CUTIE

Careful Urinary Tract Infection Evaluation

CUTIE Case Report Forms

Careful Urinary Tract Infection Evaluation

The Careful Urinary Tract Infection Evaluation (CUTIE) study is an ancillary study under the Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR) clinical trial. The CUTIE study protocol is similar to the RIVUR study with the exception that it is an observational study that did not assign treatment arms and the participants did not have vesicoureteral reflux (VUR).

CUTIE based all of its documentation on the RIVUR materials. All aspects of the RIVUR trial that were not applicable to the CUTIE study are crossed out in the manual of operations (MOP) and on the case report forms (CRFs).

CUTIE
Careful Urinary Tract Infection Evaluation

ADVERSE EVENTS FORM

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

Line Number | |

Participant Name: _____

Instructions: *This form is to be completed for all adverse events or serious adverse events reported during the study.*

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

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

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

INSERT (=) FOR QUESTIONS 7 & 8

~~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~~

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~~

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 → **Go to Item 13**		N	AEF12A
b. Treated at CUTIE clinic	Y		N	AEF12B
c. Referred	Y		N	AEF12C
~~d. Study drug temporary discontinued~~	~~Y~~		~~N~~	
~~e. Study drug permanently discontinued~~	~~Y~~		~~N~~	
f. Medical intervention	Y		N	AEF12F
g. Surgical intervention	Y		N	AEF12G
h. Hospitalization	Y		N	AEF12H
i. Other	Y		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

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: _____

INSERT (=) FOR QUESTION 17

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

~~Definitely unrelated ..... A~~
~~Unlikely to be related ..... B~~
~~Possibly related ..... C~~
~~Probably related ..... D~~
~~Definitely related ..... E~~

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

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

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

Resolved ..... A
Recovered with minor sequelae ..... B AEF19
Recovered with major sequelae C
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

Participant Name: _____

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

																			BLIND_AUTHORITY

C. ADMINISTRATIVE INFORMATION

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

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

Computer C
Paper .....P

AEF23

24. Recorder's initials: ..... | | | BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

BASELINE DEMOGRAPHIC FORM

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

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 enrl_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

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

D. ADMINISTRATIVE INFORMATION

11. **[PC]** Date of demographic interview (mm/dd/yyyy): ..... |_|_|/|_|_|/|_|_|_|_| BDFA11

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

Computer C
Paper..... P

BDFA12

13. **[PC]** Interviewer's initials: ..... |_|_|_| BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

BASELINE MEDICAL HISTORY FORM

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

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=currently breastfed only)

3. What age did your child stop breastfeeding (months)? ..... | | BMHA3
   (99=currently 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: | | | | | | | | FORM CODE: BMH
VERSION: A 01/25/07 | Contact Occasion | | SEQ # | |

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): ..... | | / | | / | | | | | BMHA16

17. **[PC]** Method of data collection *(circle one)*:
Computer C
Paper ..... P
BMHA17

18. **[PC]** Interviewer's initials: ..... | | | BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

Blood Specimen Results Form

ID NUMBER:								FORM CODE: BSR VERSION: A 06/28/07	Contact Occasion		SEQ #	

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?~~

~~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**~~

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

3. ~~White blood cell count (WBC) (countx10^9/L) ..... ☐☐.☐~~

4. ~~Hemoglobin (Hgb) (g/dL) ..... ☐☐.☐~~

5. ~~Hematocrit (Hct) (%) ..... ☐☐.☐~~

6. ~~Platelet count (countx10^9/L) ..... ☐☐☐~~

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): ..... ☐☐/☐☐/☐☐☐☐ BSRA8

9. BUN (mg/dL) ..... ☐☐ BSRA9

10. Creatinine (mg/dL) ..... ☐.☐ BSRA10

11. Sodium (mmol/L) ..... ☐☐☐ BSRA11

12. Potassium (mmol/L) ..... ☐.☐ BSRA12

13. Chloride (mmol/L) ..... | | | | BSRA13

14. Carbon dioxide (mmol/L) ..... | | | . | | BSRA14

C. ADMINISTRATIVE INFORMATION

15. Date of data collection (mm/dd/yyyy): ..... | | / | | / | | | | | BSRA15

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

Computer C
Paper ..... P

BSRA16

17. Recorder's initials: ..... | | | BLIND_STAFF_ID

CUTIE ELIGIBILITY AND ENROLLMENT FORM

Careful Urinary Tract Infection Evaluation

ID NUMBER:								FORM CODE: CEE VERSION: B 5/27/09	Contact Occasion		SEQ #	

Participant Name: _____

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

A. ADMINISTRATIVE INFORMATION

1. **[PC]** a. Date of enrollment (TODAY) (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CEE1A

   [PC] b. Beginning work-up date of the most recent (index) UTI? ..... ☐☐/☐☐/☐☐☐☐ CEE1B

   c. **[PC]** Date of consent (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CEE1C

   d. **[PC]** Method of data collection *(circle one)*:
   Computer C
   Paper ..... P CEE1D

   e. **[PC]** Interviewer's initials: ..... ☐☐☐ BLIND_STAFF_ID

B. AGE

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

3. **[PC]** Age in months: ..... **[determined by DMS]** CEE3

	Yes	No	Not Applicable	
4. If child's age < 6 months, was gestational age ≥ 34 weeks?	Y	N → **Ineligible**	X	CEE4
5. **[PC]** Is child's age ≥ 2 months and < 72 months (6 yrs)?	Y	N → **Ineligible**		CEE5
6. a. Has your child had more than one UTI?	Y	N → **Go to Item 7**		CEE6A

   b. How many? ..... ☐ → **Ineligible if >2** CEE6B

   c. Did your child take prophylactic anti-microbials for UTI prior to the second UTI? ..... Y → **Ineligible** N CEE6C

C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Was a temperature measured during the index UTI event? ..... Y N → **Go to Item 14** CEE7

8. a. What was your child's highest measured temperature 24 hrs prior to or following the initial index UTI work-up? ..... |_|_|_|.|_| CEE8A

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

°F ..... F
°C C

CEE8B

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

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

CEE9

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

Home ..... H
Medical care professional ..... M

CEE10

11. a. What was the highest measured temperature during the index UTI? ..... |_|_|_|.|_| CEE11A

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

°F ..... F
°C C

CEE11B

c. What was the date of the highest temperature (mm/dd/yyyy)? ..... |_|_|/|_|_|/|_|_|_|_| CEE11C

12. What was the total duration of fever prior to index UTI antimicrobial treatment (hrs)? ..... |_|_|_| CEE12

13. What was the time from index UTI antimicrobial treatment to a sustained (> 24 hrs) normal temperature (hrs)? ..... |_|_|_| CEE13

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	CEE14A
b. Urinary urgency	Y	N	U	CEE14B
c. Urinary frequency	Y	N	U	CEE14C
d. Urinary hesitancy	Y	N	U	CEE14D
e. Dysuria	Y	N	U	CEE14E

		Yes	No	Unknown	Not Applicable	
f.	Foul-smelling urine	Y	N	U		CEE14F
g.	Failure to thrive (if child ≤ 4 mo.)	Y	N	U	X	CEE14G
h.	Dehydration (if child ≤ 4 mo.)	Y	N	U	X	CEE14H
i.	Hypothermia (if child ≤ 4 mo.)	Y	N	U	X	CEE14I

15. What was the total number of days that your child experienced these symptoms? | | CEE15

16. **[PC]** Was there a temperature ≥ 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** CEE16

D. INDEX UTI URINALYSIS RESULTS

17. a. **[PC]** Date of dipstick urine collection (mm/dd/yyyy): | | / | | / | | | | | CEE17A

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

Negative A CEE17B
Trace B
Small (+) C
Moderate (++) D
Large (+++) E

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

Negative N CEE17C
Positive P

18. a. **[PC]** Date of microscopy urine collection (mm/dd/yyyy): | | / | | / | | | | | CEE18A

b. **[PC]** WBC *(Enter count. Use 999.999 for values ≥ 999.999)*: | | | | . | | | CEE18B

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

WBC/mm^3 A CEE18C
WBC/hpf B

19. **[PC]** Was pyuria present, noted as either leukocyte esterase on dipstick greater than or equal to trace *(see Q17b)* **OR** WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf *(see Q18)*? Y N → **Ineligible** CEE19

ID NUMBER: | | | | | | | | FORM CODE: CEE
VERSION: B 5/27/09 Contact Occasion | | SEQ # | |

E. INDEX UTI URINE CULTURE RESULTS

20. a. **[PC]** Date of urine collection for culture (mm/dd/yyyy): ..... | | / | | / | | | | | CEE20A

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

Catheterization ..... A CEE20B

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** CEE21A

b. **[PC]** How many organisms were present? ..... | → **Ineligible if more than 2** CEE21B

22. a. **[PC]** Primary organism *(select from list)*: ..... | | CEE22A

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

= (equal to) ..... A → **Skip field c2** CEE22B

> (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. | | | | | | | CEE22C1 - c2. | | | | | | | CEE22C2

23. a. **[PC]** Secondary organism *(select from list)*: ..... | | CEE23A

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

= (equal to) ..... A → **Skip field c2** CEE23B

> (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. | | | | | | | CEE23C1 - c2. | | | | | | | CEE23C2

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** CEE24A

b. **[PC]** Was the colony count for the secondary organism ≤ 10,000 CFU/ml? *(See Q23.)* ..... Y N → **Ineligible** CEE24B

F. INDEX UTI TREATMENT

25. **[PC]** How many different antimicrobials were prescribed to treat the index UTI? *(Describe in Q26-Q29.)* CEE25

	Antimicrobial *(code from list)*:	Date prescribed (mm/dd/yyyy):	Duration of treatment (days):	Pathogen sensitive to drug:
26. **[PC]** a. / b. / c. / d.	CEE26A	CEE26B	CEE26C	Y N U CEE26D
27. **[PC]** a. / b. / c. / d.	CEE27A	CEE27B	CEE27C	Y N U CEE27D
28. **[PC]** a. / b. / c. / d.	CEE28A	CEE28B	CEE28C	Y N U CEE28D
29. **[PC]** a. / b. / c. / d.	CEE29A	CEE29B	CEE29C	Y N U CEE29D

30. **[PC]** a. Was the index UTI treated at least 7 days? *(Sum Q26c, Q27c, Q28c, and Q29c.)* Y N → **Ineligible** CEE30A

[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 CEE30B

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** CEE31

32. **[PC]** Date of follow-up urine culture (mm/dd/yyyy): ..... / / CEE32

G. VCUG LOCAL REPORT

33. **[PC]** Date of VCUG (mm/dd/yyyy): ..... / / CEE33

34. **[PC]** Is date of VCUG within 112 days after index UTI? ..... Y N → **Ineligible** CEE34

35. **[PC]** Does the VCUG demonstrate VUR? ..... Y → **Ineligible** N CEE35

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

a. Ureterocele ..... Y → **Ineligible** N CEE36A

b. Urethral valve ..... Y → **Ineligible** N CEE36B

H. RENAL ULTRASOUND LOCAL REPORT

37. a. **[PC]** Date of ultrasound (mm/dd/yyyy): ____/____/____ CEE37A

b. **[PC]** Is date of ultrasound within 112 days after index UTI? ..... Y N → **Ineligible** CEE37B

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

a. Gr 4 Hydronephrosis w/renal parenchyma atrophy..... Y→**Ineligible** N CEE38A

b. Ureterocele ..... Y→**Ineligible** N CEE38B

c. Solitary kidney ..... Y→**Ineligible** N CEE38C

d. Profoundly small kidney (more than 2 SD below mean) ..... Y→**Ineligible** N CEE38D

e. Multicystic dysplastic kidney..... Y→**Ineligible** N CEE38E

f. Pelvic kidney..... Y→**Ineligible** N CEE38F

g. Fused kidney ..... Y→**Ineligible** N CEE38G

h. Neurogenic bladder ..... Y→**Ineligible** N CEE38H

I. OTHER MEDICAL EXCLUSIONS

39. 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 CEE39

40. 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 CEE40

41. 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 CEE41

42. Do the parents or siblings have a history of anaphylactic reaction to sulfa? ..... Y→**Ineligible** N CEE42

43. Has your child ever had renal or bladder surgery? ..... Y→**Ineligible** N CEE43

J. AVAILABILITY

44. Is your child currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown?..... Y→**Ineligible** N CEE44

45. a. Is your child currently taking continuous antimicrobial prophylaxis?..... Y N → **Go to Item 46** CEE45A

b. Is the family willing to discontinue current prophylaxis? ..... Y N → **Ineligible** CEE45B

46. Is there any reason that would make completing the study protocol impossible (i.e. visiting the clinic semiannually for data collection, or receiving bimonthly phone calls from study staff)? ..... Y→**Ineligible** N CEE46

47. Does the family have plans to move to an area that will make it no longer convenient for study participation? ..... Y→**Ineligible** N CEE47

K. RECENT FEVER AND PYURIA

48. Has your child had a temperature ≥ 100.4˚F or 38˚C anytime in the last 24 hours? ..... Y→**STOP** N CEEB48

49. a. **[PC]** Was pyuria present on today's urine dipstick, or the previous urine dipstick, noted as leukocyte esterase ≥ trace **OR** microscopy results of WBC ≥ 10 WBC/mm^3 or WBC ≥ 5 WBC/hpf? ..... Y N→**Go to Item 50** CEE49

b. **[PC]** Is this an attempt at enrollment following pyuria present (either on dip or microscopy) at a previous enrollment visit? ..... Y N→**Stop** CEEB49B

c. **[PC]** Date of last enrollment attempt (mm/dd/yyyy): ..... ☐☐/☐☐/☐☐☐☐ CEEB49C

d. **[PC]** Is there a negative culture from a specimen collected at the previous enrollment attempt when pyuria was present? ..... Y N→**Stop** CEEB49D

L. ENROLLMENT

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

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ BLIND_AUTHORITY

Note: *choosing 'Y' to question #51 will enroll the participant in CUTIE. Items on this form will not be able to be changed following the enrollment procedure. Please verify that the responses you have entered above are accurate before continuing.*

51. **[PC]** Do you wish to enroll this child into the CUTIE study? ..... Y N CEE51

Careful Urinary Tract Infection Evaluation

Concomitant Medication Form

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

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): ..... __ __/__ __/__ __ __ __ CMF1

2. Method of data collection *(circle one)*:
   Computer C
   Paper .....P
   CMF2

3. a. Recorder's initials: ..... 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

	D. Medication	D. Date Start	E. Date Stop *If continuing use 00/00/0000*	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:								FORM CODE: CMF VERSION: B 07/18/08	Contact Occasion		SEQ #	

	A. Medication	D. Date Start	E. Date Stop *If continuing use 00/00/0000*	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__ __	CMFB28E

CUTIE used version B only

DMSA RESULTS FORM

Careful Urinary Tract Infection Evaluation

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: DM_4A

	None	Mild	Moderate	Severe	
a. Right	A	B	C	D	→ **If A, skip Q5a**
b. Left	A	B	C	D	→ **If A, skip Q5b**

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:

	None	Mild	Moderate	Severe	Atrophy	
a. Right	A	B	C	D	E	→ **If A or E, skip Q7a**
b. Left	A	B	C	D	E	→ **If A or E, skip Q7b**

DM_6A

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)*:

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ DM_7B12

DM_7B1 DM_7B2 DM_7B3 DM_7B4 DM_7B5 DM_7B6 DM_7B7 DM_7B8 DM_7B9 DM_7B10 DM_7B11

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): ..... |_|_|/|_|_|/|_|_|_|_|

DM_9

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

Computer C
Paper ..... P

DM_10

12. Radiologist's initials: ..... |_|_|_|

BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

DMSA Sedation Form

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

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): ..... | |/| |/| | | | | 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. |||.|	DSFA5B	c. Y N U	DSFA5C
6.	Diazepam (Valium) ..... a. Y N	DSFA6A	b. |||.|	DSFA6B	c. Y N U	DSFA6C
7.	Fentanyl ..... a. Y N	DSFA7A	b. |||.|	DSFA7B	c. Y N U	DSFA7C
8.	Midazolam (Versed) ..... a. Y N	DSFA8A	b. |||.|	DSFA8B	c. Y N U	DSFA8C
9.	Pentobarbital ..... a. Y N	DSFA9A	b. |||.|	DSFA9B	c. Y N U	DSFA9C
10.	Other Drug ..... a. Y N	DSFA10A	b. |||.|	DSFA10B	c. Y N U	DSFA10C

d. If other, specify: _____ DSFA10D

C. ADMINISTRATIVE INFORMATION

11. Date of data collection (mm/dd/yyyy): ..... | |/| |/| | | | | DSFA11

12. Method of data collection *(circle one)*:
    Computer C
    Paper ..... P DSFA12

13. Recorder's initials: ..... | | | BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

DES TREATMENT FORM

ID NUMBER: | | | | | | | |

FORM CODE: DTF
VERSION: A 4/4/08

Contact Occasion | |

SEQ # | |

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 males or* ***>9*** *for females.*

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→**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): ..... | |/| |/| | | | | DTFA6

7. Method of data collection *(circle one)*:
   Computer C
   Paper ..... P DTFA7

8. Recorder's initials: ..... | | | BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

DV QUESTIONNAIRE

ID NUMBER: | | | | | | | |

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

Contact Occasion | |

SEQ # | |

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 wait	A	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** DVQA11A

    b. If yes, indicate how often:

    Never A
    Once per month B
    Two or three times per month C DVQA11B
    Once per week D
    More than once per week E

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 DVQA12B
Once per week ..... D
More than once per week ..... E

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 DVQA13B
Once per week ..... D
More than once per week ..... E

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 DVQA14B
Two or three times per month C
Once per week ..... D
More than once per week ..... E

Thank you!

C. Administrative Use Only

15. Date of Form (mm/dd/yyyy) | | / | | / | | | | DVQA15

16. Reviewer's Initials | | | BLIND_STAFF_ID

CUTIE used version B and C only

CUTIE
Careful Urinary Tract Infection Evaluation

PROTOCOL SCHEDULED FOLLOW-UP CONTACT FORM

ID NUMBER:								FORM CODE: FUP VERSION: C 07/18/08	Contact Occasion		SEQ #	

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** FUP1
   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

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

   Participant refused.....A → **Go to Item 23** FUP2
   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**

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

Insert (=) for questions 3a-3b

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?..... | | → **MCN, MCA, (USR) for each** FUPC5

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 → **Add to the CMF** N FUP7

C. STUDY MEDICATION STATUS

Insert (=) for questions 8-16

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 → **Go to 19**
Previously trained ..... P → **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

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**
Previously trained ..... P → **Go to 22**

FUP19

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
Paper ..... P

FUP24

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

BLIND_STAFF_ID

INFORMED CONSENT TRACKING FORM

Careful Urinary Tract Infection Evaluation

ID NUMBER:							

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

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 — ICT1
   - Modification of consent ..... M

2. Type of consent or modification *(circle one)*:
   - Full consent ..... F → Go to Item 14
   - Partial consent ..... P — ICT2
   - Partial withdrawal of consent ..... D
   - 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 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 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

8. a. Is there a <u>date</u> 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
   ICT9

   If partial access, please specify: _____

   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
   ICTB9B

   If partial data allowed, please specify: _____

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

    Yes, full contact of informants ..... Y
    No contact ..... N
    Limited contact ..... P
    ICT10

    If limited, please specify: _____

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
    ICT11

    If partial release, please specify: _____

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
    ICTB12

    If limited, please specify: _____

13. Any other restrictions not specified in items 3 to 12? ..... Y N ICT12

    If yes, specify restrictions: _____

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

Careful Urinary Tract Infection Evaluation

LIA Questionnaire

ID NUMBER:							

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

Contact Occasion | | |

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:

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 imaginable health — Perfect health

3. ~~How worried are you about your child's vesicoureteral reflux/VUR? *(Circle **one** number.)*~~

~~**0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10**~~

~~Not worried — Very worried~~

~~4. How difficult has it been for you to give your child medication every day? *(Circle **one** number.)*~~

~~**0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10**~~

~~Not difficult ——— Very 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**~~

~~Not a burden ——— Huge 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 bothersome — Very 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 imaginable health — Perfect 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 discomfort — Worst 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 discomfort — Worst 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 discomfort — Worst discomfort — Not Applicable

Thank you!

B. Administrative Use Only

11. Date of Form (mm/dd/yyyy) ... LIQA11 ..... ☐☐/☐☐/☐☐☐☐

12. Reviewer's initials: ..... BLIND_STAFF_ID ..... ☐☐☐

CUTIE used version B and C only

CUTIE
Careful Urinary Tract Infection Evaluation

MEDICAL CARE ABSTRACTION FORM

ID NUMBER: | | | | | | | |

FORM CODE: MCA
VERSION: C 01/21/10

Contact Occasion | |

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, 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: MCA2
   - 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**

B. HOSPITALIZATION OR ER VISIT

MCAB7

7a. Was this a hospitalization or an ER visit?.....Y→ **Complete AEF** N → **Go to Item 12**

b. Specify if the participant was hospitalized or visited the emergency room *(circle one)*: MCAC7B
   - Emergency room visit.....E
   - Hospitalization.....H
   - Other.....O

   Specify If other: _____

8. Date of discharge (nonfatal cases) or death (mm/dd/yyyy): ..... | |/| |/| | | | | MCA8

9. What was the disposition of the patient on discharge? MCA11
   - 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

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
b. ☐☐☐☐ MCA14B
c. ☐☐☐☐ MCA14C
d. ☐☐☐☐ MCA14D
e. ☐☐☐☐ MCA14E
f. ☐☐☐☐ MCA14F
g. ☐☐☐☐ MCA14G
h. ☐☐☐☐ MCA14H
i. ☐☐☐☐ MCA14I
j. ☐☐☐☐ MCA14J
k. ☐☐☐☐ MCA14K
l. ☐☐☐☐ MCA14L
m. ☐☐☐☐ MCA14M
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
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. 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

	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?
f Dehydration (<= 4 months old)	Y N U X MCAB19F1	Y N U X MCAB19F2	MCAB19F3	Y N U X MCAB19F4
g. Hypothermia (<= 4 months old)	Y N U X MCAB19G1	Y N U X MCAB19G2	MCAB19G3	Y N U X MCAB19G4

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 MCA20B

d. Recorded temperature measurement route during the medical visit *(circle one)*:

Oral .....O
Axillary.....A
Tympanic.....T MCAB23D
Rectal .....R
Temporal .....F
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** MCAB24A

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

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
    Pounds ..... P MCA31B

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): ..... __/__/____ MCA35I

INSERT (=) FOR QUESTIONS 32 j-l

~~j. **Procedure to correct VUR** ..... Y N → **Go to item 33**~~

~~k. If yes, date of procedure: (mm/dd/yyyy): ..... __/__/____~~

~~l. Name of procedure: _____~~

I. ADMINISTRATIVE INFORMATION

33. Date of data collection (mm/dd/yyyy): ..... __/__/____ MCA36

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

Computer C

Paper ..... P

MCA37

35. Recorder's initials: ..... ___ BLIND_STAFF_ID

CUTIE used version C and D only

CUTIE
Careful Urinary Tract Infection Evaluation

MEDICAL CARE NOTIFICATION FORM

ID NUMBER:								FORM CODE: MCN VERSION: D 02/23/10	Contact Occasion		SEQ #	

Participant Name: _____

Instructions: *Complete this form for all medical care reported/received since the last study contact, including in-clinic CUTIE 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: ..... BLIND_MCID

2. Date of medical care visit (mm/dd/yyyy): MCN2

   Provider name: _____ **[no data entry]**

   Provider address/contact information: _____ **[no data entry]**

   _____

   _____

3. a. **[PC]** Location of Medical Visit *(select one)*: MCNC3

   Private Physician Office .....A → **Go to item 3c**

   The CUTIE Clinic.....B→ **Go to item 3c**

   Specialty clinic at CUTIE center .....C→ **Go to item 3c**

   Other specialty clinic not affiliated with CUTIE center.....D→ **Go to item 3c**

   Hospitalization or ER visit at CUTIE-affiliated Hospital .....E→ **Complete AEF**

   Hospitalization or ER visit at Hospital not affiliated with CUTIE.....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

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
    °C ..... C MCN10B

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? ..... | | / | | / | | | | MCAB14A

    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

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	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	X MCN15E	MCNC17E2		Y	N	X	MCNC17E3
f	Dehydration (<= 4 months old)	Y	N	U	X MCN15F	MCNC17F2		Y	N	X	MCNC17F3
g.	Hypothermia (<= 4 months old)	Y	N	U	X MCN15G	MCNC17G2		Y	N	X	MCNC17G3

18. Date symptoms started: ..... | | / | | / | | | | | MCAB16A

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

INSERT (=) FOR QUESTION 20a-b

20 ~~a. Was study medication temporarily discontinued during this event? Y N →Go to Item 21~~

~~b. How many days was study medication discontinued? .....~~ | |

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

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. ADMINSTRATIVE 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: ..... | | | BLIND_STAFF_ID

PHYSICAL EXAM FORM

Careful Urinary Tract Infection Evaluation

ID NUMBER: | | | | | | | |

FORM CODE: PEF
VERSION: B 09/18/12

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):* 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
   - ˚C C

   PEF4B

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

10. a. Weight: ..... | | | | . | | PEF10A

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): ..... | | / | | / | | | | PEF12

13. Method of data collection *(circle one)*:
Computer C
Paper ..... P
PEF13

14. Examiner's initials: ..... | | | BLIND_EXAM_ID

15. Recorder's initials: ..... | | | BLIND_STAFF_ID

CUTIE
Careful Urinary Tract Infection Evaluation

Participant Screening Log

CUTIE used version B only

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion | | SEQ # | |

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		PSL9	PSL10	PSL11A-B	PSL12
02											
03											
04											
05											
06											
07											
08											
09											
10											

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 Or Uricult done
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

Careful Urinary Tract Infection Evaluation

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion: ____ SEQ #: ____

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		PSL9	PSL10	PSL11A-B	PSL12
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
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C = Asian
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E = Am. Indian/Alaska Native
F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes
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C = Unknown/Refused

7. If not Protocol UTI, why?
A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA Or Uricult done
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

Careful Urinary Tract Infection Evaluation

SiteID:			0	0	0	0	0

FORM CODE: PSL
VERSION: B 06/20/08

Contact Occasion: ____ SEQ #: ____

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		PSL9	PSL10	PSL11A-B	PSL12
22											
23											
24											
25											
26											
27											
28											
29											
30											

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
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F = Other or Mixed (notelog)
G = Unknown/Refused

5. Ethnicity codes
A = Hispanic / Latino
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C = Unknown/Refused

7. If not Protocol UTI, why?
A = Not 1st or 2nd UTI
B = Timing
C = Bagged Spec
D = No UA Or Uricult done
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F = Ins. growth
G = Mult. Org.
H = No fever/Sx
I = Other (notelog)

~~8. VCUG Result~~
~~A = Not Done~~
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~~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
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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)

CUTIE
Careful Urinary Tract Infection Evaluation

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

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 SCFA11
Clean Voided C
Bag collected ..... D

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**~~

~~If no, specify reason _____~~

~~16. Date of rectal swab specimen collection (mm/dd/yyyy): ..... | | / | | / | | | |~~

~~17. Rectal swab specimen shipping date (mm/dd/yyyy): ..... | | / | | / | | | |~~

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

CUTIE used version C only

Careful Urinary Tract Infection Evaluation

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 UR_2C
     - No ..... N
     - 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 UR_3C
     - No ..... N
     - Unevaluated ..... U
   - d. Hydronephrosis: ..... Y N →**Go to Q4** 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): UR_7
   - None, bladder is empty, post void ..... A
   - Small, nearly empty, post void ..... B
   - Moderate, volume less, still distended post void C
   - 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

9. Bladder wall (posterior) measured? ..... Y N →**Go to Q11** UR_9

10. Bladder wall (posterior) measurement (mm): ..... | | . | 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

CUTIE used version B, C, D, and E only

Careful Urinary Tract Infection Evaluation

URINE SPECIMEN RESULTS FORM

ID NUMBER: | | | | | | | |

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): ..... | | / | | / | | | | | USR2

3. Method of urine collection for dipstick *(circle one)*: USR3
   - Catheterization ..... A
   - Suprapubic aspiration ..... B
   - Clean voided C
   - 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)*: USR5A
      - Negative ..... A
      - Trace ..... B
      - Small (+) C
      - Moderate (++) ..... D
      - Large (+++) ..... E

   b. Nitrite *(circle one)*: USR5B
      - Negative ..... N
      - 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

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/mm^3 ..... A
WBC/hpf ..... B

USR7B

C. URINE CULTURE RESULTS

8. Are urine culture results available?

Yes ..... Y

USR8

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: | | | | | | | |

FORM CODE: USR
VERSION: E 02/18/13

Contact Occasion | | |

SEQ # | | |

Participant Name: _____

Line Number | | |

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.
USRORG13A01	USR13B	USR13C1	USR13C2	USRD13D1	USRD13D2	USRD13D3
14. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG14A01	USR14B	USR14C1	USR14C2	USRD14D1	USRD14D2	USRD14D3
15. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG15A01	USR15B	USR15C1	USR15C2	USRD15D1	USRD15D2	USRD15D3
16. a.	b.	c1.	- c2.	d1.	d2.	d3.
USRORG16A01	USR16B	USR16C1	USR16C2	USRD16D1	USRD16D2	USRD16D3

D. DRUG SENSITIVITY RESULTS

17. How many different antimicrobials were tested for sensitivity?

(Describe sensitivity item 18-item 39.) ..... | | USR17

a. Antimicrobial tested (code from list)	b. Organism #1	c. Organism #2	d. Organism #3	e. Organism #4
	Sensitivity of each isolated organism (S=sensitive, I=intermediate, R=resistant, N=not tested):			
18. USR18A	USR18B S I R N	USR18C S I R N	USR18D S I R N	USR18E S I R N
19. USR19A	USR19B S I R N	USR19C S I R N	USR19D S I R N	USR19E S I R N
20. USR20A	USR20 S I R N	USR20C S I R N	USR20D S I R N	USR20E S I R N
21. USR21A	USR21 S I R N	USR21C S I R N	USR21D S I R N	USR21E S I R N
22. USR22A	USR22B S I R N	USR22C S I R N	USR22D S I R N	USR22E S I R N
23. USR23A	USR23B S I R N	USR23C S I R N	USR23D S I R N	USR23E S I R N

ID NUMBER:								FORM CODE: USR VERSION: E 02/18/13	Contact Occasion		SEQ #	

Participant Name: _____ Line Number

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
24.	USR24A	USR24B S I R N	USR24C S I R N	USR24D S I R N	USR24E S I R N
25.	USR25A	USR25B S I R N	USR25C S I R N	USR25D S I R N	USR25E S I R N
26.	USR26A	USR26B S I R N	USR26C S I R N	USR26D S I R N	USR26E S I R N
27.	USR27A	USR27B S I R N	USR27C S I R N	USR27D S I R N	USR27E S I R N
28.	USR28A	USR28B S I R N	USR28C S I R N	USR28D S I R N	USR28E S I R N
29.	USR29A	USR29B S I R N	USR29C S I R N	USR29D S I R N	USR29E S I R N
30.	USR30A	USR30B S I R N	USR30C S I R N	USR30D S I R N	USR30E S I R N
31.	USR31A	USR31B S I R N	USR31C S I R N	USR31D S I R N	USR31E S I R N
32.	USR32A	USR32B S I R N	USR32C S I R N	USR32D S I R N	USR32E S I R N
33.	USR33A	USR33B S I R N	USR33C S I R N	USR33D S I R N	USR33E S I R N
34.	USR34A	USR34B S I R N	USR34C S I R N	USR34D S I R N	USR34E S I R N
35.	USR35A	USR35B S I R N	USR35C S I R N	USR35D S I R N	USR35E S I R N
36.	USR36A	USR36B S I R N	USR36C S I R N	USR36D S I R N	USR36E S I R N
37.	USR37A	USR37B S I R N	USR37C S I R N	USR37D S I R N	USR37E S I R N
38.	USR38A	USR38B S I R N	USR38C S I R N	USR38D S I R N	USR38E S I R N
39.	USR39A	USR39B S I R N	USR39C S I R N	USR39D S I R N	USR39E 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

ID NUMBER: | | | | | | | |

FORM CODE: USR
VERSION: E 02/18/13

Contact Occasion | | SEQ # | |

Participant Name: _____

Line Number | |

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
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 | | | . | 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

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/dL

If other, please specify: _____

d. Reference range

d1. ☐☐☐.☐ - d2. ☐☐☐.☐

USRC49D1 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

Variable removed, all are in mg/dL

If other, please specify: _____

d. Reference range

d1. ☐☐☐.☐ - d2. ☐☐☐.☐

USRC51D1 USRC51D2

52. Did the laboratory provide results for the microalbumin/creatinine ratio? .....Y N → **Go to Item 54** USRC52

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
If other, please specify: _____

Variable removed, all are in mg/g

d. Reference range

d1. | | | | . | | - d2. | | | | . | |

USRC53D1 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: ..... | | | BLIND_STAFF_ID

CODES for USR

Bacteria	Code
Aerobic gram negative Enterobacteriaceae	10
Escherichia	11
Klebsiella	12
Enterobacter	13
Citrobacter	14
Proteus	15
Providencia	16
Morganella	17
Serratia	18
Salmonella	19
Pseudomonas	20
Staphylococcus aureus	21
Staphylococcus—coagulase negative	22
Staphylococcus epidermidis	23
Enterococcus	81
Gardnerella	82
Lactobacillus	26
Candida	27
Streptococcus	28
Corynebacterium	29
Mixed	80
Other	99

Antibiotic/Antimicrobial Code List

Antibiotic/Antimicrobial	Code
Amikacin	010
Amoxicillin	100
Amoxicillin-clavulanate (Augmentin)	110
Ampicillin	120
Ampicillin/Sulbactam	011
Aztreonam	121
Cefadroxil	130
Cefazolin (Cefazoline **or** Cephazolin)	141
Cefepime	131
Cefixime	170
Cefotaxime	140
Cefotetan	171
Cefoxitin	142
Cefpodoxine	284
Ceftazidime	150
Ceftriaxone	160
Cefuroxime	180
Cefuroxime-Axetil	172
Centamicin	181
Cephalexin	190
Cephalothin (Cefalothin)	191
Ciprofloxacin (Cipro)	200
Clindamycin	201
Ertapenem	202
Erythromycin	203
ESBL/Beta Lactamase	204
Gatifloxacin	283
Gemifloxacin	205
Gentamicin	210

Antibiotic/Antimicrobial	Code
Imipenem	212
Levofloxacin	213
Loracarbef (Lorabid)	220
Linezolid	211
Meropenem	221
Nalidixic acid	230
Nitrofurantoin	240
Norfloxacin tz (Norflox-TZ)	244
Oxacillin	245
Penicillin	242
Piperacillin	246
Piperacillin/Tazobactam	243
Quinupristin/Dalfopristin (Synercid)	282
Rifampin	247
Sulfisoxazole (Sulphafurazole)	250
Tetracycline	251
Ticarcillin (Ticar)	281
Ticarcillin/ Clavulanate K (Timentin)	253
Tigecycline	254
TMP-SMZ (Trimethoprim/Sulfamethoxazole **or** Co-trimoxazole)	270
Tobramycin	255
Trimethoprim	260
Tripenem	271
Vancomycin	280
Other	500