorder's initials: _____

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BLIND_STAFF_ID

B. CONCOMITANT MEDICATION USE

4. Is the child currently taking medication (baseline), or, have there been any changes in their medication use since the last contact? Y N → **Exit form** **CMF4**

CMF5B - CMF28B (DMS only): Medication Preferred Name selected from list using the Master Drug Data Base v2 from Medi-Spa

CMF5C - CMF28C (DMS only): Medication Code

	Medication	B. Date Start	C. Date Stop
5.	CMF5A	CMF5D ___ / ___ / 20__	CMF5E ___ / ___ / 20__
6.	CMF6A	CMF6D ___ / ___ / 20__	CMF6E ___ / ___ / 20__
7.	CMF7A	CMF7D ___ / ___ / 20__	CMF7E ___ / ___ / 20__
8.	CMF8A	CMF8D ___ / ___ / 20__	CMF8E ___ / ___ / 20__
9.	CMF9A	CMF9D ___ / ___ / 20__	CMF9E ___ / ___ / 20__
10.	CMF10A	CMF10D ___ / ___ / 20__	CMF10E ___ / ___ / 20__
11.	CMF11A	CMF11D ___ / ___ / 20__	CMF11E ___ / ___ / 20__

ID NUMBER:							
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FORM CODE: CMF
VERSION: A 11/27/07

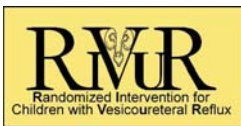
Contact
Occasion

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SEQ #

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	A. Medication	B. Date Start	C. Date Stop
12.	CMF12A	CMF12D ___/___/20__	CMF12E ___/___/20__
13.	CMF13A	CMF13D ___/___/20__	CMF13E ___/___/20__
14.	CMF14A	CMF14D ___/___/20__	CMF14E ___/___/20__
15.	CMF15A	CMF15D ___/___/20__	CMF15E ___/___/20__
16.	CMF16A	CMF16D ___/___/20__	CMF16E ___/___/20__
17.	CMF17A	CMF17D ___/___/20__	CMF17E ___/___/20__
18.	CMF18A	CMF18D ___/___/20__	CMF18E ___/___/20__
19.	CMF19A	CMF19D ___/___/20__	CMF19E ___/___/20__
20.	CMF20A	CMF20D ___/___/20__	CMF20E ___/___/20__
21.	CMF21A	CMF21D ___/___/20__	CMF21E ___/___/20__
22.	CMF22A	CMF22D ___/___/20__	CMF22E ___/___/20__
23.	CMF23A	CMF23D ___/___/20__	CMF23E ___/___/20__
24.	CMF24A	CMF24D ___/___/20__	CMF24E ___/___/20__
25.	CMF25A	CMF25D ___/___/20__	CMF25E ___/___/20__
26.	CMF26A	CMF26D ___/___/20__	CMF26E ___/___/20__
27.	CMF27A	CMF27D ___/___/20__	CMF27E ___/___/20__
28.	CMF28A	CMF28D ___/___/20__	CMF28E ___/___/20__



Concomitant Medication Form

ID NUMBER:							
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FORM CODE: CMF
VERSION: A 12/05/06

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form to provide information on current concomitant medication use. See DMS follow-up report for summary of previous concomitant medication use, and review participant diary with parent. Medication codes are listed in the Manual of Procedures and in the DMS medication look-up table.

A. ADMINISTRATIVE INFORMATION

1. Date of data collection (mm/dd/yyyy): _____

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CMF1

2. Method of data collection (circle one):

Computer C

Paper P

CMF2

3. Recorder's initials: _____

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BLIND_STAFF_ID

B. CONCOMITANT MEDICATION USE

4. Have there been any changes in the child's concomitant

medication use since the last contact? Y N → **Exit form** **CMF4**

**CMF5B - CMF28B (DMS only): Medication
Preferred Name selected from list**

CMF5C - CMF28C (DMS only): Medication Code

	A. Medication	B. Date Start	C. Date Stop
5.	CMF5A	CMF5D ___ / ___ / 20__	CMF5E ___ / ___ / 20__
6.	CMF6A	CMF6D ___ / ___ / 20__	CMF6E ___ / ___ / 20__
7.	CMF7A	CMF7D ___ / ___ / 20__	CMF7E ___ / ___ / 20__
8.	CMF8A	CMF8D ___ / ___ / 20__	CMF8E ___ / ___ / 20__
9.	CMF9A	CMF9D ___ / ___ / 20__	CMF9E ___ / ___ / 20__
10.	CMF10A	CMF10D ___ / ___ / 20__	CMF10E ___ / ___ / 20__
11.	CMF11A	CMF11D ___ / ___ / 20__	CMF11E ___ / ___ / 20__

ID NUMBER:							
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FORM CODE: CMF
VERSION: A 12/05/06

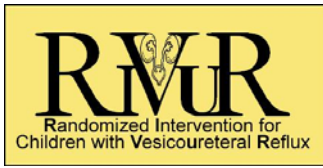
Contact
Occasion

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SEQ #

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	A. Medication	B. Date Start	C. Date Stop
12.	CMF12A	CMF12D ___ / ___ / 20__	CMF12E ___ / ___ / 20__
13.	CMF13A	CMF13D ___ / ___ / 20__	CMF13E ___ / ___ / 20__
14.	CMF14A	CMF14D ___ / ___ / 20__	CMF14E ___ / ___ / 20__
15.	CMF15A	CMF15D ___ / ___ / 20__	CMF15E ___ / ___ / 20__
16.	CMF16A	CMF16D ___ / ___ / 20__	CMF16E ___ / ___ / 20__
17.	CMF17A	CMF17D ___ / ___ / 20__	CMF17E ___ / ___ / 20__
18.	CMF18A	CMF18D ___ / ___ / 20__	CMF18E ___ / ___ / 20__
19.	CMF19A	CMF19D ___ / ___ / 20__	CMF19E ___ / ___ / 20__
20.	CMF20A	CMF20D ___ / ___ / 20__	CMF20E ___ / ___ / 20__
21.	CMF21A	CMF21D ___ / ___ / 20__	CMF21E ___ / ___ / 20__
22.	CMF22A	CMF22D ___ / ___ / 20__	CMF22E ___ / ___ / 20__
23.	CMF23A	CMF23D ___ / ___ / 20__	CMF23E ___ / ___ / 20__
24.	CMF24A	CMF24D ___ / ___ / 20__	CMF24E ___ / ___ / 20__
25.	CMF25A	CMF25D ___ / ___ / 20__	CMF25E ___ / ___ / 20__
26.	CMF26A	CMF26D ___ / ___ / 20__	CMF26E ___ / ___ / 20__
27.	CMF27A	CMF27D ___ / ___ / 20__	CMF27E ___ / ___ / 20__
28.	CMF28A	CMF28D ___ / ___ / 20__	CMF28E ___ / ___ / 20__



DRUG DISCONTINUATION FORM

ID NUMBER:							
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FORM CODE: DDF
VERSION: A 04/19/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is completed to document all temporary or permanent discontinuations for study drug. This form will be linked by the assigned MCID number to the AEF and MCN form associated with the event resulting in drug discontinuation.

A. STUDY MEDICATION DISCONTINUATION

1. Date of discontinuation (mm/dd/yyyy):

--	--	--	--	--	--	--	--

DDFA1
2. Type of discontinuation:
Temporary discontinuation..... T DDFA2
Permanent discontinuation D
3. MCID number assigned from corresponding AEF or MCN:

--	--	--	--	--	--	--	--

BLIND_MCID
4. Reason for discontinuation:
Side effects S
Treatment failure F DDFA4
Other O
a. If other, please specify: _____
5. Discontinuation was reviewed and authorized by (name of investigator):

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

BLIND_AUTHORITY

B. ADMINISTRATIVE INFORMATION

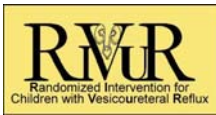
6. Date of data collection (mm/dd/yyyy):

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DDFA6
7. Method of data collection (circle one):
Computer C DDFA7
Paper..... P
8. Recorder's initials:

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BLIND_STAFF_ID



DMSA RESULTS FORM

Version A of this form
was used for pilot study

ID NUMBER:

FORM CODE: DMF
VERSION: B 05/04/07

Contact
Occasion

SEQ #

Instructions: This form should be completed by the reference radiologist. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. The coding for pyelonephritis and scarring include mild: 1-2 segments, moderate: 3-4 segments, severe: >4 segments, global atrophy: diffusely scarred, shrunken kidney.

A. LOCAL REPORT DATA

1. Date of DMSA scan (mm/dd/yyyy): // **DM_1**
2. Administered dose Tc-99m DMSA (millicuries): **DM_2**
3. Differential renal function (%): a. Right **DM_3A**
b. Left **DM_3B**

B. IMAGE READING RESULTS

4. Pyelonephritis:

	<u>None</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>	
a. Right	A	B	C	D	→ DM_4A
b. Left	A	B	C	D	→ DM_4B
- 5a. Right segments involved with pyelonephritis (check all that apply):
DM_5A1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐
DM_5A2 **DM_5A3** **DM_5A4** **DM_5A5** **DM_5A6** **DM_5A7** **DM_5A8** **DM_5A9** **DM_5A10** **DM_5A11** **DM_5A12**
- 5b. Left segments involved with pyelonephritis (check all that apply):
1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ **DM_5B12**
DM_5B1 **DM_5B2** **DM_5B3** **DM_5B4** **DM_5B5** **DM_5B6** **DM_5B7** **DM_5B8** **DM_5B9** **DM_5B10** **DM_5B11**
6. Scarring:

	<u>None</u>	<u>Mild</u>	<u>Moderate</u>	<u>Severe</u>	<u>Global Atrophy</u>	
a. Right	A	B	C	D	E	→ DM_6A
b. Left	A	B	C	D	E	→ DM_6B
- 7a. Right segments with scarring (check all that apply):
DM_7A1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐
DM_7A2 **DM_7A3** **DM_7A4** **DM_7A5** **DM_7A6** **DM_7A7** **DM_7A8** **DM_7A9** **DM_7A10** **DM_7A11** **DM_7A12**
- 7b. Left segments with scarring (check all that apply):
DM_7B1 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ **DM_7B12**
DM_7B2 **DM_7B3** **DM_7B4** **DM_7B5** **DM_7B6** **DM_7B7** **DM_7B8** **DM_7B9** **DM_7B10** **DM_7B11**

ID NUMBER:							
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FORM CODE: DMF
VERSION: B 05/04/07

Contact
Occasion

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SEQ #

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8. Quality of film:

Adequate..... A
Inadequate..... I

DM_8

C. COMPARISON WITH BASELINE

9. Was there new scarring since the baseline image?

Yes..... Y
No..... N
Not applicable X

DMB9

D. ADMINISTRATIVE INFORMATION

10. Date of reading (mm/dd/yyyy):

		/			/				
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DM_9

11. Method of data collection (*circle one*):

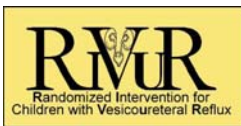
Computer C
Paper..... P

DM_10

12. Radiologist's initials:

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BLIND_STAFF_ID



DMSA Sedation Form

ID NUMBER:							
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FORM CODE: DSF
VERSION: A 02/07/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for every DMSA to provide information on possible sedation.

A. DMSA PROCEDURE

1. Date of DMSA procedure (mm/dd/yyyy):

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DSFA1
2. Was this an interim DMSA following a UTI? Y N → **Go to Item 4** **DSFA2**
Note: Not a protocol baseline, 12 months, or end-of-study scan.
3. Record the MCID # associated with the UTI event

--	--	--	--	--	--	--	--

BLIND_MCID
NOTE: Report the MCID # found on the MCN and MCA forms that correspond to the UTI event.
4. Was sedation used during the radiological procedure?
Yes Y
No N → **Go to Item 11** **DSFA4**
Unknown U → **Go to Item 11**

B. SEDATION

- | | Medication Used for Sedation: | Medication Dose (mg/kg): | General Anesthesia: | | | | |
|--|-------------------------------|---|---------------------|--|--|--|-------------------------|
| 5. Chloral hydrate | a. Y N DSFA5A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA5B | | | | | c. Y N U DSFA5C |
| | | | | | | | |
| 6. Diazepam (Valium) | a. Y N DSFA6A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA6B | | | | | c. Y N U DSFA6C |
| | | | | | | | |
| 7. Fentanyl | a. Y N DSFA7A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA7B | | | | | c. Y N U DSFA7C |
| | | | | | | | |
| 8. Midazolam (Versed) | a. Y N DSFA8A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA8B | | | | | c. Y N U DSFA8C |
| | | | | | | | |
| 9. Pentobarbital | a. Y N DSFA9A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA9B | | | | | c. Y N U DSFA9C |
| | | | | | | | |
| 10. Other Drug | a. Y N DSFA10A | b. <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> DSFA10B | | | | | c. Y N U DSFA10C |
| | | | | | | | |
| d. If other, specify: DSFA10D _____ | | | | | | | |

C. ADMINISTRATIVE INFORMATION

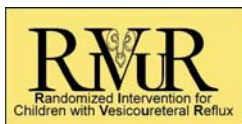
11. Date of data collection (mm/dd/yyyy):

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DSFA11
12. Method of data collection (circle one):
Computer C **DSFA12**
Paper P
13. Recorder's initials:

--	--	--

BLIND_STAFF_ID



DES TREATMENT FORM

ID NUMBER:						
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FORM CODE: DTF
VERSION: A 8/7/08

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is completed at baseline, 12 month, and end-of-study visits. This form is administered only if the child is **toilet-trained** AND if the participant's **DVQ score** is **>6** for females or **>9** for males.

A. DES TREATMENT

- | | | | |
|--|---|---|-------------------------------------|
| 1. Is the child participating in a timed voiding program? | Y | N | DTFA1 |
| 2. Is the child using miralax or other cathartics for DES? | Y | N | DTFA2 |
| 3. Is the child using any medical therapies for DES? | Y | N | N→ Go to Item 4 DTFA3 |
| a. Anti-cholinergics | Y | N | DTFA3A |
| b. DDAVP | Y | N | DTFA3B |
| c. Imipramine | Y | N | DTFA3C |
| d. Alpha blockers | Y | N | DTFA3D |
| 4. Is the child using a bedwetting alarm? | Y | N | DTFA4 |
| 5. Is the child using biofeedback therapy? | Y | N | DTFA5 |

B. ADMINISTRATIVE INFORMATION

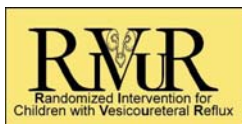
6. Date of data collection (mm/dd/yyyy):

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DTFA6
7. Method of data collection (*circle one*):
- | | | |
|----------------|---|--------------|
| Computer | C | DTFA7 |
| Paper..... | P | |
8. Recorder's initials:

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BLIND_STAFF_ID



DV QUESTIONNAIRE

ID NUMBER:						
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FORM CODE: DVQ
VERSION: A 9/19/06

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is completed by the child and parent at baseline, 12 month, and end-of-study visits. The questionnaire is intended to collect information about the child. This questionnaire is administered only if the child is **toilet-trained**. Please circle the most appropriate response for each item.

A. Child Response with Parent Help:

During the past month:	Almost never	Less than ½ the time	About ½ the time	Almost every time	Not applicable	
1. When I peed it hurt.A		B	C	D	N	DVQA1
2. I tried to hold only my pee by crossing my legs, squatting, or doing a pee dance.A		B	C	D	N	DVQA2
3. When I had to pee, I could not waitA		B	C	D	N	DVQA3
4. I had to push to pee.....A		B	C	D	N	DVQA4
5. I went to the bathroom to pee only once or twice per day.A		B	C	D	N	DVQA5
6. I wet my underwear with pee during the day.....A		B	C	D	N	DVQA6
7. When I wet myself with pee, my underwear was soaked.....A		B	C	D	N	DVQA7
8. I had to push for my bowel movements to come out.A		B	C	D	N	DVQA8
9. I usually did not have a bowel movement every day.A		B	C	D	N	DVQA9

B. Parent/Guardian Response:

10. During the past month, has your child experienced any stressful events, such as: a new baby, a new school, home problems (divorce/death), a new home, abuse (sexual/physical), school problems, or serious accident/injury?..... Y	N	DVQA10
11. a. During the last 2 months, did your child have a stool that blocked the toilet?..... Y	N →	Go to Item 12
b. If yes, indicate how often:		DVQA11A
NeverA		
Once per month.....B		
Two or three times per monthC		DVQA11B
Once per weekD		
More than once per week.....E		

ID NUMBER:							
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FORM CODE: DVQ
VERSION: A 9/19/06

Contact
Occasion

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SEQ #

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12. a. During the last 2 months, did your child hold onto his/her stool by crossing the legs or squatting? Y

N → **Go to Item 13**

DVQA12A

b. If yes, indicate how often:

Never A

Once per month B

Two or three times per month C

Once per week D

More than once per week E

DVQA12B

13. a. During the last 2 months, did your child complain of pain while having a bowel movement? Y

N → **Go to Item 14**

DVQA13A

b. If yes, indicate how often:

Never A

Once per month B

Two or three times per month C

Once per week D

More than once per week E

DVQA13B

14. a. Over the last 2 months, did your child have bowel movements in his/her underwear? Y

N → **Stop**

DVQA14A

b. If yes, indicate how often:

Never A

Once per month B

Two or three times per month C

Once per week D

More than once per week E

DVQA14B

Thank you!

C. Administrative Use Only

15. Date of Form (mm/dd/yyyy)

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 /

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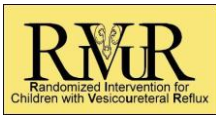
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DVQA15

16. Reviewer's initials:

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BLIND_STAFF_ID



ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER:						
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FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure. **Note: the index UTI refers to the UTI immediately preceding randomization.** The date of the index UTI is the date of the urine collection resulting in positive culture.

A. ADMINISTRATIVE INFORMATION

1. a. [PC] Date of randomization (TODAY) (mm/dd/yyyy):

--	--	--	--	--	--	--	--

 /

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 /

--	--	--	--	--	--	--	--

ERF1
- b. [PC] Beginning work-up date of the most recent (index) UTI?

--	--	--	--	--	--	--	--

 /

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 /

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ERFC1B
- c. [PC] Date of consent (mm/dd/yyyy):

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 /

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

ERF52
- d. [PC] Method of data collection (circle one):
Computer C **ERF54**
Paper P
- e. [PC] Interviewer's initials:

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BLIND_STAFF_ID

B. AGE

2. Child's date of birth (mm/dd/yyyy):

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

ERF2
3. [PC] Age in months: [determined by DMS] **ERF3**
4. If child's age < 6 months, was gestational age $\geq$ 34 weeks? Yes No Not Applicable
..... Y N **Ineligible** X **ERF4**
5. [PC] Is child's age $\geq$ 2 months and < 72 months (6 yrs)? Y N **Ineligible** **ERF5**
6. a. Has your child had more than one UTI? Y N **Go to Item 7** **ERFC6A**
- b. How many?

--

Ineligible if >2 **ERFC6B**
- c. Did your child receive a VUR diagnosis prior to the second UTI? Y **Ineligible** N **ERFC6C**
- d. Did your child take prophylactic anti-microbials for UTI prior to the second UTI? Y **Ineligible** N **ERFC6D**

ID NUMBER:							
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FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

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SEQ #

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C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? Y N → **Go to Item 14** **ERF7**

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? **ERFB8A**

b. Temperature measurement units (*circle one*):

°F F **ERFB8B**
°C C

9. What was the temperature measurement route? (*circle one*): **ERF10**

Oral O
Axillary..... A
Tympanic..... T
Rectal R
Unknown U

10. What location was the temperature measured? (*Circle one*): **ERF11**

Home..... H
Medical care professional M

11. a. What was the highest measured temperature during the index

UTI?..... **ERF8A**

b. Temperature measurement units (*circle one*):

°F F **ERF8B**
°C C

c. What was the date of the highest temperature (mm/dd/yyyy)? **ERF9**

12. What was the total duration of fever prior to index UTI antimicrobial

treatment (hrs)? **ERF12**

13. What was the time from index UTI antimicrobial treatment to a

sustained (> 24 hrs) normal temperature (hrs)?..... **ERFB13**

14. Were the following symptoms present within 24 hrs prior to or

following the initial UTI work-up?

Yes

No

Unknown

a. Suprapubic, abdominal, or flank pain or tenderness..... Y N U **ERFC14A**

b. Urinary urgency Y N U **ERFC14B**

c. Urinary frequency Y N U **ERFC14C**

ID NUMBER:							
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FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

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SEQ #

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	Yes	No	Unknown	Not Applicable
d. Urinary hesitancy.....	Y	N	U	ERFC14D
e. Dysuria	Y	N	U	ERFC14E
f. Foul-smelling urine	Y	N	U	ERFC14F
g. Failure to thrive (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14G
h. Dehydration (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14H
i. Hypothermia (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14I

15. What was the total number of days that your child

experienced these symptoms?

--	--

ERFB15

16. [PC] Was there a temperature $\geq$ 100.4°F or 38°C (see Q8) OR
were urinary tract symptoms (see Q14) present 24 hrs prior to or
following the initial index UTI work-up?

Y

N

→ Ineligible

ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. [PC] Date of dipstick urine collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ERFB17A

b. [PC] Dipstick results - leukocyte esterase (circle one):

ERF17A

Negative A

Trace B

Small (+) C

Moderate (++) D

Large (+++) E

c. [PC] Dipstick results - nitrite (circle one):

ERF17B

Negative N

Positive P

18. a. [PC] Date of microscopy urine collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ERFB18A

b. [PC] WBC (Enter count. Use 999.999 for values $\geq$ 999.999):

			.			
--	--	--	---	--	--	--

ERFB18B

c. [PC] Reporting units for WBC microscopy (circle one):

WBC/mm³ A

WBC/hpf B

ERF18B

19. [PC] Was pyuria present, noted as either leukocyte esterase on
dipstick greater than or equal to trace (see Q17b) OR

WBC $\geq$ 10 WBC/mm³ or WBC $\geq$ 5 WBC/hpf (see Q18)?

Y

N

→ Ineligible

ERFB19

ID NUMBER:							
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FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

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SEQ #

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E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy):

 /

 /

ERFB20A

b. **[PC]** Method of urine collection (*circle one*): **ERF20**

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D → **Ineligible**

Unknown E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? Y N → **Ineligible** **ERFB21A**

b. **[PC]** How many organisms were present?

 → **Ineligible if more than 2** **ERFB21B**

22. a. **[PC]** Primary organism (*select from list*):

ERFB22A

b. **[PC]** Data type from primary organism culture results (*circle one*): **ERFB22B**

= (equal to) A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range F

c. **[PC]** Colony count (CFU/ml) of primary organism: c1.

 - c2.

ERFB22C1 **ERFB22C2**

23. a. **[PC]** Secondary organism (*select from list*):

ERFB23A

b. **[PC]** Data type from secondary organism culture results (*circle one*): **ERFB23B**

= (equal to) A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range F

c. **[PC]** Colony count (CFU/ml) of secondary organism: c1.

 - c2.

ERFB23C1 **ERFB23C2**

ID NUMBER:

FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

SEQ #

24. a. [PC] Was the colony count for the primary organism $\geq 50,000$ CFU/ml in catheterized or suprapubic specimens **OR** $\geq 100,000$ CFU/ml in clean-voided specimen? (See Q22.) Y
- b. [PC] Was the colony count for the secondary organism $\leq 10,000$ CFU/ml? (See Q23.) Y

N → **Ineligible** **ERFB24A**

N → **Ineligible** **ERFC24B**

F. INDEX UTI TREATMENT

25. [PC] How many different antimicrobials were prescribed to treat the index UTI? (Describe in Q26-Q29.)

ERF25

Antimicrobial (code from list):

Date prescribed (mm/dd/yyyy):

Duration of treatment (days):

Pathogen sensitive to drug:

- | | | | | | | | |
|-------------|--|----|---|----|---|----|---------------------|
| 26. [PC] a. | <input type="text"/> <input type="text"/> <input type="text"/> ERF26A | b. | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> ERF26B | c. | <input type="text"/> <input type="text"/> ERF26C | d. | Y N U ERF26D |
| 27. [PC] a. | <input type="text"/> <input type="text"/> <input type="text"/> ERF27A | b. | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> ERF27B | c. | <input type="text"/> <input type="text"/> ERF27C | d. | Y N U ERF27D |
| 28. [PC] a. | <input type="text"/> <input type="text"/> <input type="text"/> ERF28A | b. | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> ERF28B | c. | <input type="text"/> <input type="text"/> ERF28C | d. | Y N U ERF28D |
| 29. [PC] a. | <input type="text"/> <input type="text"/> <input type="text"/> ERF29A | b. | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> ERF29B | c. | <input type="text"/> <input type="text"/> ERF29C | d. | Y N U ERF29D |

30. [PC] a. Was the index UTI treated at least 7 days? (Sum Q26c, Q27c, Q28c, and Q29c.) Y

N → **Ineligible** **ERF30A**

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? (Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.) Y

N **ERF30B**

31. [PC] Was a follow-up negative urine culture documented 1-14 days after completion of therapy? Y

N → **Ineligible if Item 30b is N** **ERF31**

32. [PC] Date of follow-up urine culture (mm/dd/yyyy): / /

ERF32

G. VCUG LOCAL REPORT

33. [PC] Date of VCUG (mm/dd/yyyy): / /

ERF33

34. [PC] Is date of VCUG within 112 days after index UTI? Y

N → **Ineligible** **ERFC34**

35. [PC] Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? Y

N → **Ineligible** **ERF35**

36. [PC] Is grade V reflux present in either ureter? Y

→ **Ineligible** N **ERF36**

37. [PC] Does the VCUG show the following bladder abnormalities?

a. Ureterocele Y

→ **Ineligible** N **ERF37A**

b. Urethral valve Y

→ **Ineligible** N **ERF37B**

ID NUMBER:							
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FORM CODE: ERF
VERSION: E 02/08/11

Contact
Occasion

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SEQ #

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H. RENAL ULTRASOUND LOCAL REPORT

38. a. [PC] Date of ultrasound (mm/dd/yyyy):.....

--	--

 /

--	--

 /

--	--	--	--

ERF38

b. [PC] Is date of ultrasound within 112 days prior to or after index UTI? Y N → Ineligible ERFC38B

39. [PC] Does the ultrasound show the following urologic abnormalities?

- | | | | |
|--|--|---|--|
| a. Gr 4 Hydronephrosis w/renal parenchyma atrophy..... | Y → Ineligible | N | ERF39A |
| b. Ureterocele | Y → Ineligible | N | ERF39B |
| c. Solitary kidney | Y → Ineligible | N | ERF39C |
| d. Profoundly small kidney (more than 2 SD below mean) | Y → Ineligible | N | ERF39D |
| e. Multicystic dysplastic kidney..... | Y → Ineligible | N | ERF39E |
| f. Pelvic kidney..... | Y → Ineligible | N | ERF39F |
| g. Fused kidney | Y → Ineligible | N | ERF39G |
| h. Neurogenic bladder | Y → Ineligible | N | ERF39H |

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)?..... Y → Ineligible N ERF40
41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)?..... Y → Ineligible N ERF41
42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? Y → Ineligible N ERF42
43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? Y → Ineligible N ERF43
44. Has your child ever had renal or bladder surgery? Y → Ineligible N ERF44

J. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown?..... Y → Ineligible N ERF45
46. a. Is your child currently taking continuous antimicrobial prophylaxis? Y N → Go to Item 47 ERF46
- b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment?..... Y N → Ineligible ERFB46B

FORM CODE: ERF
VERSION: E 02/08/11

Contact
OccasionSEQ #

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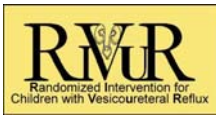
- ## K. RECENT FEVER AND PYURIA

- ## L. RANDOMIZATION

- [illegible]

Note: choosing 'Y' to question #52 will initiate randomization. Items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered above are accurate before continuing.

52. **[PC]** Do you wish to randomize this child to a treatment group? Y N **ERF51**



ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER:

FORM CODE: ERF
VERSION: D 8/29/08

Contact
Occasion

SEQ #

Participant Name: _____

Instructions: Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure. **Note: the index UTI refers to the UTI immediately preceding randomization.** The date of the index UTI is the date of the urine collection resulting in positive culture.

A. ADMINISTRATIVE INFORMATION

1. a. [PC] Date of randomization (TODAY) (mm/dd/yyyy): // **ERF1**
- b. [PC] Beginning work-up date of the most recent (index) UTI? // **ERFC1B**
- c. [PC] Date of consent (mm/dd/yyyy): // **ERF52**
- d. [PC] Method of data collection (circle one):
Computer C **ERF54**
Paper..... P
- e. [PC] Interviewer's initials: **BLIND_STAFF_ID**

B. AGE

2. Child's date of birth (mm/dd/yyyy): // **ERF2**
3. [PC] Age in months: [determined by DMS] **ERF3**
4. If child's age < 6 months, was gestational age $\geq$ 34 weeks? Yes No Not Applicable
..... Y N **→Ineligible** X **ERF4**
5. [PC] Is child's age $\geq$ 2 months and < 72 months (6 yrs)? Y N **→Ineligible** **ERF5**
6. a. Has your child had more than one UTI? Y N **→Go to Item 7** **ERFC6A**
- b. How many? **→Ineligible if >2** **ERFC6B**
- c. Did your child receive a VUR diagnosis prior to the second UTI? Y **→Ineligible** N **ERFC6C**
- d. Did your child take prophylactic anti-microbials for UTI
prior to the second UTI? Y **→Ineligible** N **ERFC6D**

ID NUMBER:							
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FORM CODE: ERF
VERSION: D 8/29/08

Contact
Occasion

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SEQ #

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C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? Y N → **Go to Item 14** **ERF7**

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? **ERFB8A**

b. Temperature measurement units (*circle one*):

°F F **ERFB8B**
°C C

9. What was the temperature measurement route? (*circle one*): **ERF10**

Oral O
Axillary..... A
Tympanic..... T
Rectal R
Unknown U

10. What location was this temperature measured? (*Circle one*): **ERF11**

Home..... H
Medical care professional M

11. a. What was the highest measured temperature during the index

UTI? **ERF8A**

b. Temperature measurement units (*circle one*):

°F F **ERF8B**
°C C

c. What was the date of the highest temperature (mm/dd/yyyy)? **ERF9**

12. What was the total duration of fever prior to index UTI antimicrobial

treatment (hrs)? **ERF12**

13. What was the time from index UTI antimicrobial treatment to a

sustained (> 24 hrs) normal temperature (hrs)? **ERFB13**

14. Were the following symptoms present within 24 hrs prior to or

following the initial UTI work-up?

Yes

No

Unknown

a. Suprapubic, abdominal, or flank pain or tenderness..... Y N U **ERFC14A**

b. Urinary urgency Y N U **ERFC14B**

c. Urinary frequency Y N U **ERFC14C**

ID NUMBER:							
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FORM CODE: ERF
VERSION: D 8/29/08

Contact
Occasion

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SEQ #

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	Yes	No	Unknown	Not Applicable
d. Urinary hesitancy.....	Y	N	U	ERFC14D
e. Dysuria	Y	N	U	ERFC14E
f. Foul-smelling urine	Y	N	U	ERFC14F
g. Failure to thrive (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14G
h. Dehydration (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14H
i. Hypothermia (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14I

15. What was the total number of days that your child

experienced these symptoms?

--	--

ERFB15

16. [PC] Was there a temperature $\geq$ 100.4°F or 38°C (see Q8) OR were urinary tract symptoms (see Q14) present 24 hrs prior to or following the initial index UTI work-up?

Y

N

→ Ineligible

ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. [PC] Date of dipstick urine collection (mm/dd/yyyy):

		/			/				
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ERFB17A

b. [PC] Dipstick results - leukocyte esterase (circle one):

ERF17A

Negative A

Trace B

Small (+) C

Moderate (++) D

Large (+++) E

c. [PC] Dipstick results - nitrite (circle one):

ERF17B

Negative N

Positive P

18. a. [PC] Date of microscopy urine collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ERFB18A

b. [PC] WBC (Enter count. Use 999.999 for values $\geq$ 999.999):

			.			
--	--	--	---	--	--	--

ERFB18B

c. [PC] Reporting units for WBC microscopy (circle one):

WBC/mm³ A

WBC/hpf B

ERF18B

19. [PC] Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace (see Q17b) OR

WBC $\geq$ 10 WBC/mm³ or WBC $\geq$ 5 WBC/hpf (see Q18)?

Y

N

→ Ineligible

ERFB19

ID NUMBER:							
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FORM CODE: ERF
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Occasion

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SEQ #

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E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy):

 /

 /

ERFB20A

b. **[PC]** Method of urine collection (*circle one*): **ERF20**

Catheterization..... A

Suprapubic aspiration B

Clean voided C

Bag collected D → **Ineligible**

Unknown E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? Y N → **Ineligible** **ERFB21A**

b. **[PC]** How many organisms were present?

 → **Ineligible if more than 2** **ERFB21B**

22. a. **[PC]** Primary organism (*select from list*):

ERFB22A

b. **[PC]** Data type from primary organism culture results (*circle one*): **ERFB22B**

= (equal to)..... A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range..... F

c. **[PC]** Colony count (CFU/ml) of primary organism:..... c1.

 - c2.

ERFB22C1 **ERFB22C2**

23. a. **[PC]** Secondary organism (*select from list*):

ERFB23A

b. **[PC]** Data type from secondary organism culture results (*circle one*): **ERFB23B**

= (equal to)..... A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range..... F

c. **[PC]** Colony count (CFU/ml) of secondary organism:..... c1.

 - c2.

ERFB23C1 **ERFB23C2**

ID NUMBER:							
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SEQ #

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24. a. **[PC]** Was the colony count for the primary organism $\geq 50,000$ CFU/ml in catheterized or suprapubic specimens **OR** $\geq 100,000$ CFU/ml in clean-voided specimen? (See Q22.) Y
- b. **[PC]** Was the colony count for the secondary organism $\leq 10,000$ CFU/ml? (See Q23.) Y

N → **Ineligible**

ERFB24A

N → **Ineligible**

ERFB24B

F. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? (Describe in Q26-Q29.)

ERF25

Antimicrobial (code from list):	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. [PC] a. ERF26A	b. ERF26B	c. ERF26C	d. Y N U ERF26D
27. [PC] a. ERF27A	b. ERF27B	c. ERF27C	d. Y N U ERF27D
28. [PC] a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U ERF28D
29. [PC] a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U ERF29D

30. **[PC]** a. Was the index UTI treated at least 7 days? (Sum Q26c, Q27c, Q28c, and Q29c.) Y

N → **Ineligible**

ERF30A

- [PC]** b. Was the index UTI appropriately treated at least 7 days with an effective drug? (Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.) Y

N **ERF30B**

31. **[PC]** Was a follow-up negative urine culture documented 1-14 days after completion of therapy? Y

N → **Ineligible if Item 30b is N**

ERF31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy):

ERF32

G. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy):

ERF33

34. **[PC]** Is date of VCUG within 112 days after index UTI? Y

N → **Ineligible**

ERFC34

35. **[PC]** Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? Y

N → **Ineligible**

ERF35

36. **[PC]** Is grade V reflux present in either ureter? Y → **Ineligible**

N

ERF36

ID NUMBER:							
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SEQ #

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37. [PC] Does the VCUG show the following bladder abnormalities?

- a. Ureterocele Y → **Ineligible** N **ERF37A**
- b. Urethral valve Y → **Ineligible** N **ERF37B**

H. RENAL ULTRASOUND LOCAL REPORT

38. a. [PC] Date of ultrasound (mm/dd/yyyy):

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ERF38

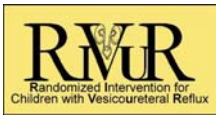
b. [PC] Is date of ultrasound within 112 days after index UTI? Y N → **Ineligible** **ERFC38B**

39. [PC] Does the ultrasound show the following urologic abnormalities?

- a. Hydronephrosis with renal parenchyma atrophy Y → **Ineligible** N **ERF39A**
- b. Ureterocele Y → **Ineligible** N **ERF39B**
- c. Solitary kidney Y → **Ineligible** N **ERF39C**
- d. Profoundly small kidney (more than 2 SD below mean) Y → **Ineligible** N **ERF39D**
- e. Multicystic dysplastic kidney Y → **Ineligible** N **ERF39E**
- f. Pelvic kidney Y → **Ineligible** N **ERF39F**
- g. Fused kidney Y → **Ineligible** N **ERF39G**
- h. Neurogenic bladder Y → **Ineligible** N **ERF39H**

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? Y → **Ineligible** N **ERF40**
41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? Y → **Ineligible** N **ERF41**
42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? Y → **Ineligible** N **ERF42**
43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? Y → **Ineligible** N **ERF43**
44. Has your child ever had renal or bladder surgery? Y → **Ineligible** N **ERF44**



ELIGIBILITY AND RANDOMIZATION FORM

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Participant Name: _____

Instructions: Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure. **Note: the index UTI refers to the UTI immediately preceding randomization.** The date of the index UTI is the date of the urine collection resulting in positive culture.

A. ADMINISTRATIVE INFORMATION

1. a. [PC] Date of randomization (TODAY) (mm/dd/yyyy):

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ERF1
- b. [PC] Beginning work-up date of the most recent (index) UTI?

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ERFC1B
- c. [PC] Date of consent (mm/dd/yyyy):

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ERF52
- d. [PC] Method of data collection (circle one):
Computer C **ERF54**
Paper P
- e. [PC] Interviewer's initials:

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BLIND_STAFF_ID

B. AGE

2. Child's date of birth (mm/dd/yyyy):

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 /

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ERF2
3. [PC] Age in months: [determined by DMS] **ERF3**
4. If child's age < 6 months, was gestational age $\geq$ 34 weeks? Yes No Not Applicable
..... Y N **→ Ineligible** X **ERF4**
5. [PC] Is child's age $\geq$ 2 months and < 72 months (6 yrs)? Y N **→ Ineligible** **ERF5**
6. a. Has your child had more than one UTI? Y N **→ Go to Item 7** **ERFC6A**
- b. How many?

--

→ Ineligible if >2 **ERFC6B**
- c. Did your child receive a VUR diagnosis prior to the second UTI? Y **→ Ineligible** N **ERFC6C**
- d. Did your child take prophylactic anti-microbials for UTI
prior to the second UTI? Y **→ Ineligible** N **ERFC6D**

ID NUMBER:							
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FORM CODE: ERF
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Occasion

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SEQ #

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C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? Y N → **Go to Item 14** **ERF7**

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? **ERFB8A**

b. Temperature measurement units (*circle one*):

°F F **ERFB8B**
°C C

9. What was the temperature measurement route? (*circle one*): **ERF10**

Oral O
Axillary..... A
Tympanic..... T
Rectal R
Unknown U

10. What location was this temperature measured? (*Circle one*): **ERF11**

Home..... H
Medical care professional M

11. a. What was the highest measured temperature during the index

UTI?..... **ERF8A**

b. Temperature measurement units (*circle one*):

°F F **ERF8B**
°C C

c. What was the date of the highest temperature (mm/dd/yyyy)? **ERF9**

12. What was the total duration of fever prior to index UTI antimicrobial

treatment (hrs)? **ERF12**

13. What was the time from index UTI antimicrobial treatment to a

sustained (> 24 hrs) normal temperature (hrs)?..... **ERFB13**

14. Were the following symptoms present within 24 hrs prior to or following the initial UTI work-up?

	<u>Yes</u>	<u>No</u>	<u>Unknown</u>	
a. Suprapubic, abdominal, or flank pain or tenderness.....	Y	N	U	ERFC14A
b. Urinary urgency	Y	N	U	ERFC14B
c. Urinary frequency	Y	N	U	ERFC14C

ID NUMBER:						
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	Yes	No	Unknown	Not Applicable
d. Urinary hesitancy.....	Y	N	U	ERFC14D
e. Dysuria	Y	N	U	ERFC14E
f. Foul-smelling urine	Y	N	U	ERFC14F
g. Failure to thrive (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14G
h. Dehydration (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14H
i. Hypothermia (if child $\leq$ 4 mo.)	Y	N	U	X ERFC14I

15. What was the total number of days that your child

experienced these symptoms?

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ERFB15

16. **[PC]** Was there a temperature $\geq$ 100.4°F or 38°C (see Q8) **OR** were urinary tract symptoms (see Q14) present 24 hrs prior to or following the initial index UTI work-up?

Y

N

→ **Ineligible**

ERFC16

D. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy):

		/			/				
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ERFB17A

b. **[PC]** Dipstick results - leukocyte esterase (*circle one*):

ERF17A

Negative A

Trace B

Small (+) C

Moderate (++) D

Large (+++) E

c. **[PC]** Dipstick results - nitrite (*circle one*):

ERF17B

Negative N

Positive P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy):

		/			/				
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ERFB18A

b. **[PC]** WBC (*Enter count. Use 999.999 for values $\geq$ 999.999*):

			.			
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ERFB18B

c. **[PC]** Reporting units for WBC microscopy (*circle one*):

WBC/mm³ A

WBC/hpf B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace (see Q17b) **OR**

WBC $\geq$ 10 WBC/mm³ or WBC $\geq$ 5 WBC/hpf (see Q18)?

Y

N

→ **Ineligible**

ERFB19

ID NUMBER:							
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E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy):

 /

 /

ERFB20A

b. **[PC]** Method of urine collection (*circle one*): **ERF20**

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D → **Ineligible**

Unknown E → **Ineligible**

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida? Y N → **Ineligible** **ERFB21A**

b. **[PC]** How many organisms were present?

 → **Ineligible if more than 2** **ERFB21B**

22. a. **[PC]** Primary organism (*select from list*):

ERFB22A

b. **[PC]** Data type from primary organism culture results (*circle one*): **ERFB22B**

= (equal to) A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range F

c. **[PC]** Colony count (CFU/ml) of primary organism: c1.

 - c2.

ERFB22C1 **ERFB22C2**

23. a. **[PC]** Secondary organism (*select from list*):

ERFB23A

b. **[PC]** Data type from secondary organism culture results (*circle one*): **ERFB23B**

= (equal to) A → **Skip field c2**

> (greater than) B → **Skip field c2**

≥ (greater than or equal to) C → **Skip field c2**

< (less than) D → **Skip field c2**

≤ (less than or equal to) E → **Skip field c2**

Range F

c. **[PC]** Colony count (CFU/ml) of secondary organism: c1.

 - c2.

ERFB23C1 **ERFB23C2**

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24. a. [PC] Was the colony count for the primary organism $\geq 50,000$ CFU/ml in catheterized or suprapubic specimens **OR** $\geq 100,000$ CFU/ml in clean-voided specimen? (See Q22.) Y N → **Ineligible** **ERFB24A**
- b. [PC] Was the colony count for the secondary organism $\leq 10,000$ CFU/ml? (See Q23.) Y N → **Ineligible** **ERFC24B**

F. INDEX UTI TREATMENT

25. [PC] How many different antimicrobials were prescribed to treat the index UTI? (Describe in Q26-Q29.) **ERF25**

Antimicrobial (code from list):	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. [PC] a. ERF26A	b. ERF26B	c. ERF26C	d. Y N U ERF26D
27. [PC] a. ERF27A	b. ERF27B	c. ERF27C	d. Y N U ERF27D
28. [PC] a. ERF28A	b. ERF28B	c. ERF28C	d. Y N U ERF28D
29. [PC] a. ERF29A	b. ERF29B	c. ERF29C	d. Y N U ERF29D

30. [PC] a. Was the index UTI treated at least 7 days? (Sum Q26c, Q27c, Q28c, and Q29c.) Y N → **Ineligible** **ERF30A**
- [PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? (Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.) Y N **ERF30B**
31. [PC] Was a follow-up negative urine culture documented 1-14 days after completion of therapy? Y N → **Ineligible if Item 30b is N** **ERF31**
32. [PC] Date of follow-up urine culture (mm/dd/yyyy): **ERF32**

G. VCUG LOCAL REPORT

33. [PC] Date of VCUG (mm/dd/yyyy): **ERF33**
34. [PC] Is date of VCUG within 112 days after index UTI? Y N → **Ineligible** **ERFC34**
35. [PC] Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? Y N → **Ineligible** **ERF35**
36. [PC] Is grade V reflux present in either ureter? Y → **Ineligible** N **ERF36**

ID NUMBER:						
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SEQ #

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37. [PC] Does the VCUG show the following bladder abnormalities?

- a. Ureterocele Y → **Ineligible** N **ERF37A**
- b. Urethral valve Y → **Ineligible** N **ERF37B**

H. RENAL ULTRASOUND LOCAL REPORT

38. a. [PC] Date of ultrasound (mm/dd/yyyy):

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ERF38

b. [PC] Is date of ultrasound within 112 days after index UTI? Y N → **Ineligible** **ERFC38B**

39. [PC] Does the ultrasound show the following urologic abnormalities?

- a. Hydronephrosis with renal parenchyma atrophy Y → **Ineligible** N **ERF39A**
- b. Ureterocele Y → **Ineligible** N **ERF39B**
- c. Solitary kidney Y → **Ineligible** N **ERF39C**
- d. Profoundly small kidney (more than 2 SD below mean) Y → **Ineligible** N **ERF39D**
- e. Multicystic dysplastic kidney Y → **Ineligible** N **ERF39E**
- f. Pelvic kidney Y → **Ineligible** N **ERF39F**
- g. Fused kidney Y → **Ineligible** N **ERF39G**
- h. Neurogenic bladder Y → **Ineligible** N **ERF30H**

I. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? Y → **Ineligible** N **ERF40**
41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? Y → **Ineligible** N **ERF41**
42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? Y → **Ineligible** N **ERF42**
43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? Y → **Ineligible** N **ERF43**
44. Has your child ever had renal or bladder surgery? Y → **Ineligible** N **ERF44**

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45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown?.....

Y → Ineligible

N

ERF45

46. a. Is your child currently taking continuous antimicrobial prophylaxis?

Y

N → **Go to Item 47**

ERF46

b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment?.....

Y

N → Ineligible

ERFB46B

47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from study staff)?.....

Y → Ineligible

N

ERF47

48. Does the family have plans to move to an area that will make it no longer convenient for study participation?.....

Y → **Ineligible**

N

ERF48

49. Has your child had a temperature $\geq 100.4^{\circ}\text{F}$ or 38°C anytime in the last three days?

Y → Stop

N

ERF49

50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase $\geq$ trace **OR** microscopy results of

WBC ≥ 10 WBC/mm³ or WBC ≥ 5 WBC/hpf? Y $\rightarrow$ Stop

Y → **Stop**

N

ERFB50

51. **[PC]** Eligibility criteria reviewed and randomization authorized by (name of investigator):

BLIND AUTHORITY

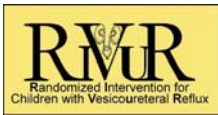
[illegible]

Note: choosing 'Y' to question #52 will initiate randomization. Items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered above are accurate before continuing.

52. [PC] Do you wish to randomize this child to a treatment group?..... Y

N

ERF51



ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER:						
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SEQ #

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Participant Name: _____

Instructions: Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.

A. AGE

1. [PC] Date of clinic visit (mm/dd/yyyy):

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ERF1
2. Child's date of birth (mm/dd/yyyy):

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ERF2
3. [PC] Age in months: **[determined by DMS]** **ERF3**
4. If child's age < 6 months, was gestational age $\geq$ 34 weeks? Y **Yes** N **No** **Not Applicable** **ERF4**
5. [PC] Is child's age $\geq$ 2 months and < 72 months (6 yrs)? Y N **ERF5**
6. Is this your child's first UTI? Y N **ERF6**

B. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the UTI event? Y N **Go to Item 14** **ERF7**
8. a. What was your child's highest measured temperature $\pm$ 24 hrs of the urine collection that diagnosed the UTI?

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ERFB8A
- b. Temperature measurement units (circle one):
- °F F **ERFB8B**
- °C C
9. What was the temperature measurement route? (circle one): **ERF10**
- Oral O
- Axillary A
- Tympanic T
- Rectal R
- Unknown U

ID NUMBER:							
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SEQ #

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10. What location was this temperature measured? (Circle one): **ERF11**

Home..... H

Medical care professional M

11. a. What was the highest measured temperature during the UTI? **ERF8A**

b. Temperature measurement units (circle one):

°F F **ERF8B**

°C C

c. What was the date of the highest temperature (mm/dd/yyyy)? **ERF9**

12. What was the total duration of fever prior to UTI antimicrobial treatment (hrs)? **ERF12**

13. What was the time from UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? **ERFB13**

14. Were the following symptoms present $\pm$ 24 hrs of the urine

collection that diagnosed the UTI?

Yes

No

Unknown

Not Applicable

- | | | | | |
|--|---|---|---|------------------|
| a. Suprapubic, abdominal, or flank pain or tenderness..... | Y | N | U | ERFB14A |
| b. Urinary urgency | Y | N | U | ERFB14B |
| c. Urinary frequency | Y | N | U | ERFB14C |
| d. Urinary hesitancy..... | Y | N | U | ERFB14D |
| e. Dysuria | Y | N | U | ERFB14E |
| f. Foul-smelling urine | Y | N | U | ERFB14F |
| g. Failure to thrive (if child $\leq$ 4 mo.) | Y | N | U | X ERFB14G |
| h. Dehydration (if child $\leq$ 4 mo.) | Y | N | U | X ERFB14H |
| i. Hypothermia (if child $\leq$ 4 mo.) | Y | N | U | X ERFB14I |

15. What was the total number of days that your child experienced these symptoms? **ERFB15**

16. [PC] Was there a temperature $\geq$ 100.4°F or 38°C (see Q8) OR were urinary tract symptoms (see Q14) present $\pm$ 24 hrs of the urine collection that diagnosed the UTI? Y N $\rightarrow$ **Ineligible** **ERFB16**

C. INDEX UTI URINALYSIS RESULTS

17. a. [PC] Date of dipstick urine collection (mm/dd/yyyy): **ERFB17A**

ID NUMBER:							
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SEQ #

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b. **[PC]** Dipstick results - leukocyte esterase (*circle one*):

ERF17A

- Negative A
Trace B
Small (+) C
Moderate (++) D
Large (+++) E

c. **[PC]** Dipstick results - nitrite (*circle one*):

ERF17B

- Negative N
Positive P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ERFB18A

b. **[PC]** WBC (*Enter count. Use 999.999 for values ≥ 999.999*):

			.			
--	--	--	---	--	--	--

ERFB18B

c. **[PC]** Reporting units for WBC microscopy (*circle one*):

- WBC/mm³ A
WBC/hpf B

ERF18B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace (see Q17b) **OR**

WBC ≥ 10 WBC/mm³ or WBC ≥ 5 WBC/hpf (see Q18)?

Y N → Ineligible

ERFB19

D. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ERFB20A

b. **[PC]** Method of urine collection (*circle one*):

ERF20

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D → Ineligible
Unknown E → Ineligible

21. a. **[PC]** Did the urine culture show a single primary organism that was neither lactobacillus nor candida?

Y N → Ineligible

ERFB21A

b. **[PC]** How many organisms were present?

→ Ineligible if more than 2

ERFB21B

22. a. **[PC]** Primary organism (*select from list*):

--	--

ERFB22A

ID NUMBER:							
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FORM CODE: ERF
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Contact
Occasion

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SEQ #

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b. [PC] Data type from primary organism culture results (circle one):

- = (equal to) A → Skip field c2
- > (greater than) B → Skip field c2
- ≥ (greater than or equal to) C → Skip field c2
- < (less than) D → Skip field c2
- ≤ (less than or equal to) E → Skip field c2
- Range F

c. [PC] Colony count (CFU/ml) of primary

organism: c1.

--	--	--	--	--	--

 - c2.

--	--	--	--	--	--

23. a. [PC] Secondary organism (select from list):

ERFB23A

b. [PC] Data type from secondary organism culture results (circle one):

- = (equal to) A → Skip field c2
- > (greater than) B → Skip field c2
- ≥ (greater than or equal to) C → Skip field c2
- < (less than) D → Skip field c2
- ≤ (less than or equal to) E → Skip field c2
- Range F

c. [PC] Colony count (CFU/ml) of secondary

organism: c1.

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 - c2.

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24. a. [PC] Was the colony count for the primary organism ≥ 50,000 CFU/ml in catheterized or suprapubic specimens OR ≥ 100,000 CFU/ml in clean-voided specimen? (See Q22.) Y

N → Ineligible

ERFB24A

b. [PC] Was the colony count for the secondary organism < 5,000 CFU/ml? (See Q23.) Y

N → Ineligible

ERFB24B

E. INDEX UTI TREATMENT

25. [PC] How many different antimicrobials were prescribed to treat the index UTI? (Describe in Q26-Q29.)

ERF25

Antimicrobial (code from list):

Date prescribed (mm/dd/yyyy):

Duration of
treatment (days):

Pathogen
sensitive to drug:

26. [PC] a.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					b.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							c.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					d.	Y N U	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>				
27. [PC] a.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					b.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							c.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					d.	Y N U	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>				
28. [PC] a.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					b.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>							c.	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					d.	Y N U	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>				

ID NUMBER:							
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Occasion

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SEQ #

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Antimicrobial (code from list):

Date prescribed (mm/dd/yyyy):

Duration of
treatment (days):

Pathogen
sensitive to drug:

29. [PC] a. b. / / c. d. Y N U **ERF29D**
ERF29A **ERF29B** **ERF29C**

30. [PC] a. Was the index UTI treated at least 7 days? (Sum Q26c, Q27c, Q28c, and Q29c.) Y N → **Ineligible** **ERF30A**

[PC] b. Was the index UTI appropriately treated at least 7 days with an effective drug? (Sum Q26c, Q27c, Q28c, and Q29c only where corresponding Q26d, Q27d, Q28d, and Q29d='Y'.) Y N **ERF30B**

31. [PC] Was a follow-up negative urine culture documented 1-14 days after completion of therapy? Y N → **Ineligible if Item 30b is N** **ERF31**

32. [PC] Date of follow-up urine culture (mm/dd/yyyy): / / **ERF32**

F. VCUG LOCAL REPORT

33. [PC] Date of VCUG (mm/dd/yyyy): / / **ERF33**

34. [PC] Is date of VCUG within 70 days after index UTI? Y N → **Ineligible** **ERFB34**

35. [PC] Does the VCUG demonstrate grade I, II, III or IV reflux in at least one ureter? Y N → **Ineligible** **ERF35**

36. [PC] Is grade V reflux present in either ureter? Y → **Ineligible** N **ERF36**

37. [PC] Does the VCUG show the following bladder abnormalities?

a. Ureterocele Y → **Ineligible** N **ERF37A**

b. Urethral valve Y → **Ineligible** N **ERF37B**

G. RENAL ULTRASOUND LOCAL REPORT

38. a. [PC] Date of ultrasound (mm/dd/yyyy): / / **ERF38**

b. [PC] Is date of ultrasound within 70 days after index UTI? Y N → **Ineligible** **ERFB38B**

39. [PC] Does the ultrasound show the following urologic abnormalities?

a. Hydronephrosis with renal parenchyma atrophy Y → **Ineligible** N **ERF39A**

b. Ureterocele Y → **Ineligible** N **ERF39B**

c. Solitary kidney Y → **Ineligible** N **ERF39C**

d. Profoundly small kidney (more than 2 SD below mean) Y → **Ineligible** N **ERF39D**

e. Multicystic dysplastic kidney Y → **Ineligible** N **ERF39E**

f. Pelvic kidney Y → **Ineligible** N **ERF39F**

ID NUMBER:							
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Occasion

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SEQ #

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- g. Fused kidney Y→**Ineligible** N **ERF39G**
- h. Neurogenic bladder Y→**Ineligible** N **ERF39H**

H. OTHER MEDICAL EXCLUSIONS

40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)? Y→**Ineligible** N **ERF40**
41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)? Y→**Ineligible** N **ERF41**
42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? Y→**Ineligible** N **ERF42**
43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? Y→**Ineligible** N **ERF43**
44. Has your child ever had renal or bladder surgery? Y→**Ineligible** N **ERF44**

I. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown? Y→**Ineligible** N **ERF45**
46. a. Is your child currently taking continuous antimicrobial prophylaxis? Y N →**Go to Item 47** **ERF46**
- b. Is the family willing to discontinue current prophylaxis to begin RIVUR treatment? Y N →**Ineligible** **ERFB46B**
47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from a nurse)? Y→**Ineligible** N **ERF47**
48. Does the family have plans to move to an area that will make it no longer convenient for study participation? Y→**Ineligible** N **ERF48**

J. RANDOMIZATION

49. Has your child had a temperature $\geq 100.4^{\circ}\text{F}$ or 38°C anytime in the last three days? Y→**Go to Item 52** N **ERF49**
50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase $\geq$ trace? Y→**Go to Item 52** N **ERFB50**

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Occasion

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SEQ #

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Note: choosing 'Y' to question #51 will initiate randomization. Some items on this form will not be able to be changed following the randomization procedure. Please verify that the responses you have entered are accurate before continuing.

N

ERF51

K. ADMINISTRATIVE INFORMATION

□ □ / □ □ / □ □ □ □

ERF52

53. **[PC]** Method of data collection (*circle one*):

C

ERF54

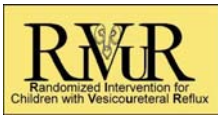
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Page 10

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[illegible]



ELIGIBILITY AND RANDOMIZATION FORM

ID NUMBER:

FORM CODE: ERF
VERSION: A 04/16/07

Contact
Occasion

SEQ #

Participant Name: _____

Instructions: Complete this form for RIVUR-eligible children. The form is completed during the child's eligibility and randomization clinic visit to document the child meeting all eligibility criteria. Enter data into the data management system (DMS) to run the randomization procedure.

A. AGE

1. [PC] Date of clinic visit (mm/dd/yyyy): // [ERF1]
2. Child's date of birth (mm/dd/yyyy): // [ERF2]
3. [PC] Age in months: [determined by DMS] [ERF3]
4. If child's age < 6 months, was gestational age $\geq$ 34 weeks? Y Yes No Not Applicable
N → Ineligible X [ERF4]
5. Is child's age $\geq$ 2 months and < 72 months (6 yrs)? Y N → Ineligible [ERF5]
6. Are you able to assess that this is your child's first UTI? Y N → Ineligible [ERF6]

B. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the UTI event? Y N → Go to Item 14 [ERF7]
8. a. What was your child's highest measured temperature? [ERF8A]
- b. Temperature measurement units (circle one):
°F F [ERF8B]
°C C
- c. [PC] Was there a temperature $\geq$ 100.4°F or 38°C? Y N → Go to Item 14 [ERF8C]
9. What was the date of highest temperature (mm/dd/yyyy)? // [ERF9]
10. What was the temperature measurement route? (circle one): [ERF10]
Oral O
Axillary A
Tympanic T
Rectal R
Unknown U

ID NUMBER:						
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FORM CODE: ERF
VERSION: A 04/16/07

Contact
Occasion

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SEQ #

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11. What location was the highest temperature measured? (Circle one): **ERF11**

Home..... H

Medical care professional M

12. What was the duration of fever prior to treatment (hrs)?..... **ERF12**

13. What was the time from treatment to normal temperature (hrs)? **ERF13**

14. Were the following symptoms present during the index UTI?	Yes	No	Unknown	Not Applicable
a. Suprapubic, abdominal, or flank pain or tenderness.....	Y	N	U	ERFA14A
b. Urinary urgency	ERFA14B Y	N	U	
c. Urinary frequency	ERFA14C Y	N	U	
d. Urinary hesitancy.....	ERFA14D Y	N	U	
e. Dysuria	ERFA14E Y	N	U	
f. Foul-smelling urine	ERFA14F Y	N	U	
g. Failure to thrive (if child $\leq$ 4 mo.)	ERFA14G Y	N	U	X
h. Dehydration (if child $\leq$ 4 mo.)	ERFA14H Y	N	U	X
i. Hypothermia (if child $\leq$ 4 mo.)	ERFA14I Y	N	U	X

15. **[PC]** Was there a temperature $\geq$ 100.4°F or 38°C (see Q8c)
OR were urinary tract symptoms (see Q14) present during
the index UTI? Y N → **Ineligible** **ERFA15**

C. INDEX UTI URINALYSIS RESULTS

16. **[PC]** Date of urine collection (mm/dd/yyyy):..... **ERFA16**

17. **[PC]** Urinalysis dipstick results:

a. Leukocyte esterase (circle one): **ERF17A**

Negative A

Trace B

Small (+) C

Moderate (++)..... D

Large (+++)..... E

b. Nitrite (circle one): **ERF17B**

Negative N

Positive P

ID NUMBER:							
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FORM CODE: ERF
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Contact
Occasion

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SEQ #

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18. [PC] Urinalysis microscopy results:

a. WBC (enter 000 for <1, 999 for >150):

--	--	--

ERFA18A

b. Reporting units for WBC microscopy (circle one):

WBC/mm³ A ERF18B
WBC/hpf B

19. [PC] Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to 1+ (see Q17a) **OR**

WBC ≥ 10 WBC/mm³ or WBC ≥ 5 WBC/hpf (see Q18)? Y N → Ineligible ERFA19

D. INDEX UTI URINE CULTURE RESULTS

20. [PC] Method of urine collection (circle one): ERF20

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D → Ineligible

Unknown E → Ineligible

21. [PC] Did the urine culture show a single organism? Y N → Ineligible ERFA21

22. [PC] Colony count (CFU/ml):

--	--	--	--	--	--

ERFA22

23. [PC] Was the colony count ≥ 50,000 CFU/ml in catheterized or suprapubic specimens **OR** ≥ 100,000 CFU/ml in clean-voided specimen? (See Q22.) Y N → Ineligible ERFA23

24. [PC] Isolated organism (code from list):

--	--

ERFA24

E. INDEX UTI TREATMENT

25. [PC] How many different antimicrobials were prescribed to treat the index UTI? (Describe in Q26-Q29.)

--

ERF25

Antimicrobial (code from list):	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:											
26. [PC] a. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td></tr></table> ERF26A				b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> ERF26B							c. <table border="1" style="display: inline-table;"><tr><td></td><td></td></tr></table> ERF26C			d. Y N U ERF26D
27. [PC] a. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td></tr></table> ERF27A				b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> ERF27B							c. <table border="1" style="display: inline-table;"><tr><td></td><td></td></tr></table> ERF27C			d. Y N U ERF27D

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Pathogen
sensitive to drug:

ID NUMBER:							
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FORM CODE: ERF
VERSION: A 04/16/07

Contact
Occasion

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SEQ #

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- f. Pelvic kidney..... Y→**Ineligible** N **ERF39F**
- g. Fused kidney Y→**Ineligible** N **ERF39G**
- h. Neurogenic bladder Y→**Ineligible** N **ERF39H**

H. OTHER MEDICAL EXCLUSIONS

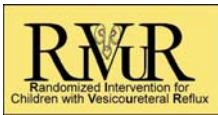
40. Does your child have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (i.e. VATER–VACTERL association, Townes-Brock syndrome, cat eye syndrome, Casamassima-Morton-Nance syndrome, renal coloboma syndrome, branchio-oto-renal syndrome, Frasier syndrome, congenital immunodeficiency, or acquired immunodeficiency)?..... Y→**Ineligible** N **ERF40**
41. Does your child have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (i.e. GI conditions, liver or kidney failure, malignancy, complex cardiac diseases)?..... Y→**Ineligible** N **ERF41**
42. Is trimethoprim or sulfa contraindicated due to an intolerance or known allergy, inadequate renal or hepatic function, G6PD deficiency or other reasons? Y→**Ineligible** N **ERF42**
43. Do the parents or siblings have a history of anaphylactic reaction to sulfa? Y→**Ineligible** N **ERF43**
44. Has your child ever had renal or bladder surgery? Y→**Ineligible** N **ERF44**

I. AVAILABILITY

45. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown?..... Y→**Ineligible** N **ERF45**
46. Is your child currently taking continuous antimicrobial prophylaxis?.... Y→**Ineligible** N **ERF46**
47. Is there any reason that would make completing the study protocol impossible (i.e. administering daily oral medication, visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from a nurse)? Y→**Ineligible** N **ERF47**
48. Does the family have plans to move to an area that will make it no longer convenient for study participation?..... Y→**Ineligible** N **ERF48**

J. RANDOMIZATION

49. Has your child had a temperature $\geq 100.4^{\circ}\text{F}$ or 38°C anytime in the last three days? Y→**Go to Item 52** N **ERF49**
50. **[PC]** Was pyuria present on today's urine dipstick, noted as leukocyte esterase $\geq 1+$? Y→**Go to Item 52** N **ERFA50**



EXIT FORM

ID NUMBER:						
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FORM CODE: EXF
VERSION: B 3/22/10

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form should be completed by project staff at the exit clinic visit or upon notification of withdrawal.
****Important:** Study Coordinator should not share his/her responses with the participant.

A. STUDY COORDINATOR'S GUESS

1. [PC] What treatment group do you believe the participant was assigned? (circle one):

Active Drug A

EXF1

Inactive Drug I

2. [PC] How certain are you that the participant was randomized to that treatment group? (circle one):

Very Certain V

Fairly Certain F

EXF2

Uncertain U → Go to Item 4

3. What makes you believe the participant was randomized into that treatment group? _____

EXF3

B. PARTICIPANT'S GUESS

We very much appreciate your participation in RIVUR and have two final questions related to the study medication. Your child received either active antibiotic prophylaxis or a similarly appearing liquid (inactive drug).

4. Which do you think you received, antibiotic or inactive drug? Guessing is okay.

Active Drug A

EXF4

Inactive Drug I

5. How certain are you about this?

Very Certain V

Fairly Certain F

EXF5

Uncertain U → Go to Item 7

6. What makes you believe that your child was receiving an active drug or inactive drug? _____

EXF6

C. FUTURE VUR TREATMENT PLANS

7. Are there future VUR treatment plans beyond surveillance of the child?

Yes Y

No N → Go to Item 14

EXFB7

ID NUMBER:							
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FORM CODE: EXF
VERSION: B 3/22/10

Contact
Occasion

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SEQ #

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Participant Name: _____

Which of the following post-RIVUR VUR treatment options are being undertaken or considered by the family?

8. a. Anti-microbial prophylaxis:

Yes, definitely Y

Yes, being considered C

No..... N → Go to Item 9a

EXFB8A

Unknown U → Go to Item 9a

Treatment not available or not applicable..... X → Go to Item 9a

b. Anti-microbial Code:

--	--	--

EXFB8B

If other, please record 500 and specify: _____

9. a. Reimplantation surgery:

Yes, definitely Y

Yes, being considered C

No..... N → Go to Item 10a

EXFB9A

Unknown U → Go to Item 10a

Treatment not available or not applicable..... X → Go to Item 10a

If 'Y' or 'C' specify procedure details: _____

b. If scheduled or completed, specify date (mm/dd/yyyy):

--	--	--	--	--	--	--	--

EXFB9B

10. a. Deflux injection:

Yes, definitely Y

Yes, being considered C

No..... N → Go to Item 11

EXFB10A

Unknown U → Go to Item 11

Treatment not available or not applicable..... X → Go to Item 11

If 'Y' or 'C' specify procedure details: _____

b. If scheduled or completed, specify date (mm/dd/yyyy):

--	--	--	--	--	--	--	--

EXFB10B

ID NUMBER:							
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FORM CODE: EXF
VERSION: B 3/22/10

Contact
Occasion

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SEQ #

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Participant Name: _____

11. Refer to another healthcare provider:

Yes, definitely Y
Yes, being considered C
No..... N
Unknown U
Treatment not available or not applicable..... X

EXFB11

If 'Y' or 'C' specify provider subspecialty: _____

12 a. Repeat VCUG (after the 24-month VCUG):

Yes, definitely Y
Yes, being considered C
No..... N
Unknown U
Treatment not available or not applicable..... X

Go to Item 13

Go to Item 13

Go to Item 13

EXFB12A

If 'Y' or 'C' specify procedure details: _____

b. If scheduled or completed, specify date (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

EXFB12B

13. Other treatment of management for VUR:

Yes, definitely Y
Yes, being considered C
No..... N

EXFB13

If 'Y' or 'C' specify other treatment details: _____

D. ADMINISTRATIVE INFORMATION

14. Date of data collection (mm/dd/yyyy):

		/			/				
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EXF7

15. Method of data collection (*circle one*):

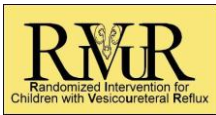
Computer C
Paper..... P

EXF8

16. Recorder's initials: .

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BLIND_STAFF_ID



EXIT FORM

ID NUMBER:						
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FORM CODE: EXF
VERSION: A 5/21/09

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form should be completed by project staff at the exit clinic visit or upon notification of withdrawal.
****Important:** Study Coordinator should not share his/her responses with the participant.

A. STUDY COORDINATOR'S GUESS

1. [PC] What treatment group do you believe the participant was assigned? (circle one):

Active Drug A

EXF1

Inactive Drug I

2. [PC] How certain are you that the participant was randomized to that treatment group? (circle one):

Very Certain V

Fairly Certain F

EXF2

Uncertain..... U → Go to Item 4

3. What makes you believe the participant was randomized into that treatment group? _____

EXF3

B. PARTICIPANT'S GUESS

We very much appreciate your participation in RIVUR and have two final questions related to the study medication. Your child received either active antibiotic prophylaxis or a similarly appearing liquid (inactive drug).

4. Which do you think you received, antibiotic or inactive drug? Guessing is okay.

Active Drug A

EXF4

Inactive Drug I

5. How certain are you about this?

Very Certain V

Fairly Certain F

EXF5

Uncertain..... U → Go to Item 7

6. What makes you believe that your child was receiving an active drug or inactive drug? _____

EXF6

C. ADMINISTRATIVE INFORMATION

7. Date of data collection (mm/dd/yyyy):

		/			/				
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EXF7

8. Method of data collection (circle one):

Computer C

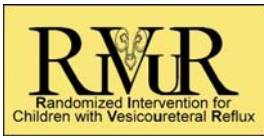
EXF8

Paper..... P

9. Recorder's initials:

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BLIND_STAFF_ID



PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

ID NUMBER:							
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FORM CODE: FUP
VERSION: C 07/18/08

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form will be completed at each protocol scheduled telephone or clinic follow-up contact, whether the contact is completed or not.

A. CONTACT INFORMATION

1. [PC] Type of contact (circle one):

- Regularly scheduled protocol clinic visit A → **Go to Item 3**
Regularly scheduled protocol phone contact B → **Go to Item 3**
Protocol phone contact replacing protocol clinic visit C → **Go to Item 3**
Protocol clinic visit replacing protocol phone contact D → **Go to Item 3**
Missed protocol scheduled contact E

FUP1

2. [PC] Indicate the main reason the contact was missed (circle one):

- Participant refused A → **Go to Item 23**
Participant incapacitated B → **Go to Item 23**
Participant withdrew consent C → **Complete ICT** → **Go to Item 23**
Participant location unknown D → **Go to Item 23**
Oversight E → **Go to Item 23**
Participant died F → **Complete AEF, MCA, MCN** → **Go to Item 23**
Unknown G → **Go to Item 23**
Unable to contact family after repeated attempts H → **Go to Item 23**

FUP2

B. SIDE EFFECTS/ SERIOUS ADVERSE EVENTS and MEDICAL CARE HISTORY

- 3a. [PC] Since the last protocol study contact on (mm/dd/yyyy), does the parent/caregiver, or the RIVUR clinic staff feel the child has experienced any side effects that are possibly associated with the study medication? Y →

FUPB3A

Complete AEF for each

N → **Go to Item 3c**

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

3b. [PC] Possible side effect determined by:

- Parent/Guardian P
Clinic Staff C
Both B

FUPB3B

ID NUMBER:							
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FORM CODE: FUP
VERSION: C 07/18/08

Contact
Occasion

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SEQ #

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- 3c. **[PC]** Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of a serious adverse event? Y →

Complete
AEF for each

N

FUPB3C

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

4. **[PC]** Since the last study contact, has the child had urine collected for analysis **OR** received medical care for symptoms that include fever, rash, abdominal or flank pain, diarrhea or loose stools, urinary urgency, painful urination, foul-smelling urine, or for children less than 4 months old, failure to thrive, dehydration, or hypothermia? Y

N → Go to Item 7

FUPC4

Note: Question parent/guardian, review parent diary, and review family contacts to clinic since last protocol-scheduled follow-up contact.

5. **[PC]** Since the last protocol-scheduled follow-up contact, how many times has the child received medical care that requires collection of medical records?

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 →

FUPC5

MCN, MCA, (USR) for each

6. **[PC]** Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above. Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.

Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

1. MCID Number		2. (Y/N)	Notes (not data entered):										
a1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6A1									a2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6A2
b1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6B1									b2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6B2
c1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6C1									c2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6C2
d1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6D1									d2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6D2
e1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6E1									e2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6E2
f1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6F1									f2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6F2
g1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6G1									g2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6G2
h1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6H1									h2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6H2
i1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6I1									i2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6I2
j1.	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6J1									j2. <table border="1"><tr><td></td><td></td></tr></table>			FUP6J2

ID NUMBER:							
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FORM CODE: FUP
VERSION: C 07/18/08

Contact
Occasion

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SEQ #

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7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications? Y → **Add to the CMF** N **FUP7**

C. STUDY MEDICATION STATUS

8. **[PC]** What is the child's current study medication status at this contact?

Note: A subject is considered discontinued only if done so by study staff and documented with DDF form, otherwise the participant is considered 'on study medication' regardless of adherence.

- On study medication A
Temporarily discontinue medication today B → **Complete DDF**
Medication was temporarily discontinued at a previous contact ... C → **Go to Item 16**
Permanently discontinue medication today D → **Complete DDF**
Medication was permanently discontinued at a previous contact . E → **Go to Item 17**

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? Y N **FUP9**

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

- Never..... A
1-2 times B
3-4 times C
> 4 times D
Don't know E
Medication was temporarily discontinued..... F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

- Takes medication every day A → **Go to Item 14**
Takes medication almost every day B → **Go to Item 14**
Takes medication approximately 75-90% of the time C
Takes medication approximately 50-74% of the time D
Takes medication approximately 25-49% of the time E
Seldom takes medication (occasionally but less than 25%)..... F
Does not take study medication..... G

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

- Forgetfulness A
Medication was misplaced B
Child experienced side effects..... C
Child refuses to take medication..... D
Parent felt child did not need the medication..... E
Medication was temporarily discontinued..... F
Other reason G
Specify: _____

FUP12

ID NUMBER:							
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FORM CODE: FUP
VERSION: C 07/18/08

Contact
Occasion

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SEQ #

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13. **[PC]** If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

Yes, parent/guardian to resume giving medication Y

No, parent/guardian will not give medication N

FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving (*read responses*)?

Very satisfied A

Satisfied B

Indifferent C

Dissatisfied D

Very dissatisfied E

Does not take study medication F

FUP14

15. Based on your child's response, how would you rate the taste of the medication (*read responses*)?

Very pleasant A

Pleasant B

Neither pleasant nor unpleasant C

Unpleasant D

Very unpleasant E

Does not take study medication F

FUP15

E. MEDICATION DISPENSING

16. a. **[PC]** Is medication being returned at this contact?

Yes Y →

No N

Complete MRF

FUPB16A

- b. **[PC]** Is medication being dispensed at this contact?

Yes Y →

No N

Complete MDD

FUP16

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?

Note: See *DMS Follow-Up Summary report*.

Trained since last study contact T

Not trained N →

Previously trained P →

Go to 19

Go to 19

FUP17

18. How old was your child when he/she began urinating in the toilet or

potty by him/herself during the day? (months)

FUP18

ID NUMBER:							
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FORM CODE: FUP
VERSION: C 07/18/08

Contact
Occasion

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SEQ #

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G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note:** See DMS Follow-Up Summary report.

Trained since last study contact T

Not trained N →

Go to 22

FUP19

Previously trained P →

Go to 22

20. How old was your child when he/she began defecating in the toilet or potty by him/herself? (months).....

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FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool?..... Y N

FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average?

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FUP22

H. ADMINISTRATIVE INFORMATION

23. [PC] Date of data collection (mm/dd/yyyy):

		/			/				
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FUP23

24. [PC] Method of data collection (circle one):

Computer C

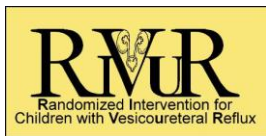
Paper..... P

FUP24

25. [PC] Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

ID NUMBER:							
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FORM CODE: FUP
VERSION: B 10/18/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form will be completed at each protocol scheduled telephone or clinic follow-up contact.

A. CONTACT INFORMATION

1. [PC] Type of contact (circle one):

- Regularly scheduled protocol clinic visit A → **Go to Item 3**
- Regularly scheduled protocol phone contact B → **Go to Item 3**
- Protocol phone contact replacing protocol clinic visit C → **Go to Item 3**
- Protocol clinic visit replacing protocol phone contact D → **Go to Item 3**
- Missed protocol scheduled contact E

FUP1

2. [PC] Indicate the main reason the contact was missed (circle one):

- Participant refused A → **Go to Item 23**
- Participant incapacitated B → **Go to Item 23**
- Participant withdrew consent C → **Complete ICT** → **Go to Item 23**
- Participant location unknown D → **Go to Item 23**
- Oversight E → **Go to Item 23**
- Participant died F → **Complete AEF, MCA, MCN** → **Go to Item 23**
- Unknown G → **Go to Item 23**

FUP2

B. SIDE EFFECTS/ SERIOUS ADVERSE EVENTS and MEDICAL CARE HISTORY

- 3a. [PC] Since the last protocol study contact on (mm/dd/yyyy), does the parent/caregiver, or the RIVUR clinic staff feel the child has experienced any side effects that are possibly associated with the study medication? Y →

Complete AEF for each

FUPB3A

N → **Go to Item 3c**

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

3b. [PC] Possible side effect determined by:

- Parent/Guardian P
- Clinic Staff C
- Both B

FUPB3B

ID NUMBER:							
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FORM CODE: FUP
VERSION: B 10/18/07

Contact
Occasion

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SEQ #

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- 3c. [PC] Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of a serious adverse event? Y →

Complete
AEF for each

N

FUPB3C

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

4. [PC] Since the last study contact, has the child received medical care for any reason?..... Y

N →

Go to Item 7

FUP4

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

5. [PC] How many times has the child received medical care since the last study contact?

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FUP5

Complete MCN & MCA for each

6. [PC] Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above. Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.

Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

1. MCID Number	2. (Y/N)	Notes (not data entered):									
a1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6A1									a2. <table border="1"><tr><td></td></tr></table>		FUP6A2
b1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6B1									b2. <table border="1"><tr><td></td></tr></table>		FUP6B2
c1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6C1									c2. <table border="1"><tr><td></td></tr></table>		FUP6C2
d1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6D1									d2. <table border="1"><tr><td></td></tr></table>		FUP6D2
e1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6E1									e2. <table border="1"><tr><td></td></tr></table>		FUP6E2
f1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6F1									f2. <table border="1"><tr><td></td></tr></table>		FUP6F2
g1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6G1									g2. <table border="1"><tr><td></td></tr></table>		FUP6G2
h1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6H1									h2. <table border="1"><tr><td></td></tr></table>		FUP6H2
i1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6I1									i2. <table border="1"><tr><td></td></tr></table>		FUP6I2
j1. <table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> BLIND_MCID6J1									j2. <table border="1"><tr><td></td></tr></table>		FUP6J2

7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications?..... Y →

Complete CMF

N

FUP7

ID NUMBER:							
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FORM CODE: FUP
VERSION: B 10/18/07

Contact
Occasion

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SEQ #

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C. STUDY MEDICATION STATUS

8. [PC] What is the child's current study medication status at this contact?

Note: A subject is considered discontinued only if done so by study staff and documented with DDF form, otherwise the participant is considered 'on study medication' regardless of adherence.

- On study medication A
- Temporarily discontinue medication today B → **Complete DDF**
- Medication was temporarily discontinued at a previous contact .. C → **Go to Item 16**
- Permanently discontinue medication today D → **Complete DDF**
- Medication was permanently discontinued at a previous contact.. E → **Go to Item 17**

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? Y N **FUP9**

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

- Never..... A
- 1-2 times B
- 3-4 times C
- > 4 times D
- Don't know E
- Medication was temporarily discontinued..... F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

- Takes medication every day A → **Go to Item 14**
- Takes medication almost every day B → **Go to Item 14**
- Takes medication approximately 75-90% of the time..... C
- Takes medication approximately 50-74% of the time..... D
- Takes medication approximately 25-49% of the time..... E
- Seldom takes medication (occasionally but less than 25%)..... F
- Does not take study medication..... G

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

- Forgetfulness A
- Medication was misplaced B
- Child experienced side effects..... C
- Child refuses to take medication..... D
- Parent felt child did not need the medication..... E
- Medication was temporarily discontinued..... F
- Other reason G
- Specify: _____

FUP12

ID NUMBER:							
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FORM CODE: FUP
VERSION: B 10/18/07

Contact
Occasion

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SEQ #

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13. [PC] If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

Yes, parent/guardian to resume giving medication Y
No, parent/guardian will not give medication N

FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving (*read responses*)?

Very satisfied A
Satisfied B
Indifferent C
Dissatisfied D
Very dissatisfied E
Does not take study medication F

FUP14

15. Based on your child's response, how would you rate the taste of the medication (*read responses*)?

Very pleasant A
Pleasant B
Neither pleasant nor unpleasant C
Unpleasant D
Very unpleasant E
Does not take study medication F

FUP15

E. MEDICATION DISPENSING

16. a. [PC] Is medication being returned at this contact?

Yes Y
No N

Complete MRF

FUPB16A

- b. [PC] Is medication being dispensed at this contact?

Yes Y
No N

Complete MDD

FUP16

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?

Note: See DMS Follow-Up Summary report.

Trained since last study contact T
Not trained N
Previously trained P

Go to 19

Go to 19

FUP17

18. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day? (months)

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FUP18

ID NUMBER:							
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FORM CODE: FUP
VERSION: B 10/18/07

Contact
Occasion

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SEQ #

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G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note:** See *DMS Follow-Up Summary report*.

Trained since last study contact T

Not trained N →

Go to 22

FUP19

Previously trained P →

Go to 22

20. How old was your child when he/she began defecating in the toilet

or potty by him/herself? (months).....

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FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool?.....

Y

N

FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average?

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FUP22

H. ADMINISTRATIVE INFORMATION

23. [PC] Date of data collection (mm/dd/yyyy):

		/			/				
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FUP23

24. [PC] Method of data collection (*circle one*):

Computer C

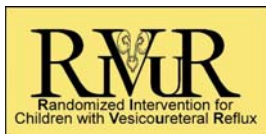
Paper..... P

FUP24

25. [PC] Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

ID NUMBER:							
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FORM CODE: FUP
VERSION: A 7/2/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form will be completed at each protocol scheduled telephone or clinic follow-up contact.

A. CONTACT INFORMATION

1. [PC] Type of contact (circle one):

- Regularly scheduled protocol clinic visit A → **Go to Item 3**
- Regularly scheduled protocol phone contact B → **Go to Item 3**
- Protocol phone contact replacing protocol clinic visit C → **Go to Item 3**
- Protocol clinic visit replacing protocol phone contact D → **Go to Item 3**
- Missed protocol scheduled contact E

FUP1

2. [PC] Indicate the main reason the contact was missed (circle one):

- Participant refused A → **Go to Item 23**
- Participant incapacitated B → **Go to Item 23**
- Participant withdrew consent C → **Complete ICT** → **Go to Item 23**
- Participant location unknown D → **Go to Item 23**
- Oversight E → **Go to Item 23**
- Participant died F → **Complete AEF, MCA, MCN** → **Go to Item 23**
- Unknown G → **Go to Item 23**

FUP2

B. ADVERSE EVENTS / SIDE EFFECTS and MEDICAL CARE HISTORY

3. [PC] Since the last protocol study contact on (mm/dd/yyyy), has the child had any new health problems that fit the study definition of an adverse event? Y →

Complete AEF for each

N

FUPA3

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

4. [PC] Since the last study contact, has the child received medical care for any reason? Y

N → **Go to Item 7**

FUP4

Note: Question parent/guardian, review parent diary, and review Follow-up Summary Report.

5. [PC] How many times has the child received medical care since the last study contact? | | | |--|--| | | | |--|--| →

FUP5

Complete MCN & MCA for each

ID NUMBER:							
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FORM CODE: FUP
VERSION: A 7/2/07

Contact
Occasion

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SEQ #

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6. **[PC]** Record the MCID numbers (or affix labels) associated with medical care visits reported in item 5 above. Items 6a2 – 6j2 (column #2) are indicators of a required associated MCN form. This field is automatically pre-filled as 'Y' upon data entry in the DMS for each MCID number listed. If after assigning an MCID number, it is eventually determined that a medical visit did not actually occur, the indicator in column #2 should be set to 'N' so an MCN form is no longer expected.

Note: Space has been provided for notes, to help you keep track of MCID numbers. (Not data entered.)

1. MCID Number	2. (Y/N)	Notes (not data entered):
a1. ☐ ☐ ☐ BLIND_MCID6A1	a2. ☐	FUP6A2
b1. ☐ ☐ ☐ BLIND_MCID6B1	b2. ☐	FUP6B2
c1. ☐ ☐ ☐ BLIND_MCID6C1	c2. ☐	FUP6C2
d1. ☐ ☐ ☐ BLIND_MCID6D1	d2. ☐	FUP6D2
e1. ☐ ☐ ☐ BLIND_MCID6E1	e2. ☐	FUP6E2
f1. ☐ ☐ ☐ BLIND_MCID6F1	f2. ☐	FUP6F2
g1. ☐ ☐ ☐ BLIND_MCID6G1	g2. ☐	FUP6G2
h1. ☐ ☐ ☐ BLIND_MCID6H1	h2. ☐	FUP6H2
i1. ☐ ☐ ☐ BLIND_MCID6I1	i2. ☐	FUP6I2
j1. ☐ ☐ ☐ BLIND_MCID6J1	j2. ☐	FUP6J2

7. Since our last study contact, has your child been treated with any prescription or over-the-counter medications? Y → Complete CMF N FUP7

C. STUDY MEDICATION STATUS

8. **[PC]** What is the child's current status of study medication use at this contact?
- On study medication A
- Temporarily discontinue medication today B → Complete DDF
- Medication was temporarily discontinued at a previous contact ... C → Go to Item 16
- Permanently discontinue medication today D → Complete DDF
- Medication was permanently discontinued at a previous contact . E → Go to Item 17

FUP8

D. STUDY MEDICATION INTERVIEW

9. Did your child take study medication today? Y N FUP9

ID NUMBER:							
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FORM CODE: FUP
VERSION: A 7/2/07

Contact
Occasion

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SEQ #

--	--

10. Sometimes doses of medication are missed. How often did your child miss a dose during the past week?

- Never..... A
1-2 times B
3-4 times C
> 4 times D
Don't know E
Medication was temporarily discontinued F

FUP10

11. Overall, during the past two months, how often did your child take the study medication?

- Takes medication every day A → **Go to Item 14**
Takes medication almost every day B → **Go to Item 14**
Takes medication approximately 75-90% of the time C
Takes medication approximately 50-74% of the time D
Takes medication approximately 25-49% of the time E
Seldom takes medication (occasionally but less than 25%) F
Does not take study medication G

FUP11

12. What is the primary reason that you did not give your child study medication every day or almost every day?

- Forgetfulness A
Medication was misplaced B
Child experienced side effects C
Child refuses to take medication D
Parent felt child did not need the medication E
Medication was temporarily discontinued F
Other reason G
Specify: _____

FUP12

13. [PC] If the child is not taking study medication, but should, can the parent/guardian be persuaded to resume giving the medication?

- Yes, parent/guardian to resume giving medication Y
No, parent/guardian will not give medication N

FUP13

14. Overall, how satisfied or dissatisfied are you with the medication your child is receiving (*read responses*)?

- Very satisfied A
Satisfied B
Indifferent C
Dissatisfied D
Very dissatisfied E

FUP14

15. Based on your child's response, how would you rate the taste of the medication (*read responses*)?

- Very pleasant A
Pleasant B
Neither pleasant nor unpleasant C

FUP15

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: FUP
VERSION: A 7/2/07

Contact
Occasion

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SEQ #

--	--

Unpleasant..... D

Very unpleasant..... E

E. MEDICATION DISPENSING

16. [PC] Is medication being dispensed at this contact?

Yes..... Y →

Complete MDD

FUP16

No N

F. INTERIM VOIDING HISTORY

17. What is the status of your child's toilet-training for urine during the day (that is, out of diapers and pull-ups, wearing underwear)?

Note: See DMS Follow-Up Summary report.

Trained since last study contact T

FUP17

Not trained N →

Go to 19

Previously trained P →

Go to 19

18. How old was your child when he/she began urinating in the toilet or potty by him/herself during the day? (months)

--	--

FUP18

G. INTERIM BOWEL HISTORY

19. What is the status of your child's toilet-training for bowel movements? **Note:** See DMS Follow-Up Summary report.

Trained since last study contact T

Not trained N →

Go to 22

FUP19

Previously trained P →

Go to 22

20. How old was your child when he/she began defecating in the toilet or potty by him/herself? (months)

--	--

FUP20

21. Since toilet/potty training, has your child had a history of soiling his/her underwear with stool?..... Y N

FUP21

22. During the last 2 months, how many bowel movements did your child have per week on average?

--	--

FUP22

H. ADMINISTRATIVE INFORMATION

23. [PC] Date of data collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

FUP23

24. [PC] Method of data collection (circle one):

Computer C

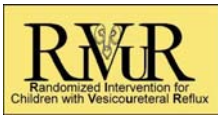
FUP24

Paper..... P

25. [PC] Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



INFORMED CONSENT TRACKING FORM

ID NUMBER:						
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FORM CODE: ICT
VERSION: B 3/18/10

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form should be completed by project staff after the initial study informed consent is signed, and, at all contact occasions when a request is made to modify consent or withdraw from the study.

A. CONSENT STATUS

1. Timing of consent (circle one):

Initial study consent I

ICT1

Modification of consent M

2. Type of consent or modification (circle one):

Full consent F

→ Go to Item 14

Partial consent P

Partial withdrawal of consent D

ICT2

Full withdrawal of consent W

→ Go to Item 14

If consent withdrawn, specify reason: _____

B. SPECIMEN CONSENT

3. Restrictions on stored (repository archived) serum (circle one):

ICT3

Yes, do not use/storage of archived serum Y

No restrictions, consented to use/store archived serum N

→ Go to Item 5

4. a. Is there a date restriction on use/storage of serum? Y

N → Go to Item 5

ICT4A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ICT4B

5. Restrictions on use/storage (genetics repository) of DNA (circle one):

Yes, do not use/storage of archived DNA Y

No restrictions, consented to use/store archived DNA N

→ Go to Item 7

ICT5

6. a. Is there a date restriction on use/storage of DNA? Y

N → Go to Item 7

ICT6A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ICT6B

7. Restrictions on stored (repository archived) urine (circle one):

Yes, do not use/store archived urine Y

No restrictions, consented to use/storage of archived urine N

→ Go to Item 9

ICT7

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: ICT
VERSION: B 3/18/10

Contact
Occasion

--	--

SEQ #

--	--

8. a. Is there a date restriction on use/storage of urine? Y

N → Go to Item 9

ICT8A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ICT8B

C. MEDICAL RECORDS AND DATA USE CONSENT

9. a. Permission to access medical records (*circle one*):

Yes, full access Y

No access N

Partial access P

If partial access, please specify: _____

ICT9

b. Permission to use data for future research studies (*circle one*):

Yes, future use of data Y

No future use of data N

Partial data may be used P

If partial data allowed, please specify: _____

ICTB9B

10. Permission to contact informants (*circle one*):

Yes, full contact of informants Y

No contact N

Limited contact P

If limited, please specify: _____

ICT10

11. Permission to release results to participant's physician (*circle one*):

Yes, release results as applicable Y

No release of results N

Partial release of results P

If partial release, please specify: _____

ICT11

12. Permission to contact parent/guardian in the future for imminent research studies (*circle one*):

Yes, future contact Y

No future contact N

Limited contact P

If limited, please specify: _____

ICTB12

13. Any other restrictions not specified in items 3 to 12? Y

N

ICT12

If yes, specify restrictions: _____

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: ICT
VERSION: B 3/18/10

Contact
Occasion

--	--

SEQ #

--	--

D. ADMINISTRATIVE INFORMATION

14. Date of consent or modified consent (mm/dd/yyyy):

--	--

 /

--	--

 /

--	--	--	--

ICT13

15. Method of data collection (*circle one*):

Computer C

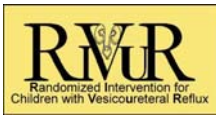
Paper P

ICT14

16. Recorder's initials:

--	--	--

BLIND_STAFF_ID



INFORMED CONSENT TRACKING FORM

ID NUMBER:						
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FORM CODE: ICT
VERSION: A 6/27/07

Contact
Occasion

--	--

SEQ #

--	--

Participant Name: _____

Instructions: This form should be completed by project staff after the initial study informed consent is signed, and, at all contact occasions when a request is made to modify consent or withdraw from the study.

A. CONSENT STATUS

1. Timing of consent (circle one):

Initial study consent I
Modification of consent M

ICT1

2. Type of consent or modification (circle one):

Full consent F → Go to Item 13
Partial consent P
Partial withdrawal of consent D
Full withdrawal of consent W → Go to Item 13
If consent withdrawn, specify reason: _____

ICT2

B. SPECIMEN CONSENT

3. Restrictions on stored (archived) blood (circle one):

Yes, do not use/storage of archived blood Y
No restrictions, consented to use/store archived blood N → Go to Item 5

ICT3

4. a. Is there a date restriction on use/storage of blood? Y

N → Go to Item 5

ICT4A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

--	--	--	--	--	--	--	--

ICT4B

5. Restrictions on use/storage of DNA (circle one):

Yes, do not use/storage of archived DNA Y
No restrictions, consented to use/store archived DNA N → Go to Item 7

ICT5

6. a. Is there a date restriction on use/storage of DNA? Y

N → Go to Item 7

ICT6A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

--	--	--	--	--	--	--	--

ICT6B

7. Restrictions on stored (archived) urine (circle one):

Yes, do not use/store archived urine Y
No restrictions, consented to use/storage of archived urine N → Go to Item 9

ICT7

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: ICT
VERSION: A 6/27/07

Contact
Occasion

--	--

SEQ #

--	--

8. a. Is there a date restriction on use/storage of urine? Y

N → Go to Item 9

ICT8A

b. If yes, specify date by which specimens must be used

(mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ICT8B

C. MEDICAL RECORDS CONSENT

9. Permission to access medical records (*circle one*):

Yes, full access Y

No access N

Partial access P

If partial access, please specify: _____

ICT9

10. Permission to contact informants (*circle one*):

Yes, full contact of informants Y

No contact N

Limited contact P

If limited, please specify: _____

ICT10

11. Permission to release results to participant's physician (*circle one*):

Yes, release results as applicable Y

No release of results N

Partial release of results P

If partial release, please specify: _____

ICT11

12. Any other restrictions not specified in items 3 to 11? Y

N

ICT12

If yes, specify restrictions: _____

D. ADMINISTRATIVE INFORMATION

13. Date of consent or modified consent (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

ICT13

14. Method of data collection (*circle one*):

Computer C

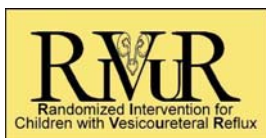
Paper P

ICT14

15. Recorder's initials:

--	--	--

BLIND_STAFF_ID



LIA Questionnaire

ID NUMBER:							
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FORM CODE: LIQ
VERSION: A 8/31/06

Contact
Occasion

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SEQ #

--	--

Participant Name: _____

Instructions: This is a self-administered questionnaire to be completed by the child's parent or guardian at baseline, 12 month, and end-of-study visits.

A. Parent/Guardian Response:

Items 1a-n are from "The Functional Status II(R) Measure which is copyrighted by R.E.K. Stein, C.K. Riessman and D.J. Jessop, 1981, 1991" Stein, R.E.K. and Jessop, D.J. "Manual for the Functional Status II(R) Measure." PACTS Papers. Bronx, New York: Albert Einstein College of Medicine, 1991.
Stein, R.E.K. and Jessop, D.J. "Functional Status II(R): A measure of Child Health Status." *Medical Care* 28, 11 (November 1990): 1041-1055.

1. Here are some statements that parents have made to describe their children. Please **circle one letter for each item a through n** that best describes your child. Please consider the previous 2 weeks as you answer. Did he/she:

	Never or rarely	Some of the time	Almost always	
a. Eat well.....	N.....	S.....	A.....	LIQA1A
b. Sleep well.....	N.....	S.....	A.....	LIQA1B
c. Seem contented and cheerful.....	N.....	S.....	A.....	LIQA1C
d. Act moody.....	N.....	S.....	A.....	LIQA1D
e. Communicate what he/she wanted.....	N.....	S.....	A.....	LIQA1E
f. Seem to feel sick and tired.....	N.....	S.....	A.....	LIQA1F
g. Occupy him / herself.....	N.....	S.....	A.....	LIQA1G
h. Seem lively and energetic.....	N.....	S.....	A.....	LIQA1H
i. Seem unusually irritable.....	N.....	S.....	A.....	LIQA1I
j. Sleep through the night.....	N.....	S.....	A.....	LIQA1J
k. Respond to your attention.....	N.....	S.....	A.....	LIQA1K
l. Seem unusually difficult.....	N.....	S.....	A.....	LIQA1L
m. React to things by crying.....	N.....	S.....	A.....	LIQA1M
n. Seem interested in what was going on around him/her	N.....	S.....	A.....	LIQA1N

2. How would you rate your child's health over the last 2 weeks? (Circle **one** number.) LIQA2

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
Worst Perfect
imaginable health health

3. How worried are you about your child's vesicoureteral reflux/VUR? (Circle **one** number.) LIQA3

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
Not Very
worried worried

ID NUMBER:							
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FORM CODE: LIQ
VERSION: A 8/31/06

Contact
Occasion

--	--

SEQ #

--	--

4. How difficult has it been for you to give your child medication every day? (Circle **one** number.) **LIQA4**

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
Not Very
difficult difficult

5. How much financial burden has your child's vesicoureteral reflux/VUR been for your family? (Circle **one** number.)

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10 **LIQA5**
Not a Huge
burden burden

6. How bothersome were the urinary tract infection symptoms for your child? (Circle **one** number.) **LIQA6**

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
Not Very
bothersome bothersome

7. How would you rate your child's health during the urinary tract infection? (Circle **one** number.) **LIQA7**

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
Worst Perfect
imaginable health
health

8. How much discomfort did your child experience with the ultrasound? (Circle **one** number.) **LIQA8**

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10
No Worst
discomfort discomfort

9. How much discomfort did your child experience with the voiding cystourethrogram (VCUG)? (Circle **one** number.)

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10 **LIQA9**
No Worst
discomfort discomfort

10. If your child has had a DMSA, how much discomfort did he/she experience with the DMSA? (Circle **one** number.)

0 ---- 1 ---- 2 ---- 3 ---- 4 ---- 5 ---- 6 ---- 7 ---- 8 ---- 9 ---- 10 99 **LIQA10**
No Worst Not
discomfort discomfort Applicable

Thank you!

B. Administrative Use Only

LIQA11

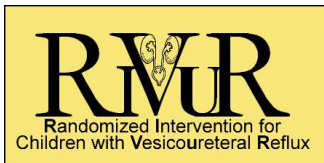
11. Date of Form (mm/dd/yyyy)

		/			/				
--	--	---	--	--	---	--	--	--	--

12. Reviewer's initials:

BLIND_STAFF_ID

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MEDICAL CARE ABSTRACTION FORM

ID NUMBER:							
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FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

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SEQ #

--	--

Participant Name: _____

Instructions: Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form including visits with fever, symptoms associated with UTI, VUR treatment, urine collection, or any hospitalization or emergency room visit.

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number:

--	--	--	--	--	--	--	--

BLIND_MCID1

NOTE: This # should match the MCID from the notification form (MCN).

2. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA3

Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

3. Is this a follow-up visit to a previously reported medical visit? Y N → **Go to Item 6** **MCA4**

4. Date of previously reported medical visit

--	--	--	--	--	--	--	--

MCA5

5. MCID Number associated with the previously reported visit:

--	--	--	--	--	--	--	--

BLIND_MCID6

6. Status of Medical Records Abstraction:

Obtained access to chart O

Pending access to chart P → **Go to Item 33**

No possibility of ever accessing chart N → **Go to Item 33**

MCA2

B. HOSPITALIZATION OR ER VISIT

7a. Was this a hospitalization or an ER visit? Y → **Complete AEF** N → **Go to Item 12** **MCAB7**

b. Specify if the participant was hospitalized or visited the emergency room (circle one):

Emergency room visit E

Hospitalization H

Other O

Specify If other: _____

MCAC7B

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA8

9. What was the disposition of the patient on discharge?

Discharged to home H → **Go to Item 12**

Admitted to Hospital from ER E → **Go to Item 12**

Transferred to another hospital T → **Go to Item 12**

Transferred to another medical care facility (e.g. rehab) M → **Go to Item 12**

Deceased D

MCA11

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

--	--

SEQ #

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10. Are any causes of death given on the discharge summary? Y

N → **Go to Item 12**

MCA12

11. Causes of death on the discharge summary:

- a. **MCA13A**
- b. **MCA13B**
- c. **MCA13C**
- d. **MCA13D**
- e. **MCA13E**
- f. **MCA13F**

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

12. Did this medical visit include a work-up for suspected UTI? Y

N → **Go to Item 14**

MCAB12

13. Date of first urine collection for suspected UTI work-up:.....

--	--	--	--	--	--	--	--	--	--

MCAB13

14. Are there ICD diagnosis codes listed in the medical record? Y

N → **Go to Item 17**

MCAB14

15. List the hospital discharge ICD codes exactly as they appear on the front sheet of the discharge summary.
If visit is not a hospitalization, list any diagnosis codes provided in the medical record:

- | | | | | | | | | | | | |
|----|--|--|--|--|---------------|----|--|--|--|--|---------------|
| a. | | | | | MCA14A | h. | | | | | MCA14H |
| b. | | | | | MCA14B | i. | | | | | MCA14I |
| c. | | | | | MCA14C | j. | | | | | MCA14J |
| d. | | | | | MCA14D | k. | | | | | MCA14K |
| e. | | | | | MCA14E | l. | | | | | MCA14L |
| f. | | | | | MCA14F | m. | | | | | MCA14M |
| g. | | | | | MCA14G | n. | | | | | MCA14N |

All ICD codes and text were evaluated by a Nosologist, please use diag_niddk1 variable "ICD_CODE" in place of MCA14A-MCA14N and MCA16A-MCA16N

16. Coding System:

ICD-9..... A

ICD-10..... B

MCA15

17. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:

- a. **MCA16A**
- b. **MCA16B**
- c. **MCA16C**

ID NUMBER:							
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FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

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SEQ #

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- d. MCA16D
- e. MCA16E
- f. MCA16F
- g. MCAC17G
- h. MCAC17H
- i. MCAC17I
- j. MCAC17J
- k. MCAC17K
- l. MCAC17L
- m. MCAC17M
- n. MCAC17N

D. SYMPTOMS

18. Do the medical records mention either a patient complaint or a medical finding for any of the symptoms listed below (see item 19 for listing of symptoms)?..... Y N → If N go to 22 MCAB18

19. Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X) as either a patient complaint or medical finding. For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and, indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form. (**Note:** if N, U, or X is selected in column 1 and 2, then skip columns 3 and 4.)

	1.	2.	3.	4.
	Documented Patient Complaint	Documented Medical Finding	Duration of symptom (days)	Occur within 24 hours of medical visit or UTI workup reported on this form?
a. Suprapubic, abdominal, or flank pain / tenderness	MCAB19A1 Y N U	MCAB19A2 Y N U	MCAB19A3 [][]	MCAB19A4 Y N U
b. Urinary urgency, frequency, hesitancy	MCAB19B1 Y N U	MCAB19B2 Y N U	MCAB19B3 [][]	MCAB19B4 Y N U
c. Dysuria	MCAB19C1 Y N U	MCAB19C2 Y N U	MCAB19C3 [][]	MCAB19C4 Y N U
d. Foul smelling urine	MCAB19D1 Y N U	MCAB19D2 Y N U	MCAB19D3 [][]	MCAB19D4 Y N U
e. Failure to thrive (<= 4 months old)	MCAB19E1 Y N U X	MCAB19E2 Y N U X	MCAB19E3 [][]	MCAB19E4 Y N U X
f. Dehydration (<= 4 months old)	MCAB19F1 Y N U X	MCAB19F2 Y N U X	MCAB19F3 [][]	MCAB19F4 Y N U X

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

--	--

SEQ #

--	--

MCAB19G1

MCAB19G2

MCAB19G3

MCAB19G4

1.

2.

3.

4.

Documented
Patient
Complaint

Documented
Medical
Finding

Duration
of
symptom
(days)

Occur within 24
hours of medical
visit or UTI workup
reported on this
form?

g. Hypothermia (≤ 4 months old)

Y N U X

Y N U X

--	--

Y N U X

20. What date does the medical record indicate that
the first symptom associated with this medical care

visit began (mm/dd/yyyy)?

--	--	--	--	--	--	--	--

MCAB20

21. Were any medications given to the child for symptoms within
24 hours prior to the medical visit or work-up for suspected UTI
(Y = yes, N = no, U = not documented)?

Y

N

U

MCAB21

If Yes, list medications:

Note: If Yes, remember to also list medication(s) on the next CMF form.

E. FEVER

22. Do the medical records mention any fever associated with this
event, either a patient complaint or a medical finding?

Y

N

→ If N go to 26

MCAB22

23. a. Was a temperature taken during the medical visit?

Y

N

→ If N go to 24

MCA19

b. What was the highest temperature recorded during the
medical visit:

--	--	--	--	--

MCA20A

c. Units of measurement during the medical visit (circle one):

°F

F

°C

C

MCAB20B

d. Recorded temperature measurement route during the medical visit (circle one):

Oral

O

Axillary

A

Tympanic

T

Rectal

R

Temporal

F

Unknown

U

MCAB23D

24. a. Does the medical record indicate that the child had a fever
of at least 100.4° F or 38° C at any time prior to the medical visit
(Y=yes, N=no, U=not documented)

Y

N

U

→ If N or U go to 26

MCAB24A

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

--	--

SEQ #

--	--

b. Highest temperature measured prior to medical visit:

--	--	--	--

MCA25A

c. Units of measurement prior to medical visit (*circle one*):

°F F

°C C

MCA25B

d. Temperature measurement route prior to medical visit (*circle one*):

Oral O

Axillary A

Tympanic T

Rectal R

Temporal F

Unknown U

MCAB24D

e. Date of highest fever prior to medical visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCAB24E

25. a. Does the medical record indicate that the child was having a fever of at least 100.4° F or 38° C within 24 hrs prior to the medical visit or UTI workup reported on this form (Y=yes, N=no, U=not documented) Y N U →

If N or U go to 26

MCAB25A

b. Highest temperature measured within 24 hrs prior to the medical visit or UTI workup reported on this form:

--	--	--	--

MCAB25B

c. Units of measurement within 24 hrs prior to the medical visit or UTI workup reported on this form (*circle one*):

°F F

°C C

MCAB25C

d. Temperature measurement route within 24 hrs prior to the medical visit or UTI workup reported on this form (*circle one*):

Oral O

Axillary A

Tympanic T

Rectal R

Temporal F

Unknown U

MCAB25D

e. Date of highest fever within 24 hrs prior to the medical visit or UTI workup reported on this form (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCAB25E

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MCA
VERSION: C 01/21/10

Contact
Occasion

--	--

SEQ #

--	--

26. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? Y N U

MCA26

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

F. WEIGHT

27. Was a weight measurement recorded? Y N →

Go to item 30

MCA30

28. a. Weight:

 .

MCA31A

- b. Weight units (*circle one*):

Kilograms K

MCA31B

Pounds P

29. Date of measured weight (mm/dd/yyyy):

 /

 /

MCA32

G. URINALYSIS

30. Was a urinalysis or urine culture performed during the medical care visit? Y N →

Go to item 32

MCA33

31. How many urinalysis or urine culture reports are there associated with this hospital admission or medical care visit?

 →

Complete USR for each

MCA34

H. MEDICAL PROCEDURES / IMAGES:

32. Were any of the following medical procedures noted in the chart review?

- a. **Urethral catheterization** (not for urine specimen collection) Y N →

Go to item 32d

MCA35A

- b. If yes, date of catheterization: (mm/dd/yyyy):

 /

 /

MCA35B

- c. If yes, number of days catheterized

MCA35C

- d. **Renal and/or bladder ultrasound** Y N →

Go to item 32f

MCA35D

- e. If yes, date of Ultrasound: (mm/dd/yyyy):

 /

 /

MCA35E

- f. **VCUG**: Y N →

Go to item 32h

MCA35F

- g. If yes, date of VCUG: (mm/dd/yyyy):

 /

 /

MCA35G

- h. **DMSA** Y N →

Go to item 32j

MCA35H

- i. If yes, date of DMSA: (mm/dd/yyyy):

 /

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MCA35I

ID NUMBER:							
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FORM CODE: MCA
VERSION: C 01/21/10

Contact Occasion			SEQ #		
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j. Procedure to correct VUR Y N → **Go to item 33** **MCAC32J**

k. If yes, date of procedure: (mm/dd/yyyy):

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MCAC32K

l. Name of procedure: **MCAC32L**

I. ADMINISTRATIVE INFORMATION

33. Date of data collection (mm/dd/yyyy):

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MCA36

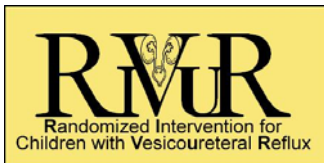
34. Method of data collection (*circle one*):

Computer C **MCA37**
Paper..... P

35. Recorder's initials:

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BLIND_STAFF_ID



MEDICAL CARE ABSTRACTION FORM

ID NUMBER:						
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FORM CODE: MCA
VERSION: B 2/22/08

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form including well child visits, and RIVUR clinic sick visits.

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number:

--	--	--	--	--	--	--

BLIND_MCID1
NOTE: This # should match the MCID from the notification form (MCN).

2. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA3
Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

3. Is this a follow-up visit to a previously reported medical visit? Y N → **Go to Item 6** **MCA4**

4. Date of previously reported medical visit?

--	--	--	--	--	--	--	--

MCA5

5. MCID Number associated with the previously reported visit:

--	--	--	--	--	--	--

BLIND_MCID6

6. Status of Medical Records Abstraction:

Obtained access to chart O

Pending access to chart P → **Go to Item 33**

No possibility of ever accessing chart N → **Go to Item 33**

MCA2

B. HOSPITALIZATION OR ER VISIT

7. Was this a hospitalization or an ER visit? Y N → **Go to Item 12** **MCAB7**

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA8

9. What was the disposition of the patient on discharge?

Discharged to home H → **Go to Item 12**

Admitted to Hospital from ER E → **Go to Item 12**

Transferred to another hospital T → **Go to Item 12**

Transferred to another medical care facility (e.g. rehab) M → **Go to Item 12**

Deceased D

MCA11

10. Are any causes of death given on the discharge summary? Y N → **Go to Item 12** **MCA12**

ID NUMBER:						
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FORM CODE: MCA
VERSION: B 2/22/08

Contact Occasion		
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SEQ #		
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11. Causes of death on the discharge summary:

- a. MCA13A
- b. MCA13B
- c. MCA13C
- d. MCA13D
- e. MCA13E
- f. MCA13F

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

12. Did this medical visit include a work-up for suspected UTI? Y N → Go to Item 14 MCAB12

13. Date of first urine collection for suspected UTI work-up:.....

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MCAB13

14. Are there ICD diagnosis codes listed in the medical record? Y N → Go to Item 17 MCAB14

15. List the hospital discharge ICD codes exactly as they appear on the front sheet of the discharge summary.
If visit is not a hospitalization, list any diagnosis codes provided in the medical record:

- | | | |
|---|---|--|
| <ul style="list-style-type: none"> a. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14A b. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14B c. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14C d. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14D e. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14E f. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14F g. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14G | <ul style="list-style-type: none"> h. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14H i. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14I j. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14J k. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14K l. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14L m. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14M n. <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table> MCA14N | |
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16. Coding System:

ICD-9..... A MCA15
ICD-10..... B

17. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:

- a. MCA16A
- b. MCA16B
- c. MCA16C
- d. MCA16D

ID NUMBER:						
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FORM CODE: MCA
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Occasion

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SEQ #

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e. **MCA16E**

f. **MCA16F**

D. SYMPTOMS

18. Do the medical records mention either a patient complaint or a medical finding for any of the symptoms listed below (see item 19 for listing of symptoms) Y N → **If N go to 22**

MCAB18

19. Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X) as either a patient complaint or medical finding. For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and, indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form.

	1. Documented Patient Complaint	2. Documented Medical Finding	3. Duration of symptom (days)	4. Occur within 24 hours of medical visit or UTI workup reported on this form?
a. Suprapubic, abdominal, or flank pain / tenderness	MCAB19A1 Y N U	MCAB19A2 Y N U	MCAB19A3 	MCAB19A4 Y N U
b. Urinary urgency, frequency, hesitancy	MCAB19B1 Y N U	MCAB19B2 Y N U	MCAB19B3 	MCAB19B4 Y N U
c. Dysuria	MCAB19C1 Y N U	MCAB19C2 Y N U	MCAB19C3 	MCAB19C4 Y N U
d. Foul smelling urine	MCAB19D1 Y N U	MCAB19D2 Y N U	MCAB19D3 	MCAB19D4 Y N U
e. Failure to thrive (<= 4 months old)	MCAB19E1 Y N U X	MCAB19E2 Y N U X	MCAB19E3 	MCAB19E4 Y N U X
f. Dehydration (<= 4 months old)	MCAB19F1 Y N U X	MCAB19F2 Y N U X	MCAB19F3 	MCAB19F4 Y N U X
g. Hypothermia (<= 4 months old)	MCAB19G1 Y N U X	MCAB19G2 Y N U X	MCAB19G3 	MCAB19G4 Y N U X

20. What date does the medical record indicate that the first symptom associated with this medical care

visit began (mm/dd/yyyy)? | | / | | / | | | |

MCAB20

21. Were any medications given to the child for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? Y N U

MCAB21

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

ID NUMBER:						
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FORM CODE: MCA
VERSION: B 2/22/08

Contact Occasion			SEQ #		
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E. FEVER

22. Do the medical records mention any fever associated with this event, either a patient complaint or a medical finding Y..... N→ **If N go to 26** **MCA22**
23. a. Was a temperature taken during the medical visit? Y N→ **If N go to 24** **MCA19**
- b. What was the highest temperature recorded during the medical visit: **MCA20A**
- c. Units of measurement during the medical visit (circle one):
- °F F **MCA20B**
- °C C
- d. Recorded temperature measurement route during the medical visit (circle one):
- Oral O
- Axillary A **MCA23D**
- Tympanic T
- Rectal R
- Unknown U
24. a. Does the medical record indicate that the child had a fever of at least 100.4° F or 38° C at any time prior to the medical visit (Y=yes, N=no, U=not documented) Y N U → **If N or U go to 26** **MCA24A**
- b. Highest temperature measured prior to medical visit: **MCA25A**
- c. Units of measurement prior to medical visit (circle one):
- °F F **MCA25B**
- °C C
- d. Temperature measurement route prior to medical visit (circle one):
- Oral O
- Axillary A **MCA24D**
- Tympanic T
- Rectal R
- Unknown U
- e. Date of highest fever prior to medical visit (mm/dd/yyyy): **MCA24E**

ID NUMBER:							
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FORM CODE: MCA
VERSION: B 2/22/08

Contact
Occasion

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SEQ #

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25. a. Does the medical record indicate that the child was having a fever of at least 100.4° F or 38° C within 24 hrs prior to the medical visit or UTI workup reported on this form (Y=yes, N=no, U=not documented) Y N U → **If N or U go to 26** **MCAB25A**

- b. Highest temperature measured within 24 hrs prior to the medical visit or UTI workup reported on this form:

--	--	--	--

MCAB25B

- c. Units of measurement within 24 hrs prior to the medical visit or UTI workup reported on this form (*circle one*):

°F F **MCAB25C**
°C C

- d. Temperature measurement route within 24 hrs prior to the medical visit or UTI workup reported on this form (*circle one*):

Oral O
Axillary A **MCAB25D**
Tympanic T
Rectal R
Unknown U

- e. Date of highest fever within 24 hrs prior to the medical visit or UTI workup reported on this form (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCAB25E

26. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? Y N U **MCAB26**

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

F. WEIGHT

27. Was a weight measurement recorded? Y N → **Go to item 30** **MCA30**

28. a. Weight:

--	--	--	--

MCA31A

- b. Weight units (*circle one*):

Kilograms K **MCA31B**
Pounds P

29. Date of measured weight (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA32

ID NUMBER:						
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FORM CODE: MCA
VERSION: B 2/22/08

Contact Occasion			SEQ #		
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G. URINALYSIS

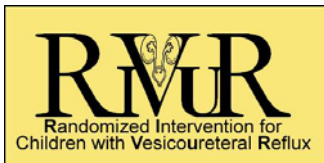
30. Was a urinalysis or urine culture performed during the medical care visit? Y N → **Go to item 32** **MCA33**
31. How many urinalysis or urine culture reports are there associated with this hospital admission or medical care visit? → **Complete USR for each** **MCA34**

H. MEDICAL PROCEDURES / IMAGES:

32. Were any of the following medical procedures noted in the chart review?
- a. **Urethral catheterization** (not for urine specimen collection) Y N → **Go to item 32d** **MCA35A**
- b. If yes, date of catheterization: (mm/dd/yyyy): / / **MCA35B**
- c. If yes, number of days catheterized **MCA35C**
- d. **Renal and/or bladder ultrasound** Y N → **Go to item 32f** **MCA35D**
- e. If yes, date of Ultrasound: (mm/dd/yyyy): / / **MCA35E**
- f. **VCUG**: Y N → **Go to item 32h** **MCA35F**
- g. If yes, date of VCUG: (mm/dd/yyyy): / / **MCA35G**
- h. **DMSA** Y N → **Go to item 33** **MCA35H**
- i. If yes, date of DMSA: (mm/dd/yyyy): / / **MCA35I**

I. ADMINISTRATIVE INFORMATION

33. Date of data collection (mm/dd/yyyy): / / **MCA36**
34. Method of data collection (*circle one*):
- Computer C **MCA37**
- Paper P
35. Recorder's initials: **BLIND_STAFF_ID**



MEDICAL CARE ABSTRACTION FORM

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form based on medical records / chart review on all medical care reported and documented initially on an MCN form, including well child visits, and RIVUR clinic sick visits.

A. TRACKING / ADMINISTRATIVE

1. Record/label MCID Number:

--	--	--	--	--	--	--	--

BLIND_MCID1

NOTE: This # should match the MCID from the notification form (MCN).

2. Status of Medical Records Abstraction:

Obtained access to chart O

Pending access to chart P → **Go to Item 36** **MCA2**

No possibility of ever accessing chart N → **Go to Item 36**

3. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA3

Note: Any follow-up visits to this medical care visit would require a separate MCN and MCA with a different MCID.

4. Is this a follow-up visit to a previously reported medical visit? Y N → **Go to Item 7** **MCA4**

5. Date of previously reported medical visit?

--	--	--	--	--	--	--	--

MCA5

6. MCID Number associated with the previously reported visit:

--	--	--	--	--	--	--	--

BLIND_MCID6

7. Type of Medical Visit from this abstraction:

RIVUR study clinic A → **Go to Item 14**

Primary care physician B → **Go to Item 14** **MCAA7**

Outpatient clinic C → **Go to Item 14**

ER visit (no hospital admission)..... D → **Go to Item 14**

Hospitalization E

B. HOSPITALIZATION

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCA8

9. Was this an unscheduled emergency admission? Y → **Go to Item 11** N **MCAA9**

10. Was this an admission for a scheduled procedure? Y N **MCAA10**

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

11. What was the disposition of the patient on discharge?

Deceased D

Transferred to another hospital..... T → **Go to Item 14**

MCA11

Transferred to another medical care facility (e.g. rehab)..... M → **Go to Item 14**

Discharged to home..... H → **Go to Item 14**

12. Are any causes of death given on the discharge summary? Y

N → **Go to Item 14**

MCA12

13. Causes of death on the discharge summary:

a. **MCA13A**

b. **MCA13B**

c. **MCA13C**

d. **MCA13D**

e. **MCA13E**

f. **MCA13F**

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

14. List the hospital discharge diagnosis codes exactly as they appear on the front sheet of the discharge summary. If visit is not a hospitalization, list any diagnosis codes provided in the medical record (if none appear then leave item blank):

a.

--	--	--	--	--	--	--

MCA14A

b.

--	--	--	--	--	--	--

MCA14B

c.

--	--	--	--	--	--	--

MCA14C

d.

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MCA14D

e.

--	--	--	--	--	--	--

MCA14E

f.

--	--	--	--	--	--	--

MCA14F

g.

--	--	--	--	--	--	--

MCA14G

h.

--	--	--	--	--	--	--

MCA14H

i.

--	--	--	--	--	--	--

MCA14I

j.

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MCA14J

k.

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MCA14K

l.

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MCA14L

m.

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MCA14M

n.

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MCA14N

15. Coding System:

ICD-9..... A

ICD-10..... B

No codes entered in item 14..... C

MCA15

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

16. Medical diagnosis or discharge diagnosis (**Text descriptors**, not ICD CODES). Do not split a single diagnosis across two or more response items:

- a. MCA16A
- b. MCA16B
- c. MCA16C
- d. MCA16D
- e. MCA16E
- f. MCA16F

D. SYMPTOMS

17. Were any of the following symptoms documented anywhere among the participant Complaints or Medical findings?
Note: Respond to both, Y=yes, N=no, X=does not apply.

	1. Patient Complaints		2. Medical Findings	
a. Fever	Y	N	MCAA17A1	Y N MCAA17A2
b. Suprapubic, abdominal, or flank pain or tenderness	Y	N	MCAA17B1	Y N MCAA17B2
c. Urinary urgency, frequency, hesitancy	Y	N	MCAA17C1	Y N MCAA17C2
d. Dysuria	Y	N	MCAA17D1	Y N MCAA17D2
e. Foul smelling urine	Y	N	MCAA17E1	Y N MCAA17E2
f. Failure to thrive (<= 4 months old)	Y	N	MCAA17F1	Y N X MCAA17F2
g. Dehydration (<= 4 months old)	Y	N	MCAA17G1	Y N X MCAA17G2
h. Hypothermia (<= 4 months old)	Y	N	MCAA17H1	Y N X MCAA17H2

18. Indicate any other symptoms/complaints/medical findings as described on hospital or medical care chart:

- a. MCAA18A
- b. MCAA18B
- c. MCAA18C
- d. MCAA18D
- e. MCAA18E
- f. MCAA18F

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

E. TEMPERATURE and WEIGHT

19. Was a temperature recorded during the medical visit? Y N → **Go to 24** **MCA19**

20. a. Highest temperature measured during medical care:

 .

MCA20A

b. Units (*circle one*):

°F F **MCA20B**
°C C

21. Date of highest temperature (mm/dd/yyyy):

 /

 /

MCAA21

22. Time of highest temperature (24 hr):.....

 :

MCAA22

23. Temperature measurement route (*circle one*):

Oral O
Axillary..... A
Tympanic..... T
Rectal R
Unknown U

MCAA23

24. Was the child reported as having a fever prior to the medical visit? Y N → **Go to 30** **MCAA24**

25. a. Highest temperature measured prior to medical visit:

 .

MCA25A

b. Units (*circle one*):

°F F **MCA25B**
°C C

26. Date of highest temperature (mm/dd/yyyy):

 /

 /

MCAA26

27. Time of highest temperature (24 hr):.....

 :

MCAA27

28. Temperature measurement route (*circle one*):

Oral O
Axillary..... A
Tympanic..... T
Rectal R
Unknown U

MCAA28

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

29. Duration of fever prior to treatment (hrs):

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MCAA29

30. Was a weight measurement recorded? Y N → Go to 33 MCA30

31. a. Weight:

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MCA31A

b. Weight units (*circle one*):

Kilograms K

Pounds P

MCA31B

32. Date of measured weight (mm/dd/yyyy):

--	--

 /

--	--

 /

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MCA32

F. URINALYSIS

33. Was a urinalysis performed during the medical care visit? Y N → Go to 35 MCA33

34. How many urinalysis/urine culture reports are there associated with this hospital admission or medical care visit?

--	--

 → Complete USR for each MCA34

Note: Complete a USR for each urinalysis/urine culture, noting MCID associated with this form. If urinalysis collected at home and in medical office, report only the urinalysis result collected during the medical visit.

G. MEDICAL PROCEDURES / IMAGES:

35. Were any of the following medical procedures noted in the chart review?

a. Urethral catheterization Y N → Go to 35d MCA35A

b. If yes, date of catheterization: (mm/dd/yyyy):

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 /

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 /

--	--	--	--

MCA35B

c. If yes, number of days catheterized

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MCA35C

d. Renal and bladder ultrasound Y N → Go to 35f MCA35D

e. If yes, date of Ultrasound: (mm/dd/yyyy):

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MCA35E

f. VCUG: Y N → Go to 35h MCA35F

g. If yes, date of VCUG: (mm/dd/yyyy):

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MCA35G

h. DMSA Y N → Go to 36 MCA35H

i. If yes, date of DMSA: (mm/dd/yyyy):

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MCA35I

ID NUMBER:							
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FORM CODE: MCA
VERSION: A 3/30/07

Contact
Occasion

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SEQ #

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Participant Name: _____

H. ADMINISTRATIVE INFORMATION

36. Date of data collection (mm/dd/yyyy):

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MCA36

37. Method of data collection (*circle one*):

Computer C

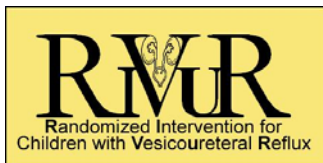
Paper..... P

MCA37

38. Recorder's initials:

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BLIND_STAFF_ID



MEDICAL CARE NOTIFICATION FORM

ID NUMBER:							
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FORM CODE: MCN
VERSION: D 02/23/10

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.

A. MEDICAL CARE INFORMATION

1. [PC] Assigned MCID number: _____

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BLIND_MCID

2. Date of medical care visit (mm/dd/yyyy): _____

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MCN2

Provider name: _____ [no data entry]

Provider address/contact information: _____ [no data entry]

3. a. [PC] Location of Medical Visit (select one): **MCNC3** **MCN3A**
- Private Physician Office A → **Go to item 3c**
- The RIVUR Clinic B → **Go to item 3c**
- Specialty clinic at RIVUR center C → **Go to item 3c**
- Other specialty clinic not affiliated with RIVUR center D → **Go to item 3c**
- Hospitalization or ER visit at RIVUR-affiliated Hospital E → **Complete AEF**
- Hospitalization or ER visit at Hospital not affiliated with RIVUR F → **Complete AEF**
- Other location G → **Record, Go to item 3c**

If other, please specify: _____

- b. [PC] Specify if the participant was hospitalized or visited the emergency room (circle one): **MCND3B**
- Emergency room visit E
- Hospitalization H
- Other O

If other, please specify: _____

- c. [PC] Is the family providing information about the medical care visit? Y N → **Answer items 8, 23-25** **MCND3C**

4. Was urine collected at this medical visit? Y N → **Go to item 6** **MCN4**

ID NUMBER:							
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FORM CODE: MCN
VERSION: D 02/23/10

Contact
Occasion

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SEQ #

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5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? Y N **MCN5**
6. Was the child well at the visit (displaying NO symptoms, NO fever, and no medication was prescribed)? Y → **Go to item 20** N **MCN6**
7. During this visit, did your child get referred to another physician or specialist? Y N **MCN7**
- (Note: if 'Y', record MD name: _____ this will require another MCN)
8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? Y → **Complete AEF** N **MCN8**

B. FEVER

9. Did your child have a fever during his/her illness? Y N → **Go to 15** **MCN9**
10. a. Highest temperature reported:

--	--	--	--	--

MCN10A
- b. Units (*circle one*):
- °F F **MCN10B**
- °C C
11. Date of highest temperature (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCN11
12. Time of highest temperature (24 hr):

--	--	--	--	--

MCN12
13. Temperature measurement route (*circle one*): **MCN13**
- Oral O
- Axillary A
- Tympanic T
- Rectal R
- Temporal F
- Unknown U
14. a. Date fever started?

--	--	--	--	--	--	--	--

MCNB14A
- b. Duration of fever (hrs):

--	--	--	--

MCN14
15. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? Y N U **MCNC15**
- If Yes, list medications: _____
- Note:** If Yes, remember to also list medication(s) on the CMF.

ID NUMBER:							
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FORM CODE: MCN
VERSION: D 02/23/10

Contact
Occasion

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SEQ #

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C. SYMPTOMS

16. Has your child experienced any of the following symptoms

(see item 17 for listing of symptoms)..... Y

N → **If N go to 20**

MCNC16

17. **[PC]** Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X). For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form. (**Note:** if N, U, or X selected in column 1, then skip columns 2 and 3.)

	1. Did symptom occur?	2. Duration of symptom (days):	3. Occur within 24 hours of medical visit?	
a. Suprapubic, abdominal, or flank pain / tenderness	Y N U		Y N X	
b. Urinary urgency, frequency, hesitancy	Y N U		Y N X	
c. Dysuria	Y N U		Y N X	
d. Foul smelling urine	Y N U		Y N X	
e. Failure to thrive (<= 4 months old)	Y N U X		Y N X	
f. Dehydration (<= 4 months old)	Y N U X		Y N X	
g. Hypothermia (<= 4 months old)	Y N U X		Y N X	

18. Date symptoms started:

		/			/				
--	--	---	--	--	---	--	--	--	--

MCNB16A

19. Did you give your child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI

(Y = yes, N = no, U = not documented)? Y

N

U

MCNC19

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

D. STUDY MEDICATION

20 a. Was study medication temporarily discontinued during this event?

Y

N

→ **Go to Item 21**

MCN16

b. How many days was study medication discontinued?

--	--

MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 21 and 22 will need to be completed as a follow-up.

21. a. Did a parent or caregiver miss work due to this illness/event?..... Y

N

→ **Go to Item 22**

MCN18A

ID NUMBER:							
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FORM CODE: MCN
VERSION: D 02/23/10

Contact
Occasion

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SEQ #

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b. Total number of days work missed by all caregivers:

--	--

MCN18B

22. a. Did alternative child care arrangements have to be made
during this illness/event?..... Y

N → Go to Item 23

MCN19A

b. Total number of days alternate care arrangements needed:

--	--

MCN19B

F. ADMINISTRATIVE INFORMATION

23. [PC] Date of form (mm/dd/yyyy):.....

		/			/				
--	--	---	--	--	---	--	--	--	--

MCN20

24. [PC] Method of data collection (*circle one*):

Computer C

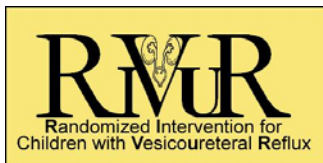
Paper..... P

MCN21

25. [PC] Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



MEDICAL CARE NOTIFICATION FORM

ID NUMBER:							
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FORM CODE: MCN
VERSION: C 2/13/08

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.

A. MEDICAL CARE INFORMATION

1. [PC] Assigned MCID number:

--	--	--	--	--	--	--	--

MCN1

2. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

MCN2

Provider name: _____ [no data entry]

Provider address/contact information: _____ [no data entry]

3a. [PC] Location of Medical Visit (select one): **MCNC3A**

- Private Physician Office A
The RIVUR Clinic B
Specialty clinic at RIVUR center C
Other specialty clinic not affiliated with RIVUR center D
Hospitalization or ER visit at RIVUR-affiliated Hospital E
Hospitalization or ER visit at Hospital not affiliated with RIVUR F
Other location G

If other, please specify: _____

4. Was urine collected at this medical visit? Y N → **Go to item 6** **MCN4**

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? Y N **MCN5**

6. Was this a well-child visit (with no current symptoms, no specimens, and no medication prescribed)? Y → **Go to item 20** N **MCN6**

7. During this visit, did your child get referred to another physician or specialist? Y N **MCN7**

(Note: if 'Y', record MD name: _____
this will require another MCN)

ID NUMBER:							
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FORM CODE: MCN
VERSION: C 2/13/08

Contact
Occasion

--	--

SEQ #

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8. **[PC]** Does the illness or reason for sick visit fit the definition for an adverse event? Y → **Complete AEF** N **MCN8**

B. FEVER

9. Did your child have a fever during his/her illness? Y N → **Go to 15** **MCN9**

10. a. Highest temperature reported:

--	--	--	--

MCN10A

b. Units (*circle one*):

°F F **MCN10B**

°C C

11. Date of highest temperature (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCN11

12. Time of highest temperature (24 hr):

--	--	--	--

MCN12

13. Temperature measurement route (*circle one*): **MCN13**

Oral O

Axillary A

Tympanic T

Rectal R

Unknown U

- 14 a. Date fever started?

--	--	--	--	--	--	--	--

MCNB14A

- b. Duration of fever (hrs):

--	--	--

MCN14

15. Were any antipyretics given to the child within 24 hours prior to the medical visit or work-up for suspected UTI (Y=yes, N=no, U=not documented)? Y N U **MCNC15**

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the CMF.

C. SYMPTOMS

16. Has your child experienced any of the following symptoms (see item 17 for listing of symptoms) Y N → **If N go to 20** **MCNC16**

ID NUMBER:						
------------	--	--	--	--	--	--

FORM CODE: MCN
VERSION: C 2/13/08

Contact
Occasion

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SEQ #

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17. [PC] Please indicate which of the symptoms listed below were documented as having occurred (Y), documented as not having occurred (N), were not mentioned anywhere in the medical records (U), or do not apply (X). For each symptom that has occurred, please record the number of days the symptom has occurred up to and including the visit, and indicate if the symptom occurred within 24hr of the medical visit or UTI workup reported on this form.

	1. Did symptom occur?			2. Duration of symptom (days):		3. Occur within 24 hours of medical visit?			
a. Suprapubic, abdominal, or flank pain / tenderness	Y	N	U	MCN15A	MCNC17A2	Y	N	X	MCNC17A3
b. Urinary urgency, frequency, hesitancy	Y	N	U	MCN15B	MCNC17B2	Y	N	X	MCNC17B3
c. Dysuria	Y	N	U	MCN15C	MCNC17C2	Y	N	X	MCNC17C3
d. Foul smelling urine	Y	N	U	MCN15D	MCNC17D2	Y	N	X	MCNC17D3
e. Failure to thrive (<= 4 months old)	Y	N	U	MCN15E	MCNC17E2	Y	N	X	MCNC17E3
f. Dehydration (<= 4 months old)	Y	N	U	MCN15F	MCNC17F2	Y	N	X	MCNC17F3
g. Hypothermia (<= 4 months old)	Y	N	U	MCN15G	MCNC17G2	Y	N	X	MCNC17G3

18. Date symptoms started: / / MCNB16A

19. Did you give your child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI (Y = yes, N = no, U = not documented)? Y N U MCNC19

If Yes, list medications: _____

Note: If Yes, remember to also list medication(s) on the next CMF form.

D. STUDY MEDICATION

20 a. Was study medication temporarily discontinued during this event? Y N → Go to Item 21 MCN16

b. How many days was study medication discontinued? MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

21. a. Did a parent or caregiver miss work due to this illness/event? Y N → Go to Item 22 MCN18A

b. Total number of days work missed by all caregivers: MCN18B

22. a. Did alternative child care arrangements have to be made during this illness/event? Y N → Go to Item 23 MCN19A

b. Total number of days alternate care arrangements needed: MCN19B

ID NUMBER:							
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FORM CODE: MCN
VERSION: C 2/13/08

Contact
Occasion

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SEQ #

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F. ADMINSTRATIVE INFORMATION

23. [PC] Date of form (mm/dd/yyyy):.....

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 /

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 MCN20

24. [PC] Method of data collection (*circle one*):

Computer C

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 MCN21
Paper..... P

25. [PC] Interviewer's or Examiner's initials:

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 BLIND_STAFF_ID



MEDICAL CARE NOTIFICATION FORM

ID NUMBER:						
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FORM CODE: MCN
VERSION: B 8/13/07

Contact
Occasion

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SEQ #

--	--

Participant Name: _____

Instructions: Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.

A. MEDICAL CARE INFORMATION

1. [PC] Assigned MCID number:

--	--	--	--	--	--	--

MCN1

2. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCN2

Provider name: _____ [no data entry]

Provider address/contact information: _____ [no data entry]

- 3a. [PC] Provider of care (circle one): **MCN3A**
- RIVUR Clinic A
 - Other clinic or health care center B
 - A private doctor's office C
 - Hospital Outpatient Department D
 - Emergency room in a hospital E
 - Hospital F
 - Other location G

3b. If other, please specify: _____ **MCN3B**

4. Was urine collected at this medical visit? Y N → **Go to 6** **MCN4**

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? Y N **MCN5**

6. Was this a well-child visit (with no current symptoms, no specimens, and no medication prescribed)? Y → **Go to 20** N **MCN6**

7. During this visit, did your child get referred to another physician or specialist? Y N **MCN7**

(Note: if 'Y', record MD name: _____
this will require another MCN)

ID NUMBER:							
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FORM CODE: MCN
VERSION: B 8/13/07

Contact
Occasion

--	--

SEQ #

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8. [PC] Does the illness or reason for sick visit fit the definition for an adverse event? Y → **Complete AEF** N **MCN8**

B. HISTORY OF FEVER

9. Did your child have a fever during his/her illness? Y N → **Go to 15** **MCN9**

10. a. Highest temperature reported:

--	--	--	--

MCN10A

b. Units (*circle one*):

°F F

MCN10B

°C C

11. Date of highest temperature (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCN11

12. Time of highest temperature (24 hr):

--	--	--	--

MCN12

13. Temperature measurement route (*circle one*): **MCN13**

Oral O

Axillary A

Tympanic T

Rectal R

Unknown U

MCNB14A

- 14 a. Date fever started?

--	--	--	--	--	--	--	--

- b. Duration of fever (hrs):

--	--	--

MCN14

C. HISTORY OF SYMPTOMS

- | 15. Did the child have any of the following symptoms? | Yes | No | Unknown | Not Apply | |
|---|-----|----|---------|-----------|---------------|
| a. Suprapubic, abdominal, or flank pain or tenderness | Y | N | U | | MCN15A |
| b. Urinary urgency, frequency, hesitancy | Y | N | U | | MCN15B |
| c. Dysuria | Y | N | U | | MCN15C |
| d. Foul smelling urine | Y | N | U | | MCN15D |
| e. Failure to thrive (<= 4 months old) | Y | N | U | X | MCN15E |
| f. Dehydration (<= 4 months old) | Y | N | U | X | MCN15F |
| g. Hypothermia (<= 4 months old) | Y | N | U | X | MCN15G |

- 16 a. Date symptoms started:

--	--	--	--	--	--	--	--

MCNB16A

- b. Duration of symptoms (days):

--	--

MCNB16B

D. STUDY MEDICATION

- 17 a. Was study medication temporarily discontinued during this event? Y N **MCN16**

ID NUMBER:							
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FORM CODE: MCN
VERSION: B 8/13/07

Contact
Occasion

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SEQ #

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b. How many days was study medication discontinued?

--	--

MCN17

E. RESOURCE UTILIZATION

Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

18. a. Did a parent or caregiver miss work due to this illness/event?..... Y

N

→Go to Item 19

MCN18A

b. Total number of days work missed by all caregivers:

--	--

MCN18B

19. a. Did alternative child care arrangements have to be made during this illness/event?..... Y

N

→Go to Item 20

MCN19A

b. Total number of days alternate care arrangements needed:

--	--

MCN19B

F. ADMINISTRATIVE INFORMATION

20. [PC] Date of form (mm/dd/yyyy):.....

		/			/				
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MCN20

21. [PC] Method of data collection (*circle one*):

Computer C

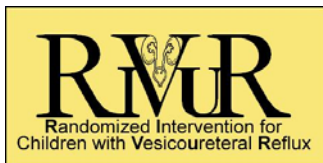
Paper..... P

MCN21

22. [PC] Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



MEDICAL CARE NOTIFICATION FORM

ID NUMBER:							
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FORM CODE: MCN
VERSION: A 11/17/06

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for all medical care reported/received since the last study contact, including in-clinic RIVUR sick visits. Each MCN form will also have a corresponding MCA form once medical records have been received. Forms are linked with an assigned MCID number.

A. MEDICAL CARE INFORMATION

1. [PC] Assigned MCID number:

--	--	--	--	--	--	--	--

MCN1

2. Date of medical care visit (mm/dd/yyyy):

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

 /

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MCN2

Provider name: _____ [no data entry]

Provider address/contact information: _____ [no data entry]

3a. [PC] Provider of care (circle one): **MCN3A**

- RIVUR Clinic A
Other clinic or health care center B
A private doctor's office C
Hospital Outpatient Department D
Emergency room in a hospital E
Hospital F
Other location G

3b. If other, please specify: _____ **MCN3B**

4. Was urine collected at this medical visit? Y N → **Go to 6** **MCN4**

5. Were you informed that a urinary tract infection was/is suspected or diagnosed during this medical visit? Y N **MCN5**

6. Was this a well-child visit? Y → **Go to 20** N **MCN6**

7. During this visit, did your child get referred to another physician or specialist? Y N **MCN7**

(Note: if 'Y', record MD name: _____
this will require another MCN)

ID NUMBER:							
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FORM CODE: MCN
VERSION: A 11/17/06

Contact
Occasion

--	--

SEQ #

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8. [PC] Does the illness or reason for sick visit fit the definition for an adverse event? Y → **Complete AEF** N **MCN8**

B. HISTORY OF FEVER

9. Did the child have a fever? Y N → **Go to 15** **MCN9**

10. a. Highest temperature reported?:

--	--	--	--

MCN10A

b. Units (*circle one*):

°F F **MCN10B**
°C C

11. Date of highest temperature (mm/dd/yyyy):

--	--	--	--	--	--	--	--

MCN11

12. Time of highest temperature (24 hr):

--	--	--	--

MCN12

13. Temperature measurement route (*circle one*): **MCN13**

Oral O
Axillary A
Tympanic T
Rectal R
Unknown U

14. Duration of fever (hrs):

--	--	--

MCN14

C. HISTORY OF SYMPTOMS

- | 15. Did the child have any of the following symptoms? | Yes | No | Unknown | Not Apply | |
|---|-----|----|---------|-----------|---------------|
| a. Suprapubic, abdominal, or flank pain or tenderness | Y | N | U | | MCN15A |
| b. Urinary urgency, frequency, hesitancy | Y | N | U | | MCN15B |
| c. Dysuria | Y | N | U | | MCN15C |
| d. Foul smelling urine | Y | N | U | | MCN15D |
| e. Failure to thrive (<= 4 months old) | Y | N | U | X | MCN15E |
| f. Dehydration (<= 4 months old) | Y | N | U | X | MCN15F |
| g. Hypothermia (<= 4 months old) | Y | N | U | X | MCN15G |

D. STUDY MEDICATION

16. Was study medication temporarily discontinued during this event? Y N **MCN16**

17. How many days was study medication discontinued?

--	--

MCN17

E. RESOURCE UTILIZATION

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MCN
VERSION: A 11/17/06

Contact
Occasion

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SEQ #

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Note to Coordinator: If this form is being completed at the time of an event, questions 18 and 19 will need to be completed as a follow-up.

18. a. Did a parent or caregiver miss work due to this illness/event?..... Y N → **Go to Item 19** **MCN18A**

b. Total number of days work missed by all caregivers:

--	--

MCN18B

19. a. Did alternative child care arrangements have to be made during this illness/event?..... Y N → **Go to Item 20** **MCN19A**

b. Total number of days alternate care arrangements needed:

--	--

MCN19B

F. ADMINSTRATIVE INFORMATION

20. **[PC]** Date of form (mm/dd/yyyy):.....

		/			/				
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MCN20

21. **[PC]** Method of data collection (*circle one*):

Computer C **MCN21**
Paper..... P

22. **[PC]** Interviewer's or Examiner's initials:

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BLIND_STAFF_ID



MEDICATION DISPENSING AND DOSING FORM

ID NUMBER:							
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FORM CODE: MDD
VERSION: B 05/11/10

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is to be completed any time that study drug is dispensed to patient.

A. TIMING OF MEDICATION DISPENSING

1. **[PC]** Why is medication being dispensed today?

Unscheduled contact U

MDD1

Protocol-scheduled clinic visit (randomization or follow-up) S → **Go to Item 9**

B. UNSCHEDULED CONTACT

2. How many months supply of medication is needed before the next

clinic follow-up visit?

MDD2

3. **[PC]** What type of visit is occurring today (*circle one*)?

Telephone T

MDD3

Clinic C → **Go to Item 9**

C. TELEPHONE CONTACT

NOTE: The dose should remain constant for 6 months at most. If more than 6 months will elapse between the last measured weight and the next clinic visit, then adjust the child's weight by either asking the parents for the last known weight of the child and/or estimate the child's weight from the 2000 CDC Growth Curves (Advance Data No. 314 Dec 4, 2000).

4. **[PC]** a. What is the child's last known weight?

 .

MDD4A

b. Units (*circle one*): Kilograms K

Pounds P

MDD4B

5. **[PC]** What is the date this weight was measured?

 /

 /

MDD5

6. **[PC]** Is the time between the last weight measurement and the next clinic visit going to exceed 6 months? Y

N → **Go to Item 10**

MDD6

7. a. What is the child's current weight?

 .

MDD7A

b. Units (*circle one*): Kilograms K

Pounds P

MDD7B

8. **[PC]** Where was this weight measured (*circle one*)?

Parent measured P → **Go to Item 10**

Estimated from CDC Growth Curve G → **Go to Item 10**

MDD8

ID NUMBER:							
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FORM CODE: MDD
VERSION: B 05/11/10

Contact
Occasion

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SEQ #

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D. CLINIC CONTACT

9. **[PC]** a. What was the child's weight measured today?

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MDD9A
- b. Units (*circle one*): Kilograms K
 Pounds P **MDD9B**

E. DISPENSING

Instruction: Entry of a 'Y' into the DMS for Item 10 will automatically run the medication dispensing and dosing program, providing you with the bottle numbers to dispense, and the dosing instructions appropriate for the child's weight.

10. Are you ready for medication bottle numbers and dosing? Y N **MDD10**
11. **[Provided by DMS]** Dose (mL/day):

--	--	--

MDD11
12. **[Provided by DMS]** How many bottles are being dispensed?

--

MDD12
13. **[Provided by DMS]** Bottles to Distribute: a.

--	--	--	--	--	--

MDD13A
- b.

--	--	--	--	--	--

MDD13B
- c.

--	--	--	--	--	--

MDD13C
- d.

--	--	--	--	--	--

MDD13D
- e.

--	--	--	--	--	--

MDD13E
- f.

--	--	--	--	--	--

MDD13F
- g.

--	--	--	--	--	--

MDDB13G
- h.

--	--	--	--	--	--

MDDB13H
- i.

--	--	--	--	--	--

MDDB13I

F. ADMINISTRATIVE INFORMATION

14. Date of drug distribution (mm/dd/yyyy):

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 /

--	--

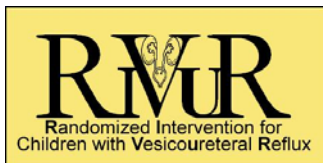
 /

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MDD14
15. Method of data collection (*circle one*):
Computer C **MDD15**
Paper P
16. Recorders initials:

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BLIND_STAFF_ID



MEDICATION DISPENSING AND DOSING FORM

ID NUMBER:							
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FORM CODE: MDD
VERSION: A 06/29/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form is to be completed any time that study drug is dispensed to patient.

A. TIMING OF MEDICATION DISPENSING

1. [PC] Why is medication being dispensed today?

Unscheduled contact U

MDD1

Protocol-scheduled clinic visit (randomization or follow-up) S → **Go to Item 9**

B. UNSCHEDULED CONTACT

2. How many months supply of medication is needed before the next

clinic follow-up visit?

--

MDD2

3. [PC] What type of visit is occurring today (circle one)?

Telephone T

MDD3

Clinic C → **Go to Item 9**

C. TELEPHONE CONTACT

NOTE: The dose should remain constant for 6 months at most. If more than 6 months will elapse between the last measured weight and the next clinic visit, then adjust the child's weight by either asking the parents for the last known weight of the child and/or estimate the child's weight from the 2000 CDC Growth Curves (Advance Data No. 314 Dec 4, 2000).

4. [PC] a. What is the child's last known weight?

--	--	--	--

MDD4A

b. Units (circle one): Kilograms K

Pounds P

MDD4B

5. [PC] What is the date this weight was measured?

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MDD5

6. [PC] Is the time between the last weight measurement and the next clinic visit going to exceed 6 months? Y

N → **Go to Item 10**

MDD6

7. a. What is the child's current weight?

--	--	--	--

MDD7A

b. Units (circle one): Kilograms K

Pounds P

MDD7B

8. [PC] Where was this weight measured (circle one)?

Parent measured P → **Go to Item 10**

Estimated from CDC Growth Curve G → **Go to Item 10**

MDD8

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: MDD
VERSION: A 06/29/07

Contact
Occasion

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SEQ #

--	--

D. CLINIC CONTACT

9. **[PC]** a. What was the child's weight measured today?

--	--	--	--

MDD9A
- b. Units (*circle one*): Kilograms K **MDD9B**
Pounds P

E. DISPENSING

Instruction: Entry of a 'Y' into the DMS for Item 10 will automatically run the medication dispensing and dosing program, providing you with the bottle numbers to dispense, and the dosing instructions appropriate for the child's weight.

10. Are you ready for medication bottle numbers and dosing? Y N **MDD10**
11. **[Provided by DMS]** Dose (mL/day):

--	--	--

MDD11
12. **[Provided by DMS]** How many bottles are being dispensed?

--

MDD12
13. **[Provided by DMS]** Bottles to Distribute: a.

--	--	--	--	--	--

MDD13A
b.

--	--	--	--	--	--

MDD13B
c.

--	--	--	--	--	--

MDD13C
d.

--	--	--	--	--	--

MDD13D
e.

--	--	--	--	--	--

MDD13E
f.

--	--	--	--	--	--

MDD13F

F. ADMINISTRATIVE INFORMATION

14. Date of drug distribution (mm/dd/yyyy):

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 /

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 /

--	--	--	--

MDD14
15. Method of data collection (*circle one*):
Computer C **MDD15**
Paper P
16. Recorders initials:

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BLIND_STAFF_ID

ID NUMBER:							
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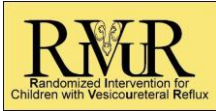
FORM CODE: MRF
VERSION: A 01/08/07

Contact Occasion		
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SEQ #		
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i. Bottle 12:	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6L1</td></tr></table>	MRFA6L1	Y→	<table border="1"><tr><td>Next line</td></tr></table>	Next line	N	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6L2</td></tr></table>	MRFA6L2		<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6L3</td></tr></table>	MRFA6L3
MRFA6L1																										
Next line																										
MRFA6L2																										
MRFA6L3																										
m. Bottle 13:	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6M1</td></tr></table>	MRFA6M1	Y→	<table border="1"><tr><td>Next line</td></tr></table>	Next line	N	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6M2</td></tr></table>	MRFA6M2		<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6M3</td></tr></table>	MRFA6M3
MRFA6M1																										
Next line																										
MRFA6M2																										
MRFA6M3																										
n. Bottle 14:	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6N1</td></tr></table>	MRFA6N1	Y→	<table border="1"><tr><td>Exit form</td></tr></table>	Exit form	N	<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6N2</td></tr></table>	MRFA6N2		<table border="1"><tr><td></td><td></td><td></td><td></td></tr></table>					<table border="1"><tr><td>MRFA6N3</td></tr></table>	MRFA6N3
MRFA6N1																										
Exit form																										
MRFA6N2																										
MRFA6N3																										

12 or bottles were never distributed to a participant, therefor variables MRFAL1, MRFAL2, MRFAL3, MRFAM1, MRFAM2, MRFAM3, MRFAN1, MRFAN2, MRFAN3 are not included in the closed NIDDK dataset



PHYSICAL EXAM FORM

ID NUMBER:						
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FORM CODE: PEF
VERSION: B 09/18/12

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: This form should be completed at baseline and during all protocol-scheduled clinic follow-up visits.

A. PHYSICAL EXAM

1. Has your child been circumcised? (Circle one): **PEF1**

Male, circumcised C

Male, uncircumcised U → **Go to Item 4**

Male, circumcision reported at earlier contact occasion R → **Go to Item 4**

Female F → **Go to Item 4**

2. Date of circumcision (mm/dd/yyyy): **PEF2**

3. How old was the child when he was circumcised (months)? **PEF3**

4. a. Temperature: **PEF4A**

b. Units (circle one):

°F F **PEF4B**

°C C

5. Temperature measurement route (circle one): **PEF5**

Oral O

Axillary A

Tympanic T

Rectal R

Temporal F

Unknown U

6. Is the child showing any of the following during the abdominal examination today?

a. Suprapubic pain or tenderness Y N **PEF6A**

b. Abdominal pain or tenderness Y N **PEF6B**

c. Flank pain or tenderness Y N **PEF6C**

7. Is the child experiencing dysuria today? Y N **PEF7**

8. Does the child have foul-smelling urine today? Y N **PEF8**

9. a. Systolic blood pressure (mm Hg): **PEF9A**

b. Diastolic blood pressure (mm Hg): **PEF9B**

ID NUMBER:							
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FORM CODE: PEF
VERSION: B 09/18/12

Contact
Occasion

--	--

SEQ #

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10. a. Weight:

--	--	--	--

PEF10A

b. Weight units (*circle one*):

Kilograms K PEF10B

Pounds P

11. a. Length / Height:

--	--	--	--

PEF11A

b. Units (*circle one*):

Centimeters C PEF11B

Inches I

B. ADMINISTRATIVE INFORMATION

12. Date of physical exam (mm/dd/yyyy):

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PEF12

13. Method of data collection (*circle one*):

Computer C PEF13

Paper P

14. Examiner's initials:

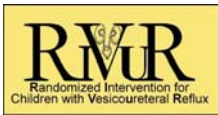
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BLIND_EXAM_ID

15. Recorder's initials:

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BLIND_STAFF_ID



PHYSICAL EXAM FORM

ID NUMBER:						
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FORM CODE: PEF
VERSION: A 03/30/07

Contact
Occasion

--	--

SEQ #

--	--

Participant Name: _____

Instructions: This form should be completed at baseline and during all protocol-scheduled clinic follow-up visits.

A. PHYSICAL EXAM

1. Has your child been circumcised? (Circle one):

Male, circumcised C

Male, uncircumcised U → **Go to Item 4**

PEF1

Male, circumcision reported at earlier contact occasion R → **Go to Item 4**

Female F → **Go to Item 4**

2. Date of circumcision (mm/dd/yyyy):

--	--	--	--	--	--	--	--

PEF2

3. How old was the child when he was circumcised (months)?

--	--

PEF3

4. a. Temperature:

--	--	--	--

PEF4A

b. Units (circle one):

°F F **PEF4B**

°C C

5. Temperature measurement route (circle one):

Oral O

Axillary A **PEF5**

Tympanic T

Rectal R

6. Is the child showing any of the following during the abdominal examination today?

a. Suprapubic pain or tenderness Y N **PEF6A**

b. Abdominal pain or tenderness Y N **PEF6B**

c. Flank pain or tenderness Y N **PEF6C**

7. Is the child experiencing dysuria today? Y N **PEF7**

8. Does the child have foul-smelling urine today? Y N **PEF8**

9. a. Systolic blood pressure (mm Hg):

--	--	--

PEF9A

b. Diastolic blood pressure (mm Hg):

--	--	--

PEF9B

10. a. Weight:

--	--	--	--

PEF10A

ID NUMBER:							
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FORM CODE: PEF
VERSION: A 03/30/07

Contact
Occasion

--	--

SEQ #

--	--

b. Weight units (*circle one*):

Kilograms K

Pounds P

PEF10B

11. a. Length / Height:

			.	
--	--	--	---	--

PEF11A

b. Units (*circle one*):

Centimeters C

Inches I

PEF11B

B. ADMINISTRATIVE INFORMATION

12. Date of physical exam (mm/dd/yyyy):

		/			/				
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PEF12

13. Method of data collection (*circle one*):

Computer C

Paper P

PEF13

14. Examiner's initials:

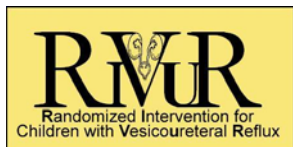
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PEF14

15. Recorder's initials:

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PEF15



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: B 06/20/08

Contact
Occasion

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SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	___/___/20___
02						___				___	___/___/20___
03						___				___	___/___/20___
04						___				___	___/___/20___
05						___				___	___/___/20___
06						___				___	___/___/20___
07						___				___	___/___/20___
08						___				___	___/___/20___
09						___				___	___/___/20___
10						___				___	___/___/20___

Entry Codes

2. Referral Source:

A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes

A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes

A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why?

A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

8. VCUG Result

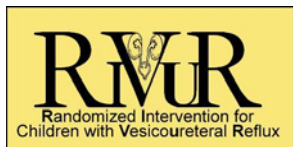
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions

A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F = Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?

A = Ineligible
B = Refused
C = Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: B 06/20/08

Contact
Occasion

--	--

SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	— — PSL12 /20 — —
12						— —				— —	— — / — — /20 — —
13						— —				— —	— — / — — /20 — —
14						— —				— —	— — / — — /20 — —
15						— —				— —	— — / — — /20 — —
16						— —				— —	— — / — — /20 — —
17						— —				— —	— — / — — /20 — —
18						— —				— —	— — / — — /20 — —
19						— —				— —	— — / — — /20 — —
20						— —				— —	— — / — — /20 — —

Entry Codes

2. Referral Source:

A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes

A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes

A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why? 8.

A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

VCUG Result

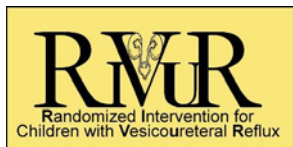
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions

A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F = Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?

A = Ineligible
B = Refused
C = Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: B 06/20/08

Contact
Occasion

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SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7b. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11b. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-B	PSL8	PSL9	PSL10	PSL11A-B	— — / — — — — PSL12 — —
22						— —				— —	— — / — — — — /20 — —
23						— —				— —	— — / — — — — /20 — —
24						— —				— —	— — / — — — — /20 — —
25						— —				— —	— — / — — — — /20 — —
26						— —				— —	— — / — — — — /20 — —
27						— —				— —	— — / — — — — /20 — —
28						— —				— —	— — / — — — — /20 — —
29						— —				— —	— — / — — — — /20 — —
30						— —				— —	— — / — — — — /20 — —

Entry Codes

2. Referral Source:

A = ED
B = Labs
C = PCP
D = Inpatient
E = Urology
F = Radiology
G = Other (notelog)

4. Race codes

A = Black or AA
B = White
C = Asian
D = Hawaiian/Pacific Islander
E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes

A = Hispanic / Latino
B = Not Hispanic / Latino
C = Unknown/Refused

7. If not Protocol UTI, why? 8.

A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA
E = No pyuria
F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

VCUG Result

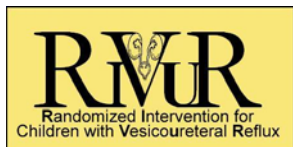
A = Not Done
B = No result
C = No VUR
D = Timing
E = Grade 1-IV
F = Grade V

9. Other Exclusions

A = None
B = Sulfatrim allergy
C = Prematurity
D = Anomaly/Syndromes
E = Chronic condition
F = Renal dis./injury
G = Can't follow
H = Other (add notelog)

11. If not Enrolled, why?

A = Ineligible
B = Refused
C = Refused - Wants bx
D = Refused - doesn't Want abx
E = Refuse DMSA
F = Other (add notelog)



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: A 11/29/07

Contact
Occasion

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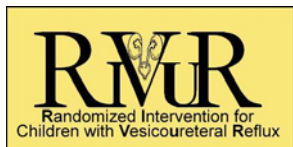
SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1.	2.	3.	4.	5.	6.	7a-7e.	8.	9.	10.	11a-11e.	12.
Line #	Referral Source	Gender (M/F)	Race Codes	Ethnicity Code	UTI per Protocol (Y/N/U)	If not UTI per Protocol, Why?	VCUG Result	Other Exclusion	Enrolled (Y/N)	If not Enrolled, Why? (enter all that apply)	Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-E	PSL8	PSL9	PSL10	PSL11A-E	PSL12 ²⁰
02											/ / 20
03											/ / 20
04											/ / 20
05											/ / 20
06											/ / 20
07											/ / 20
08											/ / 20
09											/ / 20
10											/ / 20

Entry Codes										
<u>Referral Source:</u>	<u>Race</u>	<u>codes</u>	<u>Ethnici</u>	<u>ty codes</u>	<u>If not Protocol UTI, why?</u>	<u>VCUG</u>	<u>Result</u>	<u>Ot</u>	<u>her Exclusions</u>	<u>If not Enrolled, why?</u>
1 = ED	1 = Black or AA		1 = Hispanic / Latino	1 = Not 1 st UTI	7 = Mult. Org.	1 = Not Done	1 = None		1 = Ineligible	
2 = Labs	2 = White		2 = Not Hispanic / Latino	2 = Timing	8 = No fever/Sx	2 = No result	2 = Sulfatrim allergy		2 = Wants abx	
3 = PCP	3 = Asian		3 = Unknown/Refused	3 = Bagged	9 = Uricult	3 = No VUR	3 = Prematurity		3 = Doesn't want abx	
4 = Inpatient	4 = Hawaiian/Pacific Islander			4 = No UA	10 = Other (notelog)	4 = Timing	4 = Anomaly/Syndromes		4 = Refuse DMSA	
5 = Urology	5 = Am. Indian/Alaska Native			5 = No pyuria		5 = Grade 1-IV	5 = Chronic condition		5 = Can't Follow	
6 = Radiology	6 = Other or Mixed (notelog)			6 = Ins. growth		6 = Grade V	6 = Renal dis./injury		6 = Other (add notelog)	
7 = Other (notelog)	7 = Unknown/Refused						7 = Other (add notelog)			



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: A 11/29/07

Contact
Occasion

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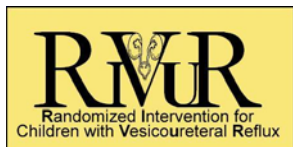
SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7e. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11e. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	PSL7A-E	PSL8	PSL9	PSL10	PSL11A-E	PSL12/20
12											/ /20
13											/ /20
14											/ /20
15											/ /20
16											/ /20
17											/ /20
18											/ /20
19											/ /20
20											/ /20

Entry Codes								
Referral Source:	Race	codes	Ethnicity codes	If not Protocol UTI, why?	VCUG	Result	Other Exclusions	If not Enrolled, why?
1 = ED	1 = Black or AA		1 = Hispanic / Latino	1 = Not 1 st UTI	7 = Mult. Org.	1 = Not Done	1 = None	1 = Ineligible
2 = Labs	2 = White		2 = Not Hispanic / Latino	2 = Timing	8 = No fever/Sx	2 = No result	2 = Sulfatrim allergy	2 = Wants abx
3 = PCP	3 = Asian		3 = Unknown/Refused	3 = Bagged	9 = Uricult	3 = No VUR	3 = Prematurity	3 = Doesn't want abx
4 = Inpatient	4 = Hawaiian/Pacific Islander			4 = No UA	10 = Other (notelog)	4 = Timing	4 = Anomaly/Syndromes	4 = Refuse DMSA
5 = Urology	5 = Am. Indian/Alaska Native			5 = No pyuria		5 = Grade 1-IV	5 = Chronic condition	5 = Can't Follow
6 = Radiology	6 = Other or Mixed (notelog)			6 = Ins. growth		6 = Grade V	6 = Renal dis./injury	6 = Other (add notelog)
7 = Other (notelog)	7 = Unknown/Refused						7 = Other (add notelog)	



Participant Screening Log

SiteID:			0	0	0	0	0
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FORM CODE: PSL
VERSION: A 11/29/07

Contact
Occasion

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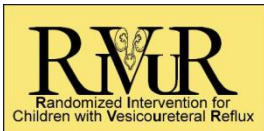
SEQ #

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- Instructions:**
- Record final eligibility disposition of all children who were considered and screened for the RIVUR study.
 - Include children with (any) UTI for whom some effort occurred to assess eligibility.
 - Enter into the study DMS weekly (preferably each Friday). Data codes are provided in footnote of form below.

1. Line #	2. Referral Source	3. Gender (M/F)	4. Race Codes	5. Ethnicity Code	6. UTI per Protocol (Y/N/U)	7a-7e. If not UTI per Protocol, Why?	8. VCUG Result	9. Other Exclusion	10. Enrolled (Y/N)	11a-11e. If not Enrolled, Why? (enter all that apply)	12. Date of Final Disposition (mm/dd/yyyy)
PSL1	PSL2	PSL3	PSL4	PSL5	PSL6	— PSL7A-E —	PSL8	PSL9	PSL10	— PSL11A-E —	— PSL12 /20 — —
22						— — — — —				— — — — —	— — / — — /20 — —
23						— — — — —				— — — — —	— — / — — /20 — —
24						— — — — —				— — — — —	— — / — — /20 — —
25						— — — — —				— — — — —	— — / — — /20 — —
26						— — — — —				— — — — —	— — / — — /20 — —
27						— — — — —				— — — — —	— — / — — /20 — —
28						— — — — —				— — — — —	— — / — — /20 — —
29						— — — — —				— — — — —	— — / — — /20 — —
30						— — — — —				— — — — —	— — / — — /20 — —

Entry Codes										
<u>Referral Source:</u>	<u>Race</u>	<u>codes</u>	<u>Ethnici</u>	<u>ty codes</u>	<u>If not Protocol UTI, why?</u>	<u>VCUG</u>	<u>Result</u>	<u>Ot</u>	<u>her Exclusions</u>	<u>If not Enrolled, why?</u>
1 = ED	1 = Black or AA		1 = Hispanic / Latino	1 = Not 1 st UTI	7 = Mult. Org.	1 = Not Done	1 = None		1 = Ineligible	
2 = Labs	2 = White		2 = Not Hispanic / Latino	2 = Timing	8 = No fever/Sx	2 = No result	2 = Sulfatrim allergy		2 = Wants abx	
3 = PCP	3 = Asian		3 = Unknown/Refused	3 = Bagged	9 = Uricult	3 = No VUR	3 = Prematurity		3 = Doesn't want abx	
4 = Inpatient	4 = Hawaiian/Pacific Islander			4 = No UA	10 = Other (notelog)	4 = Timing	4 = Anomaly/Syndromes		4 = Refuse DMSA	
5 = Urology	5 = Am. Indian/Alaska Native			5 = No pyuria		5 = Grade 1-IV	5 = Chronic condition		5 = Can't Follow	
6 = Radiology	6 = Other or Mixed (notelog)			6 = Ins. growth		6 = Grade V	6 = Renal dis./injury		6 = Other (add notelog)	
7 = Other (notelog)	7 = Unknown/Refused						7 = Other (add notelog)			



Dear Parent, thank you for your participation in the RIVUR study. We have been trying to contact you, but have not been able to reach you. We would appreciate your help by answering the 10 questions below about your child's health and mailing them back as soon as possible. Thank you!

0. Date form mailed to participant **RFFA0**
00. Staff member who mailed questionnaire **BLIND_STAFF_ID**
1. Today's Date: **RFFA1**
2. Please circle who is completing this form (*circle one*): **Mother** **Father** **Legal guardian** **Other** **RFFA2**
3. Date of your child's last RIVUR contact was **RFFA3**
4. Since your child's last RIVUR contact, do you feel your child has had any side effects that are possibly due to taking the study medication? **No** **Yes** **RFFA4**
- If yes, please describe the side effects:
5. Since the last RIVUR study contact, has your child had urine collected for medical testing? **No** **Yes** **RFFA5**
6. Since the last RIVUR study contact, has your child **received medical care** for :
- | | | | |
|---|-----------|------------|---------------|
| a. fever | No | Yes | RFFA6A |
| b. rash | No | Yes | RFFA6B |
| c. abdominal or lower back pain | No | Yes | RFFA6C |
| d. diarrhea or loose stools | No | Yes | RFFA6D |
| e. urinary urgency, painful urination, or foul-smelling urine | No | Yes | RFFA6E |
| f. urinary tract infection | No | Yes | RFFA6F |
7. Since the last RIVUR contact how many times has your child received medical care **for any of the reasons listed above**? **RFFA7**
8. If your child did receive medical care please fill out the form below
- | Date of medical care | Reason | Medical Care Provider Name or Place of Treatment |
|-----------------------------|----------------|---|
| RFFA8A1 | RFFA8A2 | RFFA8A3 |
| RFFA8B1 | RFFA8B2 | RFFA8B3 |
| RFFA8C1 | RFFA8C2 | RFFA8C3 |
9. Sometimes medication is missed. How often did your child miss a dose of the RIVUR medication during the past week (seven days)? (*circle one*) **RFFA9**
- Never**
- 1-2 times**
- 3-4 times**
- > 4 times**
- Don't know**
10. Is your child out of study medication? **No** **Yes** **RFFA10**

Thank You!! _____ **(RIVUR Study Coordinator)**

For office use only:

ID NUMBER:							
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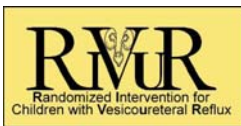
Contact
Occasion

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SEQ #

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Form Code: RFF
Version: A 08/30/10



Rectal Swab Results Form

ID NUMBER:							
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FORM CODE: RSR
VERSION: C 2/19/08

Contact
Occasion

--	--

SEQ #

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Participant Name: _____

Line
Number

--	--

*Versions A and B of this
form were never used*

Instructions: Central lab completes this form at baseline, end of study, and as needed in case of treatment failure (as determined by the Endpoints Committee).

A. E COLI (LACTOSE POSITIVE AND INDOLE POSITIVE COLONIES ON MACONKEY AGAR)

1. a. Date rectal swab was received in central lab (mm/dd/yyyy):

--	--	--	--	--	--	--	--

 /

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 /

--	--	--	--	--	--	--	--

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RSRC1A
b. Date rectal swab planted by central lab personnel (mm/dd/yyyy): ..

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

 /

--	--	--	--	--	--	--	--

--	--	--	--	--	--	--	--

RSRC1B
2. E Coli growth: **RSRC2**
Present..... P
Absent..... A → **Go to Item 11**
3. Density of E coli growth: **RSRC3**
1+ A
2+ B
3+ C
4+ D
4. E coli growth on TMP-SMZ agar: **RSRC4**
Present..... P
Absent..... A
5. E coli growth on Ceftazidime agar: **RSRC5**
Present..... P
Absent..... A
6. E coli growth on Ciprofloxacin agar: **RSRC6**
Present..... P
Absent..... A → **If Items 4-6 all A, go to Item 11**

Instruction: For items 7-9, please record (a.) the data type (see options below) and (b.) the E coli sensitivity:

(a.) Data Type:

- = (equal to) A
> (greater than) B
≥ (greater than or equal to) C
< (less than) D
≤ (less than or equal to) E

RSR7CA

RSRC7B

7. E coli sensitivities: TMP-SMZ E-test a.

--

 b.

--	--	--	--	--	--

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--	--

Line
Number

--	--

RSRC8B

--	--	--

RSRC9B

[illegible]

RSRC10

Negative N

11

RSRC12

Paper..... P

BLI

BLIND_STAFF_ID



Specimen Collection Form

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: SCF
VERSION: A 04/11/07

Contact
Occasion

--	--

SEQ #

--	--

Participant Name: _____

Instructions: Complete this form for collection of all protocol specified specimens, including blood, urine, and rectal swabs. If collection is for a QC specimen, record the QC ID provided by the DCC in the form header above.

A. QC SPECIMEN

1. Is this a QC specimen collection? Y N → **Go to Item 3** **SCFA1**
2. Record or attach the participant ID label

--	--	--	--	--	--	--

SCFA2

B. BLOOD SPECIMEN

3. Were blood specimens collected? Y N → **Go to Item 9** **SCFA3**
If no, specify reason _____
4. Date of blood specimen collection (mm/dd/yyyy):

--	--	--	--	--	--	--	--

SCFA4
5. Time of blood draw (24 hr clock):

		:		
--	--	---	--	--

SCFA5
6. Total volume of blood drawn (mL):

		.	
--	--	---	--

SCFA6
7. Phlebotomist initials:

--	--	--

BLIND_STAFF_ID7
8. Indicate blood specimens collected:
- a. Local lab CBC Y N **SCFA8A**
If no, specify reason _____
- b. Local lab metabolic/electrolyte analytes Y N **SCFA8B**
If no, specify reason _____
- c. Central lab serum Y N → **Go to Item 8d** **SCFA8C**
If no, specify reason _____
- c1. Ship date of central lab serum specimen (mm/dd/yyyy):

--	--	--	--	--	--	--	--

SCFA8C1
- d. Repository blood collection: Y N → **Go to Item 9** **SCFA8D**
If no, specify reason _____
- d1. Repository whole blood specimen Y N → **Go to Item 8d4** **SCFA8D1**
If no, specify reason _____
- d2. Volume of repository whole blood (mL)

		.	
--	--	---	--

SCFA8D2
- d3. Ship date of repository blood specimen (mm/dd/yyyy):

--	--	--	--	--	--	--	--

SCFA8D3

ID NUMBER:						
------------	--	--	--	--	--	--

FORM CODE: SCF
VERSION: A 04/11/07

Contact
Occasion

--	--

SEQ #

--	--

d4. Repository serum specimen Y

N

→ Go to Item 9

SCFA8D4

If no, specify reason _____

d5. Volume of repository serum specimen (mL)

	.	
--	---	--

SCFA8D5

d6. Ship date of repository serum specimen (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA8D6

C. URINE SPECIMEN

9. Was urine collected? Y

N

→ Go to Item 15

SCFA9

If no, specify reason _____

10. Date of urine specimen collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA10

11. Method of urine collection:

Catheterization A

Suprapubic aspiration B

Clean Voided C

Bag collected D

SCFA11

Note: bag-collected specimen may only be used if dipstick is negative for pyuria.

12. Indicate urine specimens collected:

a. Local lab urine culture Y

N

SCFA12A

b. Repository urine specimen Y

N

→ Go to Item 15

SCFA12B

If no, specify reason _____

13. Volume of urine specimen for repository (mL):

		.	
--	--	---	--

SCFA13

14. Urine repository specimen shipping date (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA14

D. RECTAL SWAB SPECIMEN

15. Was a rectal swab collected? Y

N

→ Go to Item 18

SCFA15

If no, specify reason _____

16. Date of rectal swab specimen collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA16

17. Rectal swab specimen shipping date (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA17

E. ADMINISTRATIVE INFORMATION

18. Date of data collection (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

SCFA18

19. Method of data collection (*circle one*):

Computer C

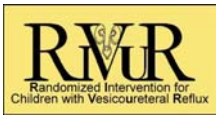
Paper P

SCFA19

20. Recorder's initials:

--	--	--

BLIND_STAFF_ID20



TREATMENT FAILURE FORM

ID NUMBER:						
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FORM CODE: TFF
VERSION: A 07/21/09

Contact
Occasion

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SEQ #

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Instructions: This form is to be completed by DCC research staff and should be used to identify RIVUR participant treatment failures. Record relevant details, particularly DSMB responses or actions, in Comments (#6).

1. a. Date identified as treatment failure by DCC staff (mm/dd/yyyy):

--	--	--	--	--	--	--	--

TFFA1A
b. Staff's initials who identified treatment failure:

--	--	--

TFFA1B TFFA1B will not be included in the NIDDK closed datasets
2. a. Date site notified (mm/dd/yyyy):

--	--	--	--	--	--	--	--

TFFA2A
b. Staff's initials who notified site of treatment failure:

--	--	--

TFFA2B TFFA2B will not be included in the NIDDK closed datasets
3. a. Date DSMB notified (mm/dd/yyyy):

--	--	--	--	--	--	--	--

TFFA3A
b. Staff's initials who notified DSMB of treatment failure:

--	--	--

TFFA3B TFFA3B will not be included in the NIDDK closed datasets
4. Type of Treatment Failure:
 - a. New or Worsening Scarring on Follow-up DMSA..... Y N **TFFA4A**
 - b. New or Worsening Scarring on post-UTI Interim DMSA on Participant with severe baseline scarring Y N **TFFA4B**
 - c. 2 Febrile UTI Y N **TFFA4C**
 - d. 4 Symptomatic OR 1 Febrile + 3 Symptomatic..... Y N **TFFA4D**
5. Date of data entry (mm/dd/yyyy):

--	--	--	--	--	--	--	--

TFFA5
6. Comments: Y N **TFFA6** TFFA6 will not be included in the NIDDK closed datasets

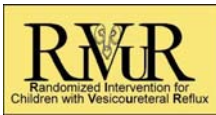
7. SC Request Number of Treatment Failure Report to DSMB

--	--	--	--	--	--

TFFA7 TFFA7 will not be included in the NIDDK closed datasets
8. Recorder's initials:

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BLIND_STAFF_ID



ULTRASOUND RESULTS FORM

ID NUMBER:

FORM CODE: URF
VERSION: C 05/08/07

Contact
Occasion

SEQ #

Instructions: This form should be completed by the reference radiologist. Affix the participant ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.

A. IMAGING RESULTS

1. Date of ultrasound (mm/dd/yyyy): // **UR_1**
2. Right kidney:
- a. Length (cm): **UR_2A**
- b. Width (cm): **UR_2B**
- c. Duplication:
- Yes Y
- No N **UR_2C**
- Unevaluated U
- d. Hydronephrosis: Y N → **Go to Q3** **UR_2D**
- e. SFU hydronephrosis grade **UR_2E**
- f. Renal pelvis A-P diameter (cm): . **UR_2F**
3. Left kidney:
- a. Length (cm): **UR_3A**
- b. Width (cm): **UR_3B**
- c. Duplication:
- Yes Y
- No N **UR_3C**
- Unevaluated U
- d. Hydronephrosis: Y N → **Go to Q3** **UR_3D**
- e. SFU hydronephrosis grade **UR_3E**
- f. Renal pelvis A-P diameter (cm): . **UR_3F**
4. Right Ureter:
- a. Dilated: Y N **UR_4A**
- b. Proximal: Y N **UR_4B**
- c. Distal: Y N **UR_4C**
5. Left Ureter:
- a. Dilated: Y N **UR_5A**
- b. Proximal: Y N **UR_5B**
- c. Distal: Y N **UR_5C**
6. Bladder post-void volume assessed? Y N → **Go to Q8** **UR_6**
7. Post void residual (circle one):
- None, bladder is empty, post void A
- Small, nearly empty, post void B
- Moderate, volume less, still distended post void C **UR_7**
- Large, volume similar pre and post void D
- Not assessed, no comparable pre/post images E
8. Bladder wall qualitatively thickened: Y N **UR_8**

ID NUMBER:							
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FORM CODE: URF
VERSION: C 05/08/07

Contact
Occasion

--	--

SEQ #

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9. Bladder wall (posterior) measured? Y N → **Go to Q11** **UR_9**

10. Bladder wall (posterior) measurement (mm):

--	--

 .

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UR_10

11. Bladder diverticulum: Y N U **UR_11**

12. Bladder masses: Y N U **UR_12**

13. Comments: Y N **UR_13**

Specify: _____

14. Quality of film:

Adequate A **UR_14**
Inadequate I

B. ADMINISTRATIVE INFORMATION

15. Date of reading (mm/dd/yyyy):

--	--

 /

--	--

 /

--	--	--	--

UR_15

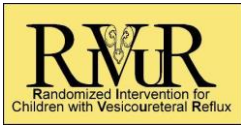
16. Method of data collection (*circle one*):

Computer C **UR_16**
Paper P

17. Radiologist's initials:

--	--	--

BLIND_STAFF_ID



URINE SPECIMEN RESULTS FORM

Version A of this form
was used for pilot study

ID NUMBER:							
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FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

--	--

SEQ #

--	--

Line
Number

--	--

Participant Name: _____

Instructions: Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? Y N → **Go to Item 6** **USR1**
2. Date of urine sample collection for dipstick (mm/dd/yyyy):

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 /

--	--

 /

--	--	--	--

USR2
3. Method of urine collection for dipstick (*circle one*):
Catheterization A
Suprapubic aspiration B
Clean voided C **USR3**
Bag collected D
Unknown E
4. Are the dipstick results based on urine collected at home? Y N **USR4**
5. Dipstick results:
 - a. Leukocyte esterase (*circle one*):
Negative A
Trace B
Small (+) C **USR5A**
Moderate (++) D
Large (+++) E
 - b. Nitrite (*circle one*):
Negative N **USR5B**
Positive P

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
Yes Y
No, urine microscopy not performed N → **Go to Item 8** **USR6A**
No, other reason O
If other, please specify: _____ → **Go to Item 8**
- b. Date of urine sample collection for microscopy (mm/dd/yyyy):

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 /

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 /

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USR6B

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

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SEQ #

--	--

Line
Number

--	--

Participant Name: _____

c. Method of urine collection for microscopy (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR6C

d. Are the microscopy results based on urine collected at home? Y N

USR6D

7. Urine microscopy results:

a. WBC (*Enter count. Use 999.999 for values ≥ 999.999*):

			.			
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USR7A

b. Reporting units for WBC microscopy (*circle one*):

- WBC/mm³ A
WBC/hpf B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes Y

No, urine culture not performed N

→ Go to Item 40

No, sample contaminated C

→ Do Items 9-11, then go to Item 40

No, other reason O

If other, please specify: _____

→ Go to Item 40

9. Date of urine sample collection for culture (*mm/dd/yyyy*):

		/			/				
--	--	---	--	--	---	--	--	--	--

USR9

10. Method of urine collection for urine culture (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR10

11. Is the urine culture report based on urine collected at home? Y N

USR11

12. How many different organisms were isolated on culture? (*Describe type and colony count in Q13-Q16.*)

--

→ If 0, Go to Item 40

USR12

ID NUMBER:						
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FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Sensitivity of each isolated organism

(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested b. Organism #1 c. Organism #2 d. Organism #3 e. Organism #4

(code from list).....

24.				USR24A	S	I	R	N		USR24B	S	I	R	N		USR24C	S	I	R	N		USR24D	S	I	R	N		USR24E
25.				USR25A	S	I	R	N		USR25B	S	I	R	N		USR25C	S	I	R	N		USR25D	S	I	R	N		USR25E
26.				USR26A	S	I	R	N		USR26B	S	I	R	N		USR26C	S	I	R	N		USR26D	S	I	R	N		USR26E
27.				USR27A	S	I	R	N		USR27B	S	I	R	N		USR27C	S	I	R	N		USR27D	S	I	R	N		USR27E
28.				USR28A	S	I	R	N		USR28B	S	I	R	N		USR28C	S	I	R	N		USR28D	S	I	R	N		USR28E
29.				USR29A	S	I	R	N		USR29B	S	I	R	N		USR29C	S	I	R	N		USR29D	S	I	R	N		USR29E
30.				USR30A	S	I	R	N		USR30B	S	I	R	N		USR30C	S	I	R	N		USR30D	S	I	R	N		USR30E
31.				USR31A	S	I	R	N		USR31B	S	I	R	N		USR31C	S	I	R	N		USR31D	S	I	R	N		USR31E
32.				USR32A	S	I	R	N		USR32B	S	I	R	N		USR32C	S	I	R	N		USR32D	S	I	R	N		USR32E
33.				USR33A	S	I	R	N		USR33B	S	I	R	N		USR33C	S	I	R	N		USR33D	S	I	R	N		USR33E
34.				USR34A	S	I	R	N		USR34B	S	I	R	N		USR34C	S	I	R	N		USR34D	S	I	R	N		USR34E
35.				USR35A	S	I	R	N		USR35B	S	I	R	N		USR35C	S	I	R	N		USR35D	S	I	R	N		USR35E
36.				USR36A	S	I	R	N		USR36B	S	I	R	N		USR36C	S	I	R	N		USR36D	S	I	R	N		USR36E
37.				USR37A	S	I	R	N		USR37B	S	I	R	N		USR37C	S	I	R	N		USR37D	S	I	R	N		USR37E
38.				USR38A	S	I	R	N		USR38B	S	I	R	N		USR38C	S	I	R	N		USR38D	S	I	R	N		USR38E
39.				USR39A	S	I	R	N		USR39B	S	I	R	N		USR39C	S	I	R	N		USR39D	S	I	R	N		USR39E

E. UTI TREATMENT

40. Was UTI treatment prescribed? Y N → **Go to Item 46** **USR40**

41. How many different antimicrobials were prescribed to treat the UTI?

(Describe in item 42-item 45, and update the **CMF**.) **USR41**

ID NUMBER:							
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FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

<u>Antimicrobial (code from list):</u>	<u>Date prescribed (mm/dd/yyyy):</u>	<u>Duration of treatment (days):</u>	<u>Pathogen sensitive to drug:</u>												
42. a. <table border="1"><tr><td></td><td></td></tr></table> USR42A			b. <table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td></tr></table> USR42B			/			/			c. <table border="1"><tr><td></td><td></td></tr></table> USR42C			d. Y N U USR42D
		/			/										
43. a. <table border="1"><tr><td></td><td></td></tr></table> USR43A			b. <table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td></tr></table> USR43B			/			/			c. <table border="1"><tr><td></td><td></td></tr></table> USR43C			d. Y N U USR43D
		/			/										
44. a. <table border="1"><tr><td></td><td></td></tr></table> USR44A			b. <table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td></tr></table> USR44B			/			/			c. <table border="1"><tr><td></td><td></td></tr></table> USR44C			d. Y N U USR44D
		/			/										
45. a. <table border="1"><tr><td></td><td></td></tr></table> USR45A			b. <table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td></tr></table> USR45B			/			/			c. <table border="1"><tr><td></td><td></td></tr></table> USR45C			d. Y N U USR45D
		/			/										

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available?

USR46

Yes Y

No, urine chemistry not performed N

→ **Go to Item 54**

No, sample inadequate I

→ **Do Item 47, then go to Item 54**

No, other reason O

If other, please specify: _____

→ **Go to Item 54**

47. Date of urine sample collection for chemistry (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

USR47

48. a. Method of urine collection for chemistry (circle one):

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D

Unknown E

USR48A

b. Are the urine chemistry results based on urine collected at home?

N

USR48B

49. Creatinine

a. Value

				.	
--	--	--	--	---	--

CREATININE01

b. Data Type (circle one):

= (equal to) A

> (greater than) B

≥ (greater than or equal to) C

< (less than) D

≤ (less than) E

DT_CRE01

ID NUMBER:							
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FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

c. Units (*circle one*):

mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

If other, please specify: _____

Variable
removed,
all are in
mg/dL

d. Reference range

USRC49D1 d1.

--	--	--

.

--

 - d2.

--	--	--

.

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USRC49D2

50. Did the laboratory provide results for microalbumin? Y

N → **Go to Item 52**

USRC50

51. Microalbumin

a. Value

--	--	--	--

.

--

ALBUMIN01

b. Data Type (*circle one*):

= (equal to) A
> (greater than) B
≥ (greater than or equal to) C
< (less than) D
≤ (less than) E

DT_ALB01

c. Units (*circle one*):

mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

If other, please specify: _____

Variable
removed,
all are in
mg/dL

d. Reference range

USRC51D1 d1.

--	--	--

.

--

 - d2.

--	--	--

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USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? Y

N → **Go to Item 54**

USRC52

ID NUMBER:							
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FORM CODE: USR
VERSION: E 02/18/13

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

53. Microalbumin/Creatinine Ratio

a. Value

--	--	--	--

ACR01

b. Data Type (circle one):

- = (equal to) A
> (greater than) B
≥ (greater than or equal to) C
< (less than) D
≤ (less than) E

DT_ACR01

c. Units (circle one):

- mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

Variable
removed,
all are in
mg/g

If other, please specify: _____

d. Reference range

USRC53D1

d1.

--	--	--	--

- d2.

--	--	--	--

USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:

- Protocol scheduled baseline or end-of study P → Go to Item 56
Abstracted from medical record M
Routine office visit O → Go to Item 56

USR50

55. MCID Number if results derive from abstraction of a medical

care visit (from MCA form)

--	--	--	--	--	--	--	--

BLIND_MCID

56. Date of data entry (mm/dd/yyyy):

		/			/				
--	--	---	--	--	---	--	--	--	--

USR52

57. Method of data collection (circle one):

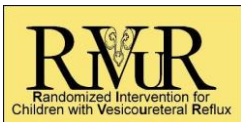
- Computer C
Paper P

USR53

58. Recorder's initials:

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BLIND_STAFF_ID



URINE SPECIMEN RESULTS FORM

ID NUMBER:						
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FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instructions: Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? Y N → **Go to Item 6** **USR1**
2. Date of urine sample collection for dipstick (mm/dd/yyyy):

--	--	--	--	--	--	--	--

USR2
3. Method of urine collection for dipstick (*circle one*):
- Catheterization A
- Suprapubic aspiration B
- Clean voided C **USR3**
- Bag collected D
- Unknown E
4. Are the dipstick results based on urine collected at home? Y N **USR4**
5. Dipstick results:
- a. Leukocyte esterase (*circle one*):
- Negative A
- Trace B
- Small (+) C **USR5A**
- Moderate (++) D
- Large (+++) E
- b. Nitrite (*circle one*):
- Negative N **USR5B**
- Positive P

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
- Yes Y
- No, urine microscopy not performed N → **Go to Item 8** **USR6A**
- No, other reason O
- If other, please specify: _____ → **Go to Item 8**
- b. Date of urine sample collection for microscopy (mm/dd/yyyy):

--	--	--	--	--	--	--	--

USR6B

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

--	--

SEQ #

--	--

Line
Number

--	--

Participant Name: _____

c. Method of urine collection for microscopy (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR6C

d. Are the microscopy results based on urine collected at home? Y

N

USR6D

7. Urine microscopy results:

a. WBC (*Enter count. Use 999.999 for values ≥ 999.999*):

			.			
--	--	--	---	--	--	--

USR7A

b. Reporting units for WBC microscopy (*circle one*):

- WBC/mm³ A
WBC/hpf B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes Y

No, urine culture not performed N

→ Go to Item 40

No, sample contaminated C

→ Do Items 9-11, then go to Item 40

No, other reason O

If other, please specify: _____

→ Go to Item 40

9. Date of urine sample collection for culture (*mm/dd/yyyy*):

		/			/				
--	--	---	--	--	---	--	--	--	--

USR9

10. Method of urine collection for urine culture (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR10

11. Is the urine culture report based on urine collected at home? Y

N

USR11

12. How many different organisms were isolated on culture? (*Describe type and colony count in Q13-Q16.*).....

--

→ If 0, Go to Item 40

USR12

ID NUMBER:						
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FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instructions: For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) (c.) the colony count (CFU/ML) of isolated organism (do **not** enter commas in the colony count) and (d) species (if there are more than 3 species please specify in a notelog):

(b.) Data Type:

- = (equal to) A → **Skip field c2 in items 13-16**
> (greater than) B → **Skip field c2 in items 13-16**
≥ (greater than or equal to) C → **Skip field c2 in items 13-16**
< (less than) D → **Skip field c2 in items 13-16**
≤ (less than or equal to) E → **Skip field c2 in items 13-16**
Range F

Organism (code from list)	Data Type	Colony Count	Species (code from list)
13. a.	b.	c1. - c2.	d1. d2. d3.
USR13A	USR13B	USR13C1	USR13C2 USR13D1 USR13D2 USR13D3
14. a.	b.	c1. - c2.	d1. d2. d3.
USR14A	USR14B	USR14C1	USR14C2 USR14D1 USR14D2 USR14D3
15. a.	b.	c1. - c2.	d1. d2. d3.
USR15A	USR15B	USR15C1	USR15C2 USR15D1 USR15D2 USR15D3
16. a.	b.	c1. - c2.	d1. d2. d3.
USR16A	USR16B	USR16C1	USR16C2 USR16D1 USR16D2 USR16D3

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) **USR17**

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
18.	USR18A	USR18B	USR18C	USR18D USR18E
19.	USR19A	USR19B	USR19C	USR19D USR19E
20.	USR20A	USR20B	USR20C	USR20D USR20E
21.	USR21A	USR21B	USR21C	USR21D USR21E
22.	USR22A	USR22B	USR22C	USR22D USR22E
23.	USR23A	USR23B	USR23C	USR23D USR23E

--	--

--	--

Participant Name: _____

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested
(code from list).....

[illegible]

E. UTI TREATMENT

40. Was UTI treatment prescribed? Y N → **Go to Item 46** **USR40**

41. How many different antimicrobials were prescribed to treat the UTI?

(Describe in item 42-item 45, and update the **CMF**.)

USR41

ID NUMBER:

FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

SEQ #

Line
Number

Participant Name: _____

<u>Antimicrobial (code from list):</u>	<u>Date prescribed (mm/dd/yyyy):</u>	<u>Duration of treatment (days):</u>	<u>Pathogen sensitive to drug:</u>
42. a. USR42A	b. / / USR42B	c. USR42C	d. Y N U USR42D
43. a. USR43A	b. / / USR43B	c. USR43C	d. Y N U USR43D
44. a. USR44A	b. / / USR44B	c. USR44C	d. Y N U USR44D
45. a. USR45A	b. / / USR45B	c. USR45C	d. Y N U USR45D

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available?

USR46

Yes Y

No, urine chemistry not performed N → **Go to Item 54**

No, sample inadequate I → **Do Item 47, then go to Item 54**

No, other reason O

If other, please specify: _____ → **Go to Item 54**

47. Date of urine sample collection for chemistry (mm/dd/yyyy): // **USR47**

48. a. Method of urine collection for chemistry (circle one):

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D

Unknown E

USR48A

b. Are the urine chemistry results based on urine collected at home? Y

N **USR48B**

49. Creatinine

a. Value **USRC49A**

b. Data Type (circle one):

= (equal to) A

> (greater than) B

≥ (greater than or equal to) C

< (less than) D

≤ (less than) E

USRC49B

ID NUMBER:							
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FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

c. Units (*circle one*):

mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

USRC49C

If other, please specify: _____

d. Reference range

USRC49D1

d1.

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--

- d2.

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USRC49D2

50. Did the laboratory provide results for microalbumin? Y

N → **Go to Item 52**

USRC50

51. Microalbumin

a. Value

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--

USRC51A

b. Data Type (*circle one*):

= (equal to) A
> (greater than) B
≥ (greater than or equal to) C
< (less than) D
≤ (less than) E

USRC51B

c. Units (*circle one*):

mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

USRC51C

If other, please specify: _____

d. Reference range

USRC51D1

d1.

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--

- d2.

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USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? Y

N → **Go to Item 54**

USRC52

ID NUMBER:							
------------	--	--	--	--	--	--	--

FORM CODE: USR
VERSION: D 07/27/12

Contact
Occasion

--	--

SEQ #

--	--

Line
Number

--	--

Participant Name: _____

53. Microalbumin/Creatinine Ratio

a. Value

--	--	--	--

USRC53A

b. Data Type (circle one):

- = (equal to) A
> (greater than) B
≥ (greater than or equal to) C
< (less than) D
≤ (less than) E

USRC53B

c. Units (circle one):

- mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

USRC53C

If other, please specify: _____

d. Reference range

USRC53D1

d1.

--	--	--	--

- d2.

--	--	--	--

USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:

- Protocol scheduled baseline or end-of study P → Go to Item 56
Abstracted from medical record M
Routine office visit O → Go to Item 56

USR50

55. MCID Number if results derive from abstraction of a medical

care visit (from MCA form)

--	--	--	--	--	--	--	--

BLIND_MCID

56. Date of data entry (mm/dd/yyyy):

--	--	--	--	--	--	--	--	--	--

USR52

57. Method of data collection (circle one):

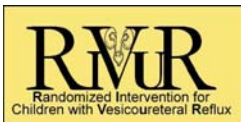
- Computer C
Paper P

USR53

58. Recorder's initials:

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BLIND_STAFF_ID



URINE SPECIMEN RESULTS FORM

ID NUMBER:						
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

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SEQ #

--	--

Line
Number

--	--

Participant Name: _____

Instructions: Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? Y N → **Go to Item 6** **USR1**
2. Date of urine sample collection for dipstick (mm/dd/yyyy):

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 /

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USR2
3. Method of urine collection for dipstick (*circle one*):
- | | | |
|-----------------------------|---|-------------|
| Catheterization | A | |
| Suprapubic aspiration | B | |
| Clean voided | C | USR3 |
| Bag collected | D | |
| Unknown | E | |
4. Are the dipstick results based on urine collected at home? Y N **USR4**
5. Dipstick results:
- a. Leukocyte esterase (*circle one*):
- | | | |
|---------------------|---|--------------|
| Negative | A | |
| Trace | B | |
| Small (+) | C | USR5A |
| Moderate (++) | D | |
| Large (+++) | E | |
- b. Nitrite (*circle one*):
- | | | |
|----------------|---|--------------|
| Negative | N | USR5B |
| Positive | P | |

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
- Yes Y
- No, urine microscopy not performed N → **Go to Item 8** **USR6A**
- No, other reason O
- If other, please specify: _____ → **Go to Item 8**
- b. Date of urine sample collection for microscopy (mm/dd/yyyy):

--	--

 /

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 /

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USR6B

ID NUMBER:							
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

--	--

SEQ #

--	--

Line
Number

--	--

Participant Name: _____

c. Method of urine collection for microscopy (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR6C

d. Are the microscopy results based on urine collected at home? Y

N USR6D

7. Urine microscopy results:

a. WBC (*Enter count. Use 999.999 for values ≥ 999.999*):

			.			
--	--	--	---	--	--	--

USR7A

b. Reporting units for WBC microscopy (*circle one*):

- WBC/mm³ A
WBC/hpf B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes Y

No, urine culture not performed N

→ Go to Item 40

No, sample contaminated C

→ Do Items 9-11, then go to Item 40

No, other reason O

If other, please specify: _____

→ Go to Item 40

9. Date of urine sample collection for culture (*mm/dd/yyyy*):

		/			/				
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USR9

10. Method of urine collection for urine culture (*circle one*):

- Catheterization A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR10

11. Is the urine culture report based on urine collected at home? Y

N USR11

12. How many different organisms were isolated on culture? (*Describe type and colony count in Q13-Q16.*)

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→ If 0, Go to Item 40

USR12

ID NUMBER:						
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instruction: For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) and (c.) the colony count (CFU/ML) of isolated organism:

(b.) Data Type:

- = (equal to) A → Skip field c2 in items 13-16
> (greater than) B → Skip field c2 in items 13-16
≥ (greater than or equal to) C → Skip field c2 in items 13-16
< (less than) D → Skip field c2 in items 13-16
≤ (less than or equal to) E → Skip field c2 in items 13-16
Range F

Organism (code from list)	Data Type	Colony Count:
13. a. USR13A	b. USR13B	c1. USR13C1 c2. USR13C2
14. a. USR14A	b. USR14B	c1. USR14C1 c2. USR14C2
15. a. USR15A	b. USR15B	c1. USR15C1 c2. USR15C2
16. a. USR16A	b. USR16B	c1. USR16C1 c2. USR16C2

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.)

--	--

USR17

Sensitivity of each isolated organism

(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
18. USR18A	 S I R N USR18B	 S I R N USR18C	 S I R N USR18D	 S I R N USR18E
19. USR19A	 S I R N USR19B	 S I R N USR19C	 S I R N USR19D	 S I R N USR19E
20. USR20A	 S I R N USR20B	 S I R N USR20C	 S I R N USR20D	 S I R N USR20E
21. USR21A	 S I R N USR21B	 S I R N USR21C	 S I R N USR21D	 S I R N USR21E
22. USR22A	 S I R N USR22B	 S I R N USR22C	 S I R N USR22D	 S I R N USR22E
23. USR23A	 S I R N USR23B	 S I R N USR23C	 S I R N USR23D	 S I R N USR23E
24. USR24A	 S I R N USR24B	 S I R N USR24C	 S I R N USR24D	 S I R N USR24E
25. USR25A	 S I R N USR25B	 S I R N USR25C	 S I R N USR25D	 S I R N USR25E

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Participant Name:

Line
Number

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested	b. <u>Organism #1</u>	c. <u>Organism #2</u>	d. <u>Organism #3</u>	e. <u>Organism #4</u>
(code from list)				
26. ☐ ☐ USR26A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
27. ☐ ☐ USR27A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
28. ☐ ☐ USR28A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
29. ☐ ☐ USR29A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
30. ☐ ☐ USR30A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
31. ☐ ☐ USR31A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
32. ☐ ☐ USR32A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
33. ☐ ☐ USR33A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
34. ☐ ☐ USR34A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
35. ☐ ☐ USR35A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
36. ☐ ☐ USR36A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
38. ☐ ☐ USR37A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
39. ☐ ☐ USR38A	S I R N.....	S I R N.....	S I R N.....	S I R N.....

E. UTI TREATMENT

40. Was UTI treatment prescribed? Y N → **Go to Item 46** **USR40**

41. How many different antimicrobials were prescribed to treat the UTI?
(Describe in item 42-item 45, and update the **CMF**.) **USR41**

<u>Antimicrobial (code from list):</u>			<u>Date prescribed (mm/dd/yyyy):</u>			<u>Duration of treatment (days):</u>	<u>Pathogen sensitive to drug:</u>					
42. a.		USR42A	b.		USR42B	c.	USR42C	d.	Y	N	U	USR42D
43. a.		USR43A	b.		USR43B	c.	USR43C	d.	Y	N	U	USR43D
44. a.		USR44A	b.		USR44B	c.	USR44C	d.	Y	N	U	USR44D

ID NUMBER:							
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Antimicrobial (code from list):

Date prescribed (mm/dd/yyyy):

Duration of
treatment (days):

Pathogen
sensitive to drug:

45. a.

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USR45A b.

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 /

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USR45B c.

--	--

USR45C d. Y N U **USR45D**

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? **USR46**

Yes Y

No, urine chemistry not performed N → **Go to Item 54**

No, sample inadequate I → **Do Item 47, then go to Item 54**

No, other reason O

If other, please specify: _____ → **Go to Item 54**

47. Date of urine sample collection for chemistry (mm/dd/yyyy):

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USR47

48. a. Method of urine collection for chemistry (circle one):

Catheterization A

Suprapubic aspiration B

Clean voided C

Bag collected D

Unknown E

USR48A

b. Are the urine chemistry results based on urine collected at home? Y N

USR48B

49. Creatinine

a. Value

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USRC49A

b. Data Type (circle one):

= (equal to) A

> (greater than) B

≥ (greater than or equal to) C

< (less than) D

≤ (less than) E

USRC49B

c. Units (circle one):

mg/dL A

mg/L B

mcg/mL C

mcg/mg D

mg/g E

Other F

USRC49C

If other, please specify: _____

ID NUMBER:							
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

d. Reference range

USRC49D1

d1.

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d2.

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USRC49D2

50. Did the laboratory provide results for microalbumin? Y

N → **Go to Item 52**

USRC50

51. Microalbumin

a. Value

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USRC51A

b. Data Type (*circle one*):

= (equal to) A

> (greater than) B

≥ (greater than or equal to) C

< (less than) D

≤ (less than) E

USRC51B

c. Units (*circle one*):

mg/dL A

mg/L B

mcg/mL C

mcg/mg D

mg/g E

Other F

USRC51C

If other, please specify: _____

d. Reference range

USRC51D1

d1.

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d2.

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USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio?Y

N → **Go to Item 54**

USRC52

53. Microalbumin/Creatinine Ratio

a. Value

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USRC53A

b. Data Type (*circle one*):

= (equal to) A

> (greater than) B

≥ (greater than or equal to) C

< (less than) D

≤ (less than) E

USRC53B

ID NUMBER:							
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FORM CODE: USR
VERSION: C 04/05/11

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

c. Units (*circle one*):

mg/dL A
mg/L B
mcg/mL C
mcg/mg D
mg/g E
Other F

USRC53C

If other, please specify: _____

d. Reference range

USRC53D1

d1.

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 - d2.

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USRC53D2

G. ADMINISTRATIVE INFORMATION

54. Source of results:

Protocol scheduled baseline or end-of study P → **Go to Item 56**
Abstracted from medical record M
Routine office visit O → **Go to Item 56**

USR50

55. MCID Number if results derive from abstraction of a medical

care visit (from MCA form)

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BLIND_MCID

56. Date of data entry (mm/dd/yyyy):

		/			/				
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USR52

57. Method of data collection (*circle one*):

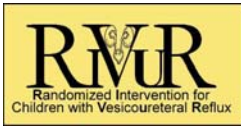
Computer C
Paper P

USR53

58. Recorder's initials:

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BLIND_STAFF_ID



URINE SPECIMEN RESULTS FORM

ID NUMBER:						
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FORM CODE: USR
VERSION: B 08/15/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instructions: Complete this form from medical records abstraction to report on all urinalysis results at baseline and end-of-study, or at any time during the study when urinalysis or urine culture is performed. Increment the line number above if multiple urinalyses are performed during one event.

A. DIPSTICK RESULTS

1. Was a urine dipstick performed? Y N → **Go to Item 6** **USR1**
2. Date of urine sample collection for dipstick (mm/dd/yyyy):

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USR2
3. Method of urine collection for dipstick (*circle one*):
- Catheterization A
- Suprapubic aspiration B
- Clean voided C **USR3**
- Bag collected D
- Unknown E
4. Are the dipstick results based on urine collected at home? Y N **USR4**
5. Dipstick results:
- a. Leukocyte esterase (*circle one*):
- Negative A
- Trace B
- Small (+) C **USR5A**
- Moderate (++) D
- Large (+++) E
- b. Nitrite (*circle one*):
- Negative N **USR5B**
- Positive P

B. MICROSCOPY RESULTS

6. a. Are urine microscopy results available?
- Yes Y
- No, urine microscopy not performed N → **Go to Item 8** **USR6A**
- No, other reason O
- If other, please specify: _____ → **Go to Item 8** **USR6B**
- b. Date of urine sample collection for microscopy (mm/dd/yyyy):

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ID NUMBER:							
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FORM CODE: USR
VERSION: B 08/15/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

c. Method of urine collection for microscopy (*circle one*):

- Catheterization A
Suprapubic aspiration..... B
Clean voided..... C
Bag collected..... D
Unknown..... E

USR6C

d. Are the microscopy results based on urine collected at home? Y

N

USR6D

7. Urine microscopy results:

a. WBC (*Enter count. Use 999.999 for values ≥ 999.999*):

			.			
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USR7A

b. Reporting units for WBC microscopy (*circle one*):

- WBC/mm³ A
WBC/hpf..... B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

USR8

Yes Y

No, urine culture not performed N

→ Go to Item 40

No, sample contaminated C

→ Do Items 9-11, then go to Item 40

No, other reason O

If other, please specify: _____

→ Go to Item 40

9. Date of urine sample collection for culture (*mm/dd/yyyy*):

		/			/				
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USR9

10. Method of urine collection for urine culture (*circle one*):

- Catheterization..... A
Suprapubic aspiration B
Clean voided C
Bag collected D
Unknown E

USR10

11. Is the urine culture report based on urine collected at home? Y

N

USR11

12. How many different organisms were isolated on culture? (*Describe type and colony count in Q13-Q16.*).....

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→ If 0, Go to Item 40

USR12

ID NUMBER:						
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FORM CODE: USR
VERSION: B 08/15/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

Instruction: For each organism isolated on culture, please record the (a.) organism from coded list, (b.) the data type (see options below) and (c.) the colony count (CFU/ML) of isolated organism:

(b.) Data Type:

- = (equal to) A → Skip field c2 in items 13-16
> (greater than)..... B → Skip field c2 in items 13-16
≥ (greater than or equal to)..... C → Skip field c2 in items 13-16
< (less than)..... D → Skip field c2 in items 13-16
≤ (less than or equal to)..... E → Skip field c2 in items 13-16
Range F

Organism (code from list)	Data Type	Colony Count:
13. a. USR13A	b. USR13B	c1. USR13C1 - c2. USR13C2
14. a. USR14A	b. USR14B	c1. USR14C1 - c2. USR14C2
15. a. USR15A	b. USR15B	c1. USR15C1 - c2. USR15C2
16. a. USR16A	b. USR16B	c1. USR16C1 - c2. USR16C2

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.)

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USR17

Sensitivity of each isolated organism

(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
18. USR18A	S I R N..... USR18B	S I R N..... USR18C	S I R N..... USR18D	S I R N..... USR18E
19. USR19A	S I R N..... USR19B	S I R N..... USR19C	S I R N..... USR19D	S I R N..... USR19E
20. USR20A	S I R N..... USR20B	S I R N..... USR20C	S I R N..... USR20D	S I R N..... USR20E
21. USR21A	S I R N..... USR21B	S I R N..... USR21C	S I R N..... USR21D	S I R N..... USR21E
22. USR22A	S I R N..... USR22B	S I R N..... USR22C	S I R N..... USR22D	S I R N..... USR22E
23. USR23A	S I R N..... USR23B	S I R N..... USR23C	S I R N..... USR23D	S I R N..... USR23E
24. USR24A	S I R N..... USR24B	S I R N..... USR24C	S I R N..... USR24D	S I R N..... USR24E
25. USR25A	S I R N..... USR25B	S I R N..... USR25C	S I R N..... USR25D	S I R N..... USR25E

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Participant Name:

Line
Number

Sensitivity of each isolated organism
(S=sensitive, I=intermediate, R=resistant, N=not tested):

a. Antimicrobial tested	b. <u>Organism #1</u>	c. <u>Organism #2</u>	d. <u>Organism #3</u>	e. <u>Organism #4</u>
(code from list)				
26. ☐ ☐ USR26A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
27. ☐ ☐ USR27A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
28. ☐ ☐ USR28A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
29. ☐ ☐ USR29A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
30. ☐ ☐ USR30A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
31. ☐ ☐ USR31A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
32. ☐ ☐ USR32A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
33. ☐ ☐ USR33A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
34. ☐ ☐ USR34A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
35. ☐ ☐ USR35A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
36. ☐ ☐ USR36A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
38. ☐ ☐ USR37A	S I R N.....	S I R N.....	S I R N.....	S I R N.....
39. ☐ ☐ USR38A	S I R N.....	S I R N.....	S I R N.....	S I R N.....

E. UTI TREATMENT

40. Was UTI treatment prescribed? Y N → **Go to Item 46** **USR40**

41. How many different antimicrobials were prescribed to treat the UTI?

(Describe in item 42-item 45, and update the **CMF**.)

Antimicrobial (code from list):		Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
42. a.	USR42A	b. / / USR42B	c. USR42C	d. Y N U USR42D
43. a.	USR43A	b. / / USR43B	c. USR43C	d. Y N U USR43D
44. a.	USR44A	b. / / USR44B	c. USR44C	d. Y N U USR44D

ID NUMBER:							
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FORM CODE: USR
VERSION: B 08/15/07

Contact
Occasion

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SEQ #

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Line
Number

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Participant Name: _____

<u>Antimicrobial (code from list):</u>	<u>Date prescribed (mm/dd/yyyy):</u>	<u>Duration of treatment (days):</u>	<u>Pathogen sensitive to drug:</u>															
45. a. <table border="1"><tr><td></td><td></td><td></td></tr></table>				b. <table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td><td>/</td><td></td><td></td><td></td><td></td></tr></table>			/			/					c. <table border="1"><tr><td></td><td></td></tr></table>			d. Y N U
		/			/													
USR45A	USR45B	USR45C	USR45D															

F. URINE CHEMISTRY RESULTS

46. Are urine chemistry results available? **USR46**

Yes Y

No, urine chemistry not performed N → **Go to Item 50**

No, sample inadequate I → **Do Item 47, then go to Item 50**

No, other reason O

If other, please specify: _____ → **Go to Item 50**

47. Date of urine sample collection for chemistry (mm/dd/yyyy):

		/			/				
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USR47

48. a. Method of urine collection for chemistry (circle one):

Catheterization A

Suprapubic aspiration B

Clean voided C **USR48A**

Bag collected D

Unknown E

b. Are the urine chemistry results based on urine collected at home? Y N **USR48B**

49. Urine chemistry results:

a. Creatinine (mg/dL)

		.	
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USR49A

b. Microalbumin (mg/dL)

			.	
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USR49B

G. ADMINISTRATIVE INFORMATION

50. Source of results:

Protocol scheduled baseline or end-of study P → **Go to Item 52** **USR50**

Abstracted from medical record M

51. MCID Number if results derive from abstraction of a medical care visit (from MCA form)

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BLIND_MCID

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C

P

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BLIND_STAFF_ID

ID NUMBER:							
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FORM CODE: VRF
VERSION: C 05/08/07

Contact
Occasion

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SEQ #

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7. Bladder trabeculations:..... Y N U VR_7
8. Bladder ureterocele: Y N U VR_8
9. Bladder wall diverticulum:..... Y N U VR_9
10. Normal urethra:..... Y N U VR_10
11. "Spinning Top" urethra Y N U VR_11
12. Osseous structures spinal dysraphism:..... Y N U VR_12
13. Comments: Y N VR_13

Specify: _____

14. Quality of film:
- Adequate..... A VR_14
- Inadequate I

B. ADMINISTRATIVE INFORMATION

15. Date of VCUG reading (mm/dd/yyyy): VR_15

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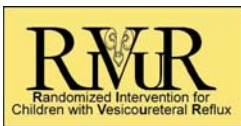
16. Method of data collection (*circle one*):

Computer VR_16 C

Paper..... P

17. Radiologist's initials: BLIND_STAFF_ID

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VCUG Sedation Form

ID NUMBER:							
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FORM CODE: VSF
VERSION: A 02/07/07

Contact
Occasion

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SEQ #

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Participant Name: _____

Instructions: Complete this form for every VCUG to provide information on possible sedation.

A. RADIOLOGICAL PROCEDURE

1. Date of VCUG procedure (mm/dd/yyyy): _____ VSFA1
2. Was sedation used during the radiological procedure? VSFA2
- Yes Y
- No N → Go to Item 9
- Unknown U → Go to Item 9

B. SEDATION

- | Medication Used for Sedation: | Medication Dose (mg/kg): | General Anesthesia: | | | | |
|---|--|---------------------|--|--|--|---|
| 3. Chloral hydrate a. VSFA3A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA3B | | | | | c. Y N U VSFA3C |
| | | | | | | |
| 4. Diazepam (Valium) a. VSFA4A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA4B | | | | | c. Y N U VSFA4C |
| | | | | | | |
| 5. Fentanyl a. VSFA5A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA5B | | | | | c. Y N U VSFA5C |
| | | | | | | |
| 6. Midazolam (Versed) a. VSFA6A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA6B | | | | | c. Y N U VSFA6C |
| | | | | | | |
| 7. Pentobarbital a. VSFA7A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA7B | | | | | c. Y N U VSFA7C |
| | | | | | | |
| 8. Other Drug a. VSFA8A Y N | b. <table border="1" style="display: inline-table;"><tr><td></td><td></td><td></td><td></td></tr></table> VSFA8B | | | | | c. Y N U VSFA8C |
| | | | | | | |
| d. If other, specify: VSFA8D _____ | | | | | | |

C. ADMINISTRATIVE INFORMATION

9. Date of data collection (mm/dd/yyyy): _____ VSFA9
10. Method of data collection (circle one):
- Computer C VSFA10
- Paper P
11. Recorder's initials: _____ BLIND_STAFF_ID