RIVUR
Randomized Intervention for Children with Vesicoureteral Reflux

ADVERSE EVENTS FORM

AEF Version B, 10/12/09

QxQ

I. GENERAL INSTRUCTIONS

The Adverse Events Form should be completed at any time that a suspected study medication side effect, adverse event, or serious adverse event/experience is reported or discovered. This form is completed based on both an interview with the participant's parent or guardian, and on Investigator assessments. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential and will in no way affect treatment or care of the participating child.

NOTE: If a question is preceded by **[PC]**, coordinator should select the best answer based on clinical assessment. Do not ask the parent/guardian these questions.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. SIDE EFFECTS AND SERIOUS ADVERSE EVENTS

1. Record the onset date of the side effect or serious adverse event as reported by the parent/guardian or as determined by the clinical investigator, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2a. Fill in the diagnosis or symptom, as determined by the clinic investigator based on information received by the parent/guardian, medical records, or examination.

A **study medication side effect** is defined as any:

- Known study medication side effect, as documented in Appendix A of the protocol, the drug packaging insert for Sulfamethoxazole and Trimethoprim Oral Suspension.
- Considered potential study medication side effects, by the parent/guardian or the clinician.

A **serious adverse experience or adverse event (SAE)** is any adverse event that results in any of the following outcomes:

- Death
- A life-threatening experience
- Inpatient hospitalization or prolongation of existing hospitalization
- An emergency room (ER) visit
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect

2b. Record the Costart Preferred Term which provides coding of RIVUR adverse events. This is done in one of two ways:

Manually – Codes can be selected by looking thought the coding list of diagnosis or symptoms that is included in the Manuals of Procedures in Appendix 4. The left hand column of the listing provides the Preferred Terms.

Electronically – Using a table look-up on this field at the time of data entry into the DMS. Enter the diagnosis or symptom as it was entered for question 2a. When you push the enter key, a look-up table will appear on the screen and provide a list of diagnoses/symptoms with similar spelling. If this listing is sufficient, select the one that provides the code for this event, by moving the cursor over the desired row and left-clicking to make the selection. NOTE: You can click on either column in the look-up table, because the same code is

If you need to find codes outside of those listed in the DMS look-up table, go to the website http://hedwig.mgh.harvard.edu/biostatistics/files/costart.html

For example, if the adverse event is a broken arm, one can search for 'fracture' to have the following choices pop up:

Fracture:
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BONE FRACTURE SPONTANEOUS
FRACTURE BONE
FRACTURE DUE TO OSTEOPOROSIS
FRACTURE PATHOLOGICAL
OSTEOPOROSIS WITH FRACTURE
```

Questions 3-9 are questions to ask the parent/guardian. Questions 3-6 ask about the effect the event/experience had on the child. Responses should be made based on their child's experience or their assessment of the event. These may be difficult for the parent to answer and/or not applicable. Select only one response for each item.

3. Select 'R' if the child experienced the adverse event RARELY since the last study contact.
Select 'S' if the child experienced the adverse event SOMETIMES since the last study contact.
Select 'O' if the child experienced the adverse event OFTEN since the last study contact.
Select 'N' if this question is not applicable to the event in question.
(For example, if the event is a broken arm, the question does not make sense.)

4. Select 'N' if the adverse event NEVER affected the child's activities.
Select 'L' if the adverse event affected the child's activities a LITTLE.
Select 'A' if the adverse event affected the child's activities A LOT.

5. Select 'M' if the adverse event was MILD when the child experienced it.
Select 'D' if the adverse event was MODERATE when the child experienced it.
Select 'S' if the adverse event was SEVERE when the child experienced it.
Select 'N' if this question is not applicable to the event in question.
(For example if the event is a broken arm, the question does not make sense.)

6. Select 'N' if the adverse event NEVER bothered the child.
   Select 'L' if the adverse event bothered the child A LITTLE.
   Select 'A' if the adverse event bothered the child A LOT.

7. Select 'N' if the parent/guardian does not think the study medication caused the adverse event
   Select 'Y' if the parent/guardian thinks the adverse event was caused by the study medication.
   Select 'D' if the parent/guardian does not know whether or not the study medication caused the adverse event
   NOTE: If 'N' or 'D' then go to item 9.

8. Select 'N' if the parent thinks the adverse event has NOT been a problem for the child.
   Select 'M' if the parent thinks the adverse event has been a MILD problem overall for the child.
   Select 'D' if the parent thinks the adverse event has been a MODERATE problem over all for the child.
   Select 'S' if the parent thinks the adverse event has been a SEVERE problem over all for the child.
   NOTE: There are no specific definitions of mild, moderate, severe for this question. The answer is based on the parents own definition and perceptions.

9a. Select 'Y' if the parent/guardian sought medical care for this adverse event.
   Select 'N' if the parent/guardian did not seek medical care for this event.
   NOTE: If 'Y' then complete an MCN and MCA forms.
   NOTE: If 'N' then go to item 11.

b. Indicate where the medical care took place. Select only one of the following options:
   Select 'E' if EMERGENCY ROOM.
   Select 'H' if HOSPITAL.
   Select 'B' if BOTH EMERGENCY ROOM AND HOSPITAL.
   Select 'O' if OTHER
   NOTE: IF 'O' then complete notelog.

10. Record the 7-digit MCID#, found on the MCN and MCA forms corresponding to this event.

11. Indicate the Investigator's assessment as to the severity of the event. Select only one of the following options:
   Select 'M' if MILD.
   Select 'D' if MODERATE.
   Select 'S' if SEVERE .
   Select 'L' if LIFE-THREATENING.
   Select 'E' if DEATH.

   The table below from the NIH Division of Infections Diseases ranks the severity of side effects using standardized criteria. It provides some examples of grading the severity of event/experiences that can be used for this ranking. These are examples from the DMID toxicity tables.

	Grade 1	Grade 2	Grade 3	Grade 4
Nausea	Mild	Moderate- Decreased oral intake	Severe – Little oral intake	Unable to ingest food or fluid for more than 24 hours
Vomiting	1 episode/day	2-3 episodes/day	4-6 episodes/day	>6 episodes/day or intractable vomiting
Abdominal pain	Mild	Moderate – No treatment needed	Moderate – Treatment needed	Severe – Hospitalization for treatment
Diarrhea	Slight change in consistency and/or frequency of stools	Liquid stools	Liquid stools greater than 4x the amount or number for this child	Liquid stools greater than 8x the amount or number for this child
Allergy	Pruritis without rash	Pruritic rash	Mild urticaria	Severe urticaria, anaphylaxis, angioedema
Cutaneous	Localized rash	Diffuse maculopapular rash	Generalized urticaria	Stevens-Johnson syndrome or erythema multiforme
Clinical symptoms not in this table	No therapy; monitor	May require minimal intervention and monitoring	Requires medical car and possible hospitalization	Requires active medical intervention, hospitalization, or hospice care

12a-i. For each of items 12a-12i, indicated whether the action was taken, as specified below. You must select an answer for each item, unless you select 'Y' for item 12a indicating no action was taken.

Select 'Y' if the action was taken.

Select 'N' if the action was not taken.

NOTE: If item 12a = 'Y' then go to item 13.

NOTE: If item 12i = 'Y' then record the 'other action' in a notelog.

13. Respond based on the Investigator's assessment of the event. For the purposes of this question, a **serious adverse experience or adverse event (SAE)** is any adverse event that results in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, an ER visit, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Select 'Y' if the adverse event fit the definition of an SAE.

Select 'N' if the adverse event does not fit the definition of an SAE.

NOTE: If 'N' then go to item 22.

B. SERIOUS ADVERSE EVENT

14. For the purposes of this question, an **unexpected adverse drug experience** is defined as "Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. Unexpected adverse drug experiences refer to an adverse drug reaction that has not been previously observed.

For non-drug related adverse events, unexpected relates to any adverse event not previously documented in the study brochure, protocol, or MOP as a possible experience for the study population.

Select 'Y' if the adverse event was unexpected.

Select 'N' if the adverse event is not unexpected and/or is a known side effect of the study medication.

15. This is the Investigators description of the serious adverse event. Select 'Y' and use the space provided to describe more fully the serious adverse event.

16. For each of items 16a-16g, indicated whether the category applies, as specified below. You must select an answer for each item.

    Select 'Y' if the category applies.

    Select 'N' if the category does not apply.

    NOTE: If participant experienced ER visit, answer item 16d = 'Y'.

    If item 16g = 'Y' then specify the other category in a notelog.

17. Record the Investigator's assessment of the relationship of the serious adverse event to the study medication. Select only one of the following options:

    Select 'A' if definitely unrelated.

    Select 'B' if unlikely to be related.

    Select 'C' if possibly related.

    Select 'D' if probably related.

    Select 'E' if definitely related.

    NOTE: if 'C' or 'D', or 'E', and item 14 = 'Y', than an FDA 3500 form must be completed to fulfill IND reporting. Refer to Chapter 9.5 for further information on reporting and the timetable for reporting experiences to the FDA.

18. Record the Investigator's assessment of the relationship of the serious adverse event to the study research. Select only one of the following options:

    Select 'A' if definitely unrelated.

    Select 'B' if unlikely to be related.

    Select 'C' if possibly related.

    Select 'D' if probably related.

    Select 'E' if definitely related.

19. Record the Investigator's assessment of the outcome of the event at the time of reporting. Select only one of the following options:

    Select 'A' if unresolved.

    Select 'B' if recovered with minor sequelae.

    Select 'C' if recovered with major sequelae.

    Select 'D' if condition still present at time of reporting.

    Select 'E' if condition continues to worsen at time of reporting.

    Select 'F' if patient died as outcome of event.

    NOTE: If 'D' or 'E' then go to item 22.

20. Record the date of event resolution or death using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

NOTE: If the event/experience is ongoing, you will not be able to answer this question at the time of reporting. If event is ongoing then leave this item blank. Follow up on the event to eventually obtain an event resolution date. Once obtained, the event resolution date should be entered into the original reporting form or DMS screen.

21. Record the name of the Investigator who reviewed and authorized this serious adverse event report. Record the last name first, followed by the first name and middle initial (if applicable). Begin filling letter in the first box provided. For example, if this event was reviewed by Dr. Ellen H. Smith, then the following would be entered:

S	M	I	T	H		E	L	L	E	N		H												

C. ADMINISTRATIVE INFORMATION

22. Record the date of the adverse event interview using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

23. Select ‘C’ if data from this form was originally captured through the DMS (on a computer). Select ‘P’ if data from this form was originally captured on paper.

24. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a ‘-‘ in the box that is to be left blank.

A	B	C

or

A	-	C

BASELINE DEMOGRAPHIC FORM

BDF Version A, 01/26/07

QxQ

I. GENERAL INSTRUCTIONS

The Baseline Demographic form should be completed at the Baseline clinic visit. This form is completed based on an interview with the participant's parent or guardian. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential and will in no way affect treatment or care of the participating child.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. Ethnicity / Race

1. Question 1 provides detailed information about the child's ethnicity. Response is based on participant's parent/guardian self report. Select only one response.

   Select 'Y' if the child is of Hispanic ethnicity (origin).
   Select 'N' if child is not of Hispanic ethnicity (origin).
   Select 'U' if the child's ethnicity (origin) is unknown.
   Select 'R' if the parent or child refuses to provide this information.

2. Question 2 provides detailed information about the child's race. Response is based on participant's parent/guardian self report.

   For items 2a-2e, select only one of the following:

   Select 'Y' if the term describes the child's race.
   Select 'N' if the term does not describe the child's race.
   Select 'U' if is unknown whether the term applies to the child's race.
   Select 'R' if the parent or child refuses to provide this information.

   For Item 2f, select only one of the following:

   Select 'Y' if there is another race category that describes the child's race. Please specify.
   Select 'N' if there are no other terms that describe the child's race.
   Select 'U' if the child's racial background is unknown.
   Select 'R' if the parent or child refuses to provide this information.

B. HOME / EDUCATION / OCCUPATION

3. Record the number of days per week that the child lives in the primary household. The primary household is the home in which the child lives for 4 or more days of the week. Acceptable values include whole numbers, range 4-7. If the definition of primary household is not obvious or clear, then the primary household is based on the respondent's choice.

4. Record the number of adults (aged 18 years or older) currently living in the primary home. Acceptable values include whole numbers greater than 0.

5. Record the number of children (aged less than 18 years) currently living in the primary home. Acceptable values include whole numbers grater than 0.

6a. Indicate the highest level of education completed by the primary care-giver. The primary care-giver is whoever the respondent identifies as the primary care-giver. Select only one.

Select 'A' if the primary care giver did not complete high school.
Select 'B' if the primary care giver completed some high school.
Select 'C' if the primary care giver has a high school diploma or GED.
Select 'D' if the primary care giver completed some college or has a 2-year degree/certificate.
Select 'E' if the primary care giver has a 4-year college degree.
Select 'F' if the primary care giver completed work toward a post graduate college degree.
Select 'G' if parent refuses to provide this information.
Select 'H' if the information is unknown.

6b. Indicate the primary care-giver's sex.

Select 'M' if the primary care-giver is male.
Select 'F' if the primary care-giver is female

7a. Indicate the highest level of education completed by the secondary care-giver. The secondary care-giver is whoever the respondent chooses who is not the primary care-giver. Response 'I' is used if there is no secondary care-giver. Selecting 'I' will trigger the DMS to automatically skip any remaining questions about the secondary care-giver. Select only one.

Select 'A' if the secondary care giver did not complete high school.
Select 'B' if the secondary care giver completed some high school.
Select 'C' if the secondary care giver has a high school diploma or GED.
Select 'D' if the secondary care giver completed some college or has a 2-year degree/certificate.
Select 'E' if the secondary care giver has a 4-year college degree.
Select 'F' if the secondary care giver completed work toward a post graduate college degree.
Select 'G' if parent refuses to provide this information.
Select 'H' if the information is unknown.
Select 'I' if there is no secondary care-giver.

NOTE: If I, then skip to question 8.

6b. Indicate the secondary care-giver's sex.

Select 'M' if the secondary care-giver is male.
Select 'F' if the secondary care-giver is female.

C. RESOURCE INFORMATION

8. Record the current total annual income in the child's primary household. The primary household is the home in which the child lives 4 or more days out of the week. Show the respondent the BDF Response Card #1, which contains a printed response set. Ask the respondant to select only one of the categories, A-I.

   Select 'A' if parent selects category 'A' from response card (less than $13,500).
   Select 'B' if parent selects category 'B' from response card ($13,500 – $23,499).
   Select 'C' if parent selects category 'C' from response card ($23,500 – $33,499).
   Select 'D' if parent selects category 'D' from response card ($33,500 – $57,999).
   Select 'E' if parent selects category 'E' from response card ($58,000 – $99,999).
   Select 'F' if parent selects category 'F' from response card ($100,000 – $149,999).
   Select 'G' if parent selects category 'G' from response card ($150,000 or greater.
   Select 'H' if total annual income is unknown.
   Select 'I' if parent refuses to provide this information.

9. Record the type of medical insurance the child currently has. Select only one.

   Select 'A' if the child is covered by a commercial insurance provider.
   Select 'B' if the child is covered by TRICARE (military healthcare program, formerly CHAMPUS)
   Select 'C' if the child is covered by Medicaid or other state-promoted program.
   Select 'D' if the child does not have any insurance coverage.
   Select 'E' if the child's medical insurance is none of the above and covered by other insurance. If other, please specify other insurance.

10. For this question, 'public assistance' includes WIC (the USDA's Women, Infants, and Children program), food stamps and SSI (Supplemental Security Income). Select only one.

    Select 'Y' if the child's primary household is currently receiving public assistance.
    Select 'N' if the child's primary household is not currently receiving public assistance.
    Select 'U' if it is unknown whether or not the child's primary household receives public assistance.
    Select 'R' if the parent refuses to provide this information.

D. ADMINISTRATIVE INFORMATION

11. Record date of demographic interview using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Select 'C' if data from this form was originally captured through the DMS (on the computer). Select 'P' if data from this form was originally captured on paper.

13. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

    or

A	-	C

BASELINE MEDICAL HISTORY FORM

BMH Version A, 01/25/07

QxQ

I. GENERAL INSTRUCTIONS

The Baseline Medical History form is completed at the Baseline clinic visit, based on an interview with the participant's parent or guardian. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential and will in no way affect treatment or care of the participating child.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. NATAL HISTORY

1. Select 'Y' if the child was ever breastfed.
   Select 'N' if the child was never breastfed.

   NOTE: If 'N' then go to item 4.

   If unknown then enter '=' for permanently missing.

2. Record the age in months at which formula or other foods were introduced to the child's diet. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).If currently breastfeeding, enter '99'. If unknown then enter '=='.

3. Record the age in months at which the child completely stopped breastfeeding. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).If currently breastfeeding, enter '99'. If unknown then enter '=='.

B. MEDICATION HISTORY

4. Record the number of times in the past 6 months the child has been prescribed antibiotics for illnesses. Acceptable answers include whole numbers 00-99. Insert whole numbers only, using leading zeros when necessary.

   If the response is 'unknown' try and probe further for responses. Ask if the child has ever been ill, been to see a pediatrician, had a fever, etc… Ask if medical records available at the time of interview.

5. Select 'Y' if the child has ever been prescribed a prophylactic antibiotic that was taken longer than 3 months.

   Select 'N' if the child has never taken a prescribed prophylactic antibiotic form more than 3 months.

   If unknown, and probing does not illicit a response, code '='.

6. Select 'Y' if the child is currently taking any prescription or over-the-counter medications, including antimicrobials.

   Select 'N' if the child is not currently taking any prescription or over-the-counter medications.

   NOTE: If 'Y' then complete the Concomitant Medication Form (CMF).

   If unknown, code '=', and include a note log explaining why the parent/guardian does not know the answer to this question.

C. VOIDING HISTORY

7. Select 'Y' if the child has been toilet-trained for urine during the day. Child is considered toilet-trained for urine during the day only if he/she does not wear diapers or pull-ups during the day.

   Select 'N' if the child is NOT toilet-trained for urine during the day (i.e. he/she still wears diapers or pull-ups during the day).

   NOTE: If 'N' then go to item 10.

   Unknown is not an acceptable response. Coordinator should probe and work with parent to determine a response to this question.

8. Record the age (in months) at which the child began urinating in the toilet or potty by him/herself. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).

D. BOWEL HISTORY

9. Select 'Y' if the child has been toilet-trained for bowel movements.

   Select 'N' if the child has not been toilet-trained for bowel movements.

   NOTE: If 'N' then go to item 13.

   Unknown is not an acceptable response, coordinator should probe and work with parent to determine a response to this question.

10. Record the age (in months) at which child began defecating in the toilet or potty by him/herself. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).

11. Response can be based on either a medical diagnosis or a parent/guardian assessment of child having any history of soiling his/her self.

    Select 'Y' if the child has had a history of soiling his/her underwear with stool since toilet/potty training.

    Select 'N' if the child has not had a history of soiling his/her underwear since toilet/potty training.

12. Record the average number of bowel movements the child has had per week during the past 2 months. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary.

13. For this question, a "history of constipation" means more than one occurrence of constipation. Response can be based on either a medical diagnosis or a parent/guardian diagnosis/assessment of child having any history of constipation.

    Select 'Y' if the parent reports the child has had a history of constipation.
    Circle 'N' if the child does not have a history of constipation.

14. For this question, treatment includes any clinical treatment or treatment initiated in the home, including dietary changes, increases in fluid intake, or stool softener.

    Select 'Y' if the child has ever been treated for constipation.
    Select 'N' if the child has not ever been treated for constipation.

E. FAMILIAL MEDICAL HISTORY

15. The purpose of this question is to establish any family history of specific medical conditions. For each of items 15a-15f, indicate whether the condition has been experienced by the child's Full or Half siblings, Parents, or Grandparents (as described below):

    Select 'Y' if any members of the specified family category have experienced this condition.
    Select 'N' if no members of the specified family category have experienced this condition.
    Select 'U' if it is unknown whether members of the specified family category have experienced this condition.
    Select 'X' if not applicable (for example, child does not have siblings)

    NOTE: Be sure to select a response in each family category for each medical condition.

F. ADMINISTRATIVE INFORMATION

16. Record date of demographic interview using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

17. Select 'C' if data from this form was originally captured through the DMS (using a computer).
    Select 'P' if data from this form was originally captured on paper.

18. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C	or	A	-	C

BLOOD SPECIMEN RESULTS FORM

BSR Version A, 06/28/07

QxQ

I. GENERAL INSTRUCTIONS

The Blood Specimen Results Form is completed when a participant's blood results are received from the local laboratory. Laboratory results are transcribed onto the BSR form, or entered directly into the DMS BSR entry screen.

Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns.

If any data is missing and unavailable, fill all spaces provided for that response with '='.

II. SPECIFIC INSTRUCTIONS

A. BLOOD COUNT (CBC)

1. Select 'Y' if the CBC test results are available.
   Select 'I' if the blood sample was inadequate.
   Select 'O' if the test results are unavailable for another reason. If 'O' then specify reason.
   NOTE: If 'N' or 'O' then go to item 7.

2. Record the date the blood sample for the CBC was drawn using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

3. Record the white blood cell (WBC) count (countx10^9/L). Insert leading zeros as necessary.

4. Record the Hemoglobin (Hgb) results (%). Insert leading zeros as necessary.

5. Record the Hematocrit (Hct) results (%). Insert leading zeros as necessary.

6. Record the Platelets results (countx10^9/L). Insert leading zeros as necessary.

B. METABOLIC / ELECTROLYTE RESULTS

7. Select 'Y' if the metabolic test results are available.
   Select 'C' if electrolytes not required at this contact.
   Select 'I' if the blood sample was inadequate.
   Select 'O' if the test results are unavailable for another reason. If 'O' then specify reason.
   NOTE: If 'C' then go to item 15.
   NOTE: If 'I' then complete item 8, then go to item 15.
   NOTE: If 'O' then go to item 13.

8. Record the date the blood sample for the metabolic panel was drawn using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

9. Record the Urea Nitrogen (BUN) results (mg/dL). Insert leading zeros as necessary.

10. Record the Serum Creatinine results (mg/dL). Insert leading zeros as necessary.

11. Record the Sodium (mmol/L) results. Insert leading zeros as necessary.

12. Record the Potassium (mmol/L) results (mg/dL). Insert leading zeros as necessary.

13. Record the Chloride results (mmol/L). Insert leading zeros as necessary.

14. Record the Carbon Dioxide results (mmol/L). Insert leading zeros as necessary.

C. ADMINISTRATIVE INFORMATION

15. Record the date the form was completed using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

16. Select 'C' if data from this form was originally captured through the DMS (on a computer). Select 'P' if data from this form was originally captured on paper.

17. Record the initials of the person who completed the form. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

CONCOMITANT MEDICATION FORM

CMF Version B, 07/18/08

QxQ

I. GENERAL INSTRUCTIONS

The Concomitant Medication Form (CMF) is completed based on information from an interview with the participant's parent or guardian during each clinic visit and phone follow-up contact, and/or recording medication names from medication bottles brought to a clinic visit, or reviewing information on the Participant Handbook/Diary. Its purpose is to capture all medications being used by the participant in addition to RIVUR treatment. At baseline, the CMF should include the prophylactic antimicrobial the child had been using prior to randomization. The CMF will also be used to record vaccinations and anesthetic drugs used in medical procedures.

This form is required at all protocol-scheduled contacts, and is queued based on responses from the forms, Baseline Medical History (BMH), Protocol Scheduled Follow-up Contact Form (FUP), Urine Specimen Results Form (USR), Medical Care Notification Form (MCN), Medical Care Abstraction Form (MCA), Adverse Event Form (AEF), and the parent diary. The form may be used between contact occasions to begin documenting changes regarding medication use. However, data entry of this form should always correspond to a baseline or follow-up contact, with a seq# of '00'. **For example**, if a parent calls to report new medication two weeks after contact 02, enter the data in the DMS or on paper with the next contact occasion. In the previous example, the data would be entered onto the CMF for contact 03 (SEQ# 00), since that is the next scheduled study contact occasion.

Reports on the DMS for follow-up history will provide information on concomitant medication reporting at the previous contact. Use the Concomitant Medication Report to generate a list of all medications from the previous contact that have information on the start date(s) of medications being used by the participant, but no information on stop date. Review the Concomitant Medication Report with the family to note if there are any changes since the previous contact, including continuing medications. Ask the family at the scheduled contacts about all medications that the participant started since the last contact. All medications that had been currently in use but had been stopped between contacts and new medications or vaccinations will be entered onto the CMF, one medication or vaccination per line..

Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns.

II. SPECIFIC INSTRUCTIONS

A. ADMINISTRATIVE INFORMATION

1. Record the date the form was completed using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Select 'C' if data from this form was originally captured through the DMS (on the computer). Select 'P' if data from this form was originally captured on paper.

3. a. Record the initials of the person who completed the form. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C	or	A	-	C

b. Select 'Y' if the CMF being entered corresponds to a missed contact. Selecting 'Y' will automatically exit the user from the form.
Select 'N' if the CMF being entered is from a normal protocol-scheduled contact.

B. CONCOMITANT MEDICATIONS

4. Select 'N' if the participant is not on any concomitant medications at baseline, or, if it is a follow-up contact and there have not been any changes to medication use since the last contact
   Select 'Y' if the participant is currently on concomitant medications at the baseline visit, or if changes to medication use at follow-up have occurred since the last contact and record medication changes in the subsequent questions.

   NOTE: If 'N' <u>DO NOT</u> complete the rest of the form.

The following instructions are relevant for lines 5 through the end of the CMF form. Each line of the form will contain information for one medication only. Continue to fill each subsequent line until all medications/vaccinations have been recorded. The paper version of the form has 28 lines. Each line has 3 fields for information. The DMS version has 30 lines. Each line in the DMS has 4 fields of information to be completed.

INSTRUCTIONS FOR COMPLETING PAPER FORM

5a. Record the name(s) of the medication or vaccination that the participant is currently using or has used since the last contact. Dosing information will not be collected.

5d. Record the date that the medication or vaccination was started using the mm/dd/yyyy format. Enter leading zeros where necessary.

5e. Record the date that the medication was stopped using the mm/dd/yyyy format. Enter leading zeros as necessary. **If the participant is still taking the medication, enter a special date code of 00/00/0000.** If vaccination information is being completed, enter the date of the vaccination into the start date and stop date. If a medication that carried over from the previous contact was stopped during the interim, record the stop date using mm/dd/yyyy format. Enter as much information of the stop date as you are able. If the exact day of the stop date is unknown, enter '==' for the 'dd' in the date.

5f. Record the reason that the medication was being taken by referring to the table at the end of these QxQ's (Table 1.)

6-28. Repeat instructions for 5a-5f until all medications or vaccinations have been recorded.

INSTRUCTIONS FOR DMS ENTRY

5a. Record the name(s) of the medication or vaccination that the participant is currently using or has used since the last contact. List all unstopped medications from the Concomitant Medication Report. Dosing information will not be collected.

5b. Record the name of the medication or vaccination exactly the way it was entered on line 5a. When you push the enter key, there will be a look-up table on the screen that lists all medications associated with the medication name that was entered. Select one of the medications from the list by moving the cursor over the desired row. Left click to make the selection.

Note: the look-up table has a code associated with each medication. The code will be used for analysis purposes. For example, the code returned for Tylenol is the same as the code returned for acetaminophen. Dosing information will not be collected.

5d. Record the date that the medication or vaccination was started using the mm/dd/yyyy format. Enter leading zeros where necessary. When completing information on medications carried over from the previous contact, enter the start date found on the Concomitant Medication Report corresponding to the medication being entered.

5e. Record the date that the medication was stopped using the mm/dd/yyyy format. Enter leading zeros as necessary. **If the medication entered is continuing, enter a special date code of 00/00/0000.** If vaccination information is being completed, enter the date of the vaccination into the start date and stop date. If a medication that carried over from the previous contact was stopped during the interim, record the stop date using mm/dd/yyyy format. Enter as much information of the stop date as you are able. If the exact day of the stop date is unknown, enter '==' for the 'dd' in the date.

5f. Record the reason that the medication was being taken by entering the code that corresponds to the reason from Table 1 found at the end of these QxQ's. Entering F1 while the 'f' field is highlighted will pop the list of codes for the reasons why a concomitant medication is used.

6-30. Repeat instructions for 5a-5f until all medications have been recorded.

Table 1. List of Codes and Reasons for Using Concomitant Medications

DMS Code	Reason for Using a Concomitant Medication
11	acute otitis media
12	asthma
13	candida diaper dermatitis
14	conjunctivitis
15	constipation
16	croup
17	diarrhea
18	eczema
19	fever
20	fracture
21	gastroenteritis
22	gastroesophageal reflux disease
23	otitis externa
24	pneumonia
25	sinusitis
26	streptococcal pharyngitis
27	teething
28	thrush
29	upper respiratory infection
30	urinary tract infection
31	urticaria
32	vesicoureteral reflux
33	vomiting
34	wheezing
99	other (notelog)

CENTRAL LAB SPECIMEN SHIPPING LOG

CSL Version B, 04/19/10

QxQ

I. GENERAL INSTRUCTIONS

The Central Lab Specimen Shipping Log is completed by the study coordinator, and provides an inventory of specimen's within a shipment to the lab. This form is not data entered into the DMS. **A copy is retained at the site and a copy is included with the shipment.**

Recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

It is recommended that you begin completing this log as you collect specimens, this way the specimen collection date is easily captured at the time of collection. If the log is completed prior to actual shipping, you must verify that all specimens listed on the log are included in the shipment at the time of shipping.

II. SPECIFIC INSTRUCTIONS

A. HEADER

Site Number – This is the site's ID number, which is made up of their 2 character site code followed by five zeros.

Shipping Date – Record the specimen shipping date using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

Shippers Contact Information (Name, Email Address, and Telephone) - Record the contact information of the Coordinator making the shipment. The information will be useful to the lab personnel who receive the specimen shipment.

Shipment Tracking Number – Record the tracking number assigned to the shipment.

Shipment Number – Enter 01 if one shipment of 10 samples or less is being sent. If multiple shipments are being sent together, increment the shipment number by 01. For example, if 30 samples will be sent on one day, complete 3 shipping logs. The first log's shipment number will be 01, the second will be 02, and the third will be 03.

B. BODY OF FORM

In items 1-10, provide the following information each specimen being shipped.

Participant ID – Place Participant ID label here, or record ID number

Specimen Collection Date – Record the specimen collection date using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

This date is needed by the lab for QC purposes in their analysis and MUST be provided for each specimen. If you have not been recording this information onto the log as you collect the specimens, then you will find the date on the appropriate Specimen Collection Form (SCF).

Serum Appearance after Spin – Circle the number that best shows the appearance of the serum sample after centrifuging using the following codes: 0=No hemolysis, 1=Pink, 2=Red/light red, 3=Dark red.

DRUG DISCONTINUATION FORM

DDF Version A, 04/19/07

QxQ

I. GENERAL INSTRUCTIONS

The Drug Discontinuation Form is designed to document all temporary or permanent discontinuation of study drug made by a **RIVUR Investigator**, and should be completed each time this occurs. This form is linked to an associated Adverse Events Form (AEF) or Medical Care Notification Form (MCN) by the assigned MCID number.

Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns.

II. SPECIFIC INSTRUCTIONS

A. STUDY MEDICATION DISCONTINUATION

1. Record the date of discontinuation of study medication, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Select ‘T’ if discontinuation is temporary and the child will restart the study medication at a later date.
   Select ‘D’ if discontinuation is permanent and the child will not restart study medication.

3. Record the assigned MCID number associated with the event that resulted in medication discontinuation.

4.a. Indicate the reason for discontinuation of study medication.
   Select ‘S’ if study medication was discontinued due to side effects.
   Select ‘F’ if study medication was discontinued due to treatment failure.
   Select ‘O’ if study medication was discontinued for any other reason.

b. If item 4a=O, then specify other reason.

5. Record the last name of the investigator who reviewed and authorized discontinuation of study medication. Use as many boxes as necessary, beginning with the left-most box. Leave extra boxes blank. Punctuation is not required.

B. ADMINISTRATIVE INFORMATION

6. Record date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

7. Select ‘C’ if data from this form was originally captured electronically through DMS.
   Select ‘P’ if data from this form was originally captured on paper.

8. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a ‘-‘ in the box that is to be left blank. For example:

A	B	C	or	A	-	C

DMSA RESULTS FORM

DMF Version B, 5/4/07

QxQ

I. GENERAL INSTRUCTIONS

The DMSA Scan Data Form should be completed by the reference radiologist each time a DMSA scan is received. On paper forms, affix the participant ID label at the top of the form where indicated. When recording numerical values, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. For example, the value 365 would be entered as:

0	0	3	6	5

Recorder should be familiar with the RIVUR Form Completion and Data Entry Guidelines, found in Chapters 13 of the Manual of Procedures. Complete only the appropriate questions. Be sure to follow the correct skip patterns.

II. SPECIFIC INSTRUCTIONS

A. LOCAL REPORT DATA

1. Record the date the DMSA scan, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Record the dose of Tc-99m DMSA administered during the DMSA (millicuries), inserting leading zeros where necessary. Round to the nearest tenth.

3. For each of items 3a and 3b, record the differential renal function (%). Insert leading zeros where necessary. If data is not available for an item, enter ==.

B. Image Reading Results

4. In this item, indicate the degree of pyelonephritis in the each kidney. For each kidney…

   Select ‘A’ if no segments affected
   Select ‘B’ if mild (1-2 segments affected),
   Select ‘C’ if moderate (3-4 segments affected)
   Select ‘D’ if severe (>4 segments affected)

   Note: If ‘D’ for 4a then skip item 5a.
   If ‘D’ for 4b then skip item 5b.

5. In each of items 5a and 5b, there are 12 boxed representing the 12 segments of each kidney. For each item, indicate all segments affected by pyelonephritis by checking the corresponding boxes. If no segments were affected by pyelonephritis, do not check any boxes.

6. In this item, indicate the degree of scarring in the each kidney. For each kidney…

   Select ‘A’ if no segments affected
   Select ‘B’ if mild (1-2 segments affected),
   Select ‘C’ if moderate (3-4 segments affected)
   Select ‘D’ if severe (>4 segments affected)
   Select ‘E’ if global atrophy (diffusely scarred or shrunken kidney)

   Note: If ‘A’ or ‘E’ for 6a then skip item 7a.
   If ‘A’ or ‘E’ for 6b then skip item 7b.

7. In each of items 7a and 7b, there are 12 boxed representing the 12 segments of each kidney. For each item, indicate all segments affected by scarring by checking the corresponding boxes. If no segments were affected by scarring, do not check any boxes.

8. Based on your experience, would you say that the image quality adequate or inadequate?

   Select 'A' if the film/image quality is adequate.
   Select 'I' if the film/image quality is poor.

C. COMPARISON WITH BASELINE

9. Select 'Y' if the image shows new scarring since the Baseline DMSA.
   Select 'N' if the image shows no new scarring since the Baseline DMSA.
   Select 'X' if this is the Baseline DMSA or the question is unanswerable due to poor image quality.

D. ADMINISTRATIVE INFORMATION

10. Record date of data collection, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

11. Select 'C' if data from this form was originally captured through the DMS (on a computer).
    Select 'P' if data from this form was originally captured on paper.

12. Record the initials of the reference radiologist who reviewed the DMSA scan data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

DMSA SEDATION FORM

DSF Version A, 02/07/07

QxQ

I. GENERAL INSTRUCTIONS

The DMSA Sedation Form should be completed by the study coordinator, based on information they request and obtain when requesting participant DMSA images.

Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns.

If any data is missing and unavailable, fill all spaces provided for that response with '='.

II. SPECIFIC INSTRUCTIONS

A. DMSA Procedure

1. Record the date the DMSA scan, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Select 'Y' if this is an interim DMSA scan requested by the DCC following a UTI.
   Select 'N' if this is a protocol-scheduled baseline, 12-month, or end of study DMSA scan.
   NOTE: if 'N' then skip to Q4.

3. Record the MCID# associated with the UTI event that resulted in the DMSA image. The associated MCID# can be found on the Medical Care Notification Form (MCN) that documents the medical visit when the positive urine culture was obtained, as well as on any Medical Care Abstraction Forms (MCAs) that correspond to that UTI event.

4. Select 'Y' if sedation was used during this DMSA scan.
   Select 'N' if sedation was not used during this DMSA scan.
   Select 'U' if you cannot determine whether or not sedation was used during this DMSA scan.
   NOTE: If 'N' or 'U' then go to item 11.

B. Sedation

Items 5 through 9 list some types of medication commonly used for sedation during DMSA scans. For each item:

a. Select 'Y' if the listed medication was used during the DMSA scan.
   Select 'N' if the medication was not used during the DMSA scan.

b. Provide the dose of the medication (mg/kg). Round to the nearest tenth, and enter leading zeros as necessary.

c. Select 'Y' if medication was administered as general anesthesia.
   Select 'N' if medication was not administered as general anesthesia.
   Select 'U' if unknown.

10. In this item, please specify any sedation medication used other than those listed in items 5-9. For this item:

    a. Select 'Y' if the listed medication was used during the DMSA scan.
    Select 'N' if the medication was not used during the DMSA scan.

    b. Provide the dose of the medication (mg/kg). Round to the nearest tenth, and enter leading zeros as necessary.

    c. Select 'Y' if medication was administered as general anesthesia.
    Select 'N' if medication was not administered as general anesthesia.
    Select 'U' if unknown.

    d. Specify the name of the medication.

C. Administrative Information

11. Record date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Select 'C' if data from this form was originally captured through DMS (on a computer).
    Select 'P' if data from this form was originally captured on paper.

13. Record the initials of the reference radiologist who reviewed the DMSA scan data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

DES TREATMENT FORM

DTF Version A, 11/01/12

QxQ

I. GENERAL INSTRUCTIONS

The DES Treatment form should be completed at the Baseline, 12-month and end-of-study clinic visits. **This form should be completed only if the child is toilet-trained for urine and bowel and if the participant's DVQ score is ≥6 for females or ≥9 for males.** To determine the DVQ score, enter the DVQ data into the DMS and run the report titled "DVQ Score Report."

This form is completed based on an interview with the participant's parent or guardian. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential and will in no way affect treatment or care of the participating child.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. DES Treatment

1. Question 1 provides information about the child's participating in a timed voiding program. Select only one response.

   Select 'Y' if the child is participating in a timed voiding program.
   Select 'N' if child is not participating in a timed voiding program.

2. Question 2 provides information about the child's use of miralax or other cathartics for DES.

   Select 'Y' if the child is using miralax or other cathartics for DES.
   Select 'N' if the child is not using miralax or other cathartics for DES.

3. Question 3 provides information about any medical therapies for DES that child is using.

   Select 'Y' if the child is using medical therapies for DES.

   Select 'N' if the child is not using medical therapies for DES.

   NOTE: if 'N', go to question 4.

   For Item 3a, select one of the following

   Select 'Y' if the child is using Anti-cholinergics.
   Select 'N' if the child is not using Anti-cholinergics.

   For Item 3b, select one of the following

   Select 'Y' if the child is using DDAVP.
   Select 'N' if the child is not using DDAVP.

   For Item 3c, select one of the following

   Select 'Y' if the child is using Imipramine.
   Select 'N' if the child is not using Imipramine.

   For Item 3d, select one of the following

   Select 'Y' if the child is using alpha blockers.
   Select 'N' if the child is not using alpha blockers

4. Question 4 asks for information about the child usage of a bedwetting alarm.

   Select 'Y' if the child is using a bedwetting alarm.
   Select 'N' if the child is not using a bedwetting alarm.

5. Question 5 asks for information about the child's usage of biofeedback therapy.

   Select 'Y' if the child is using biofeedback therapy.
   Select 'N' if the child is not using biofeedback therapy.

D. ADMINISTRATIVE INFORMATION

6. Record date of DES treatment interview using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

7. Select 'C' if data from this form was originally captured through the DMS (on the computer).
   Select 'P' if data from this form was originally captured on paper.

8. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C	or	A	-	C

DV QUESTIONNAIRE

DVQ Version A, 09/19/06

QxQ

I. GENERAL INSTRUCTIONS

This is a self administered questionnaire, to be completed by the parent/guardian with their child, if their child is **toilet-trained**. It is administered at baseline, 12-months, and 24-months. A child is considered toilet/potty trained when he or she is urinating and defecating in the toilet or potty by themselves during the day.

The questionnaire is intended to obtain information about the child,, and is worded for the child respondent. This questionnaire can be administered with help, and must be used with an interpreter for families who do not speak English.

The Coordinator must complete the header information as they would any form, and be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

When completed, the Coordinator should review the questionnaire to make sure that all items are completed appropriately.

II. SPECIFIC INSTRUCTIONS

The Coordinator should be familiar with MOP Chapter 4.3.3 addressing 'Challenges with Self Administered Questionnaires'. They should instruct the parent/guardian to start at the first question and work down through the form, completing all questions as best they can, reading all questions carefully, and circling their response choice.

Please let the parent/guardian know that you are able to help them if needed, it is acceptable to provide clarifications on words or questions within these forms when necessary. However, parents/children should be encouraged to respond based on personal experience and they way they think the answer best applies to them. Coordinators should remain accessible during their completing the questionnaire, while at the same time providing some confidentiality and privacy.

A. Child Response with Parent Help

For each of items 1-9, only one of the following options should be selected:

Select 'A' if the child's response is almost never.

Select 'B' if the child's response is less than ½ the time.

Select 'C' if the child's response is about ½ the time.

Select 'D' if the child's response is almost every time.

Select 'N' if the parent/guardian circled not applicable.

B. Parent/Guardian Response

10. Select 'Y' if child experienced a stressful event during the past month.
    Select 'N' if the child did not experience a stressful event during the past month.

11a. Select 'Y' if the child had a stool that blocked the toilet in the past 2 months.
    Select 'N' if the child did not have a stool that blocked the toilet in the past 2 months.

    NOTE: If N, then go to item 12.

11b. Select 'A' if never.
Select 'B' if stool blocked toilet once per month.
Select 'C' if stool blocked toilet two or three times per month.
Select 'D' if stool blocked toilet once per week.
Select 'E' if stool blocked toilet more than once per week.

12a. Select 'Y' if the child held on to his/her stool by crossing legs or squatting in the past 2 months.
Select 'N' if the child did not hold on to his/her stool by crossing legs or squatting in the past 2 months.

NOTE: If N, then go to item 13.

12b. Select 'A' if never.
Select 'B' if the child held on to his/her stool by crossing legs or squatting once per month.
Select 'C' if the child held on to his/her stool by crossing legs or squatting two or three times per month.
Select 'D' if the child held on to his/her stool by crossing legs or squatting once per week.
Select 'E' if the child held on to his/her stool by crossing legs or squatting more than once per week.

13a. Select 'Y' if the child complained of pain while having a bowel movement in the past 2 months.
Select 'N' if the child did not complain of pain while having a bowel movement in the past 2 months.

NOTE: If N, then go to item 13.

13b. Select 'A' if never.
Select 'B' if the child complained of pain while having a bowel movement once per month.
Select 'C' if the child complained of pain while having a bowel movement two or three times per month.
Select 'D' if the child complained of pain while having a bowel movement once per week.
Select 'E' if the child complained of pain while having a bowel movement more than once per week.

14a. Select 'Y' if the child had bowel movements in his/her underwear in the past 2 months.
Select 'N' if the child did not have bowel movements in his/her underwear in the past 2 months.

NOTE: If N, then go to item 15.

14b. Select 'A' if never.
Select 'B' if the child had bowel movements in his/her underwear once per month.
Select 'C' if the child had bowel movements in his/her underwear two or three times per month.
Select 'D' if the child had bowel movements in his/her underwear once per week.
Select 'E' if the child had bowel movements in his/her underwear more than once per week.

C. ADMINISTRATIVE INFORMATION

Questions 15 and 16 are to be completed by the study coordinator or study personnel who reviewed the completed DVQ.

15. Record date the DVQ was completed by parent using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

16. Record the initials of the person who reviewed the completed DVQ. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

ELIGIBILITY AND RANDOMIZATION FORM

ERF Version E, 02/08/11

QxQ

I. GENERAL INSTRUCTIONS

The Eligibility and Randomization Form (ERFD) is used to verify eligibility criteria so that randomization may occur. It is important that this form be entered into the DMS while the participant is present at the randomization visit. The ICT must be entered prior to completion of this form. It is recommended to have filled out the PEF prior to completion of the ERF so that the possibility of a UTI at randomization has been eliminated. Collect urine for dipstick prior to beginning ERF form. Refer to MOP chapter on randomization for instructions in handling dipped urine showing trace or greater pyuria.

This form is completed based on an interview with the participant's parent or guardian. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential.

Interviewers and data entry personnel should understand and be familiar with chapters 13 and 14 in the Manual of Procedures, prior to completing this form. Complete only the appropriate items. Be sure to follow the correct skip patterns.

Recall the following helpful DMS keystrokes:

1. F11 will enlarge the viewing screen. Pushing F11 again will reduce the viewing screen.

2. The DMS screen should say 'Add Mode' for the user to be able to enter data into the ERF. The ERF automatically saves and locks following entry of the user's initials in item 55. There is no way to return to the ERF and edit data after the form is locked.

3. To set an unskipped, empty field to unresolvable, fill the entire field with '=' signs OR cursor to the unresolved field and enter CTRL+U.

4. To confirm a valid value in a field where the number entered failed the edit check, enter the value and then enter CTRL+C. There are many fields in the ERF that will not allow the user to confirm invalid data.

5. To add a note (notelog) to any field, enter CTRL+G, add your note, and then save the notelog by entering ALT+S.

6. Press F1 to retrieve the lists of bacteria codes used on the ERF (Q24).

II. SPECIFIC INSTRUCTIONS

A. Administrative Information

This section should be completed by the study coordinator.

1. a. Record TODAY as the Date of randomization. For example, August 3, 2008 would be entered as:

0	8	/	0	3	/	2	0	0	8

NOTE: DMS will accept only today's date as a valid entry as randomization must occur with participant present.

b. b. The eligibility depends on the child experiencing fever or symptoms within 24 hours prior to or following the UTI work-up date. Enter the first date of the UTI work-up using the mm/dd/yyyy format, inserting leading zeros where necessary. The work-up date in most cases will be the same date that the urine was collected and cultured. The child is eligible if the fever and

symptoms were present 24 hours prior to or after being seen for a suspected UTI. The positive urine culture may have been collected up to 7 days after initiation of UTI work-up.

Note: the UTI immediately preceding the randomization will be referred to as the index UTI.

c. Record the date that patient gave consent, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

d. Select 'C' if data from this form was originally captured electronically (on the computer). Select 'P' if data from this form was originally captured on paper.

e. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

B. Age

2. Record the child's birth date using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

3. This item (age in months) is automatically calculated and filled into the data entry screen and database based on items 1 and 2.

4. Item 4 is only applicable for children age 6 months or younger.
   Select 'Y' if the child's age < 6 months and gestational age was 34 weeks or greater.
   Select 'N' if the child's age < 6 months and gestational age was less than 34 weeks.
   Select 'X' if the child's age ≥ 6 months.
   NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

5. Select 'Y' if child's age is at least 2 months, but less than 72 months (6 years).
   Select 'N' if child's age is less than 2 months or 72 months or greater. (Participant is excluded.)
   NOTE: DMS will not proceed with the form if the answer selected for item 5 is inconsistent with item 3 (age in months). Review the item 2 (date of birth) and/or item 5 if an 'Inconsistent' message opens on the screen.
   NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

6. a. Select 'Y' if child has experienced more than one UTI prior to randomization.
   Select 'N' if child has experienced only one UTI prior to randomization.

   NOTE: If N, then skip to item 7.

   b. Enter the number of UTI's the child has experienced prior to randomization.

   NOTE: If the number of UTI's > 2, then participant is excluded and DMS will skip all remaining questions.

   c. Select 'Y' if child received a VUR diagnosis prior to the second UTI.
   Select 'N' if child received a VUR diagnosis prior to the second UTI.

NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

d. Select 'Y' if child received prophylactic antimicrobial therapy prior to the second UTI.
Select 'N' if child received prophylactic antimicrobial therapy prior to the second UTI.

NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

C. TEMPERATURE / SYMPTOMS OF INDEX UTI

7. Select 'Y' if a temperature was measured with a thermometer during the index UTI event.
Select 'N' if a temperature was not measured during the index UTI event.

NOTE: If N, then skip to item 14.

8. a. Record the highest temperature 24 hrs prior to or following the initial index UTI work-up.

b. The unit of measurement will be automatically filled into the DMS. Enter tab to advance to next field.

9. Select 'O' if the temperature recorded in item 8 was measured orally.
Select 'A' if the temperature recorded in item 8 was measured under the arm.
Select 'T' if the temperature recorded in item 8 was measured in the ear.
Select 'R' if the temperature recorded in item 8 was measured rectally.
Select 'U' if the route of measurement for the temperature recorded in item 8 is unknown.

10. Select H if the temperature recorded in item 8 was measured in a home setting.
Select M if the temperature recorded in item 8 was measured in a medical care setting by a medical professional.

11. a. Record the highest temperature during the index UTI event (reported by the caregiver or documented in medical records).

b. The unit of measurement will be automatically filled into the DMS.

c. Record the date of the highest temperature of the index UTI event using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Record the total duration in hours of fever prior to antimicrobial treatment of the index UTI. Whole numbers only, round up to the nearest hour.

13. Record the number of hours between the time of index UTI antimicrobial treatment and sustained (> 24 hours) normal temperature (less than 100.4° F or 38°C). Whole numbers only, round up to the nearest hour.

14. Item 14 provides information about the symptoms present 24 hrs prior to or following the initial work-up of the index UTI. For each of items 14a–14f:

Select 'Y' if the symptom was present 24 hrs prior to or following the initial work-up of the index UTI. .

Select 'N' if the symptom was not present 24 hrs prior to or following the initial work-up of the index UTI.

Select 'U' if it is unknown whether or not the symptom was present 24 hrs prior to or following the initial work-up of the index UTI.

Items 14g–14i are only applicable for children age 4 months or younger. For each of items 14g – 14i:

Select 'Y' if child is age 4 months or younger and the symptom was present 24 hrs prior to or following the initial work-up of the index UTI.

Select 'N' if child is age 4 months or younger and the symptom was not present 24 hrs prior to or following the initial work-up of the index UTI.

Select 'U' if it is unknown whether or not the symptom was present 24 hrs prior to or following the initial work-up of the index UTI.

Select 'X' if child is greater than 4 months of age.

NOTE on vomiting: A recent RIVUR Executive Committee decision (01/12/09) allows for vomiting to be included in the list of allowable UTI symptoms in children aged 4 months and younger. If vomiting is one of the symptoms to be recorded, select 'Y' for the symptom, failure to thrive (14g). Enter a notelog on item 14g that says vomiting.

15. Record the total number of days the child experienced the symptoms listed in item 14. Whole numbers only, round up to the nearest hour.

16. Select 'Y' if there was a temperature of 100.4°F or greater (38°C or greater) recorded in item 8 (not item 11) **OR** if you selected yes for any symptoms in item 14.

Select 'N' if there was not a temperature of 100.4°F or greater (38°C or greater) recorded in item 8 (not item 11) **AND** did *not* select yes for any symptoms in item 14.

NOTE: DMS will not proceed with the form if the answer selected for item 16 is inconsistent with item 8a (temperature ≥ 100.4°F or 38°C) OR item 14 (UTI symptoms). Review item 8a (temperature) and/or item 14 (symptoms) if an 'Inconsistent' message opens on the screen.

NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

D. INDEX UTI URINALYSIS RESULTS

17. a. Record the date of the urine collection that was used for dipstick from the index UTI. Use the mm/dd/yyyy format, inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

b. Leukocyte esterase (select only one):
Select 'A' if negative.
Select 'B' if trace.
Select 'C' if small (+).
Select 'D' if moderate (++).
Select 'E' if large (+++).

NOTE: If A, then participant is excluded and DMS will skip all remaining questions.

c. Nitrite (select only one):
Select 'N' if negative.
Select 'P' if positive.

18. a. Record the date of the urine collection that was used for microscopy from the index UTI. Use the mm/dd/yyyy format, inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

b. Record the value of the WBC count, inserting leading zeros where necessary. Enter the value reported. Enter 999.999 for values 999.999 or greater.

c. Record the units for the WBC microscopy (select only one):
Select 'A' if WBC/mm^3.
Select 'B' if WBC/hpf.

19. To answer this item, refer to the answers from items 17 and 18. Select 'Y' if pyuria was present, as indicated by one of the following:

- item 17b=B, C, D, or E
- item 18b=10 or greater **AND** 18c=A
- item 18b=5 or greater **AND** 18c=B

Select 'N' if pyuria is not present.

NOTE: If N is entered for item 19, then participant is excluded and DMS will skip all remaining questions.

E. INDEX UTI URINE CULTURE RESULTS

20. a. Record the date of the urine collection that was used for culture from the index UTI. Use the mm/dd/yyyy format, inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

b. Indicate method of urine collection (select only one):
Select 'A' if catheterization.
Select 'B' if suprapubic aspiration.
Select 'C' if clean voided.
Select 'D' if bag collected.
Select 'E' if method of collection is unknown.

NOTE: If 'D' or 'E', then participant is excluded and DMS will skip all remaining questions.

21. a. Select 'Y' if the urine culture showed only a single primary organism other than lactobacillus or candida. A primary organism is defined as one organism with a colony count ≥ 50,000 CFU/ml in catheterized or suprapubic specimens or ≥ 100,000 CFU/ml in clean-voided specimens.

Select 'N' if the urine culture showed one primary organism that had a colony count <50,000 CFU/ml in catheterized or suprapubic specimens or <100,000 CFU/ml in clean-voided specimens.

NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

b. Record the total number of organisms reported on the urine culture.

NOTE: If more than 2 organisms, then participant is excluded and DMS will skip all remaining questions.

22. a. Enter the two-digit code of the single primary organism. The primary organism is defined as the organism with a colony count ≥ 50,000 CFU/ml in catheterized or suprapubic specimens or ≥ 100,000 CFU/ml in clean-voided specimens. For a complete listing of codes, refer to the 'Bacteria and Anti-microbial Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. If the organism is not listed, use 'other' code '99' and record the name of the organism in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b. Select 'A' if the primary organism colony count from the culture results equals the value reported.
Select 'B' if the primary organism colony count from the culture results is greater than the value reported.
Select 'C' if the primary organism colony count from the culture results is greater than or equal to the value reported.
Select 'D' if the primary organism colony count from the culture results is less than the value reported.
Select 'E' if the primary organism colony count from the culture results is less than or equal to the value reported.
Select 'F' if the primary organism colony count from the culture results is reported as a range.

NOTE: If A, B, C, D, or E are selected then skip item 22c2.

c. Record the colony count of the isolated primary organism (CFU/ml), inserting leading zeros where necessary. Where a range of values are reported on the culture results, use item 22c1 for the bottom range value and item 22c2 for the top range value.

23. a. Enter the two-digit code of the secondary organism. This is defined as any second organism with a colony count less than the colony count of the primary organism. For a complete listing of codes, refer to the 'Bacteria and Anti-microbial Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. If the organism is not listed, use 'other' code '99' and record the name of the organism in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b. Select 'A' if the secondary organism colony count from the culture results equals the value reported.
Select 'B' if the secondary organism colony count from the culture results is greater than the value reported.
Select 'C' if the secondary organism colony count from the culture results is greater than or equal to the value reported.
Select 'D' if the secondary organism colony count from the culture results is less than the value reported.
Select 'E' if the secondary organism colony count from the culture results is less than or equal to the value reported.
Select 'F' if the secondary organism colony count from the culture results is reported as a range.

NOTE: If A, B, C, D, or E are selected then skip item 23c2.

c. Record the colony count of the isolated secondary organism (CFU/ml), inserting leading zeros where necessary. Where a range of values are reported on the culture results, use item 22c1 for the bottom range value and item 22c2 for the top range value.

24. a. Select 'Y' if the colony count for the primary organism was ≥ 50,000 CFU/ml in catheterized or suprapubic specimens or ≥ 100,000 CFU/ml in clean-voided specimens.

    Select 'N' if the colony count was < 50,000 CFU/ml in a cath specimen or < 100,000 in a clean-void specimen.

    NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

    b. Select 'Y' if the colony count for the secondary organism was ≤ 10,000 CFU/ml.

    Select 'N' if the colony count exceeded 10,000.

    NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

    NOTE: DMS will not proceed with the form if the answer selected for item 24 is inconsistent with item 22 and 23. Review item 22 and 23 if an 'Inconsistent' message opens on the screen.

F. INDEX UTI TREATMENT

25. Record the number of different antimicrobials prescribed to treat the index UTI.

26–29. Provide documentation of up to four different treatments for the index UTI, as specified below:

a. Record the antimicrobial code associated with the treatment from the antimicrobial code list. For a complete listing of codes, refer to the 'Bacteria and Antimicrobial Code List' following this QxQ, or press F1 in the DMS to see the list of antimicrobial codes. If the antimicrobial is not listed, use 'other' code '500' and record the name of the antimicrobial in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b. Record the date this antimicrobial was prescribed using the mm/dd/yyyy convention and inserting leading zeros if necessary.

c. Record the total number of days the participant was on this treatment, whole numbers only.

d. Indicate the sensitivity of the pathogen to the treatment prescribed as reported on the sensitivity report.

Select 'Y' if organism is reported sensitive to antimicrobial listed in a.

Select 'N' if organism is reported sensitive to antimicrobial listed in a.

Select 'U' if there are no sensitivity results for the organism.

30. a. To answer this item, refer to the answers from items 26-29, column c. Sum the duration of treatment days (item 26c-29c) for each antimicrobial.
Select 'Y' if this sum is 7 days or more.

Select 'N' if this sum is less than 7 days.

NOTE If N, then participant is excluded and DMS will skip all remaining questions.

b. To answer this item, refer to the answers from items 26-29, column c. Sum the duration of treatment days (item 26c-29c) for each antimicrobial where a 'Y' in 26d-29d indicates pathogen sensitivity.

Select 'Y' if this sum is 7 days or more.

Select 'N' if this sum is less than 7 days.

31. Select 'Y' if a follow-up urine culture was reported (in medical records) within 1-14 days after completion of antimicrobial therapy (as reported in items 26b-29b).

    Select 'N' if no follow-up urine culture was reported (in medical records) within 1-14 days after completion of therapy (as reported in items 26b-29b).

    NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

32. Record the date of the follow-up urine culture. Use the mm/dd/yyyy format, inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

G. VCUG LOCAL REPORT

33. Record the date of the VCUG, using the mm/dd/yyyy format and inserting leading zeros as necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

34. To answer this item, refer to the answers from items 20a and 33.

    Select 'Y' if date of VCUG (item 33) is within 112 days date of the urine collection that resulted in a positive urine culture (diagnosis date of index UTI, item 20a). Select 'Y' if date if VCUG is exactly 112 days after diagnosis date of the index UTI.

    Select 'N' if date of VCUG (item 33) is *not* within, but beyond 112 days after the diagnosis date of the index UTI (as reported in item 20a).

    NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

35. Select 'Y' if VCUG demonstrated grade I, II, III, or IV reflux in at least one ureter.
    Select 'N' if VCUG demonstrated no reflux in both ureters **OR** grade V reflux in both ureters.

    NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

36. Select 'Y' if VCUG demonstrated grade V reflux in either ureter.
    Select 'N' if VCUG demonstrated less than grade V reflux in both ureters.

    NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

37. Record any bladder abnormalities demonstrated on VCUG. For each item, a and b:

    Select 'Y' if the abnormality was demonstrated on VCUG.
    Select 'N' if the abnormality was not demonstrated on VCUG.

    NOTE: If Y for either a or b, then participant is excluded and DMS will skip all remaining questions.

H. RENAL ULTRASOUND LOCAL REPORT

38. a. Record the date of the ultrasound, using the mm/dd/yyyy format and inserting leading zeros as necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

    b. Select 'Y' if the date of ultrasound is within 112 days prior to or after the date of the urine collection that resulted in a positive urine culture (date of index UTI, item 20a).

Select 'N' if the date of ultrasound is greater than 112 days prior to or after the date of the urine collection that resulted in a positive urine culture (date of index UTI, item 20a).

39. In item 39, indicate any urologic abnormalities present on ultrasound. For each urologic abnormality, a through h:

    Select 'Y' if the abnormality was present on ultrasound.
    Select 'N' if the abnormality was not present on ultrasound.

    NOTE: If Y for any a to h, then participant is excluded and DMS will skip all remaining questions.

I. OTHER MEDICAL EXCLUSIONS

40. Select 'Y' if the child has any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease (including 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).

    Select 'N' if child does not have any underlying syndromes that may display VUR, recurrent infection, or progressive renal disease.

    NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

41. Select 'Y' if the child has any underlying anomalies or chronic diseases that could potentially interfere with response to therapy (including GI conditions, liver or kidney failure, malignancy, and complex cardiac diseases).

    Select 'N' if child does not have any underlying anomalies or chronic diseases that could potentially interfere with response to therapy.

    NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

42. Select 'Y' if trimethoprim is contraindicated for this child due to intolerance, known allergy, inadequate renal or hepatic function, G6PD deficiency or any other reason.

    Select 'N' if trimethoprim or sulfa is *not* contraindicated.

    NOTE: If Y is entered for item 42, then participant is excluded and DMS will skip to item 54.

43. Select 'Y' if a parent or sibling has a history of anaphylactic reaction to any sulfa medication.
    Select 'N' if there is no known history of a parent or sibling having an anaphylactic reaction to any sulfa medication.

    NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

44. Select 'Y' if the child has had renal or bladder surgery.
    Select 'N' if the child has never had renal or bladder surgery.

    NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

J. AVAILABILITY

45. Select 'Y' if the child is currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown.

    Select 'N' if the child is not currently enrolled in a randomized trial in which the specific treatment the child is receiving is unknown.

NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

46. a. Select 'Y' if child is currently taking continuous antimicrobial prophylaxis.
Select 'N' if child is not currently taking continuous antimicrobial prophylaxis.

NOTE: If N, then skip to 47.

b. Select 'Y' if the family is willing to discontinue current prophylaxis to begin RIVUR treatment.
Select 'N' if family is unwilling to replace current prophylaxis for RIVUR treatment.

NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

47. Select 'Y' if there is any reason that would make completing this protocol impossible (such as an inability to administer daily oral medication, visit the clinic semiannually for data collection, or receive bimonthly phone calls from study personnel).

Select 'N' if there is no known reason that completing this protocol would be impossible.

NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

48. Select 'Y' if the family has plans to move to an area before the 2 year follow-up period has elapsed that will make it no longer convenient for study participation.

Select 'N' if the family does not plan to move to an area that would prevent them from participating in the study.

NOTE: If Y, then participant is excluded and DMS will skip all remaining questions.

K. RECENT FEVER AND PYURIA

49. Select 'Y' if the child had a temperature of 100.4°F (38°C) or greater anytime in the last 24 hours.

Select 'N' if the child has not had a temperature of 100.4°F (38°C) or greater anytime in the last 24 hours.

NOTE: If 'Y' then skip all remaining questions.

50. a. Select 'Y' if pyuria was present on today's urine dipstick (trace, 1+, 2+, or 3+) or microscopy results $\geq$10 WBC/mm3 or >5WBC/hpf) **OR** if pyuria was present on a previous attempt at randomization.
Select 'N' if pyuria was not present on today's urine dipstick (negative).

NOTE: If N, then skip to item 51. This response indicates that there was not a previous attempt at randomizing this participant.

NOTE: If Y AND this is a second attempt to randomize the child, there must be a negative urine culture on the urine collected at the previous attempt. Enter the urine dipstick results from the previous attempt as well as the urine culture results on the USR (contact occasion=01, sequence number=00, AND line number=01. Enter the urine results from the second attempt in the same USR form, but increment the line number to 02.

b. Select "Y" if this is an attempt at randomization following pyuria present at previous randomization visit.
Select "N" if this is NOT an attempt at randomization following pyuria present at previous randomization visit.

NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

c. Record the date of last randomization attempt, using the mm/dd/yyyy format and inserting leading zeros as necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

d. Select "Y" if there is a negative culture from a specimen collected at the previous randomization attempt when pyuria was present.
Select "N" if there is NOT a negative culture from a specimen collected at the previous randomization attempt when pyuria was present.

NOTE: If N, then participant is excluded and DMS will skip all remaining questions.

K. RANDOMIZATION

51. Record last name of investigator who reviewed eligibility and authorized randomization. Use as many boxes as necessary, beginning with the left-most box. Leave extra boxes blank.

52. NOTE: Selecting 'Y' for this item will initiate the 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.

Select 'Y' if you wish to randomize the child to a treatment group.
Select 'N' if you do *not* wish to randomize the child to a treatment group.

NOTE: A pop-up will appear after selecting 'Y' that asks the user to wait while the randomization algorithm is processing. Click the OK button to close the pop-up, but do not key or click anything else as doing so may interrupt the successful execution of the randomization program. You will receive another pop-up after the algorithm has successfully executed.

EXIT FORM

EXF Version B, 3/22/10

QxQ

I. GENERAL INSTRUCTIONS

The Exit Form (EXF) is completed based on both the coordinator's opinion and information from an interview with the participant's parent or guardian during the 24-month visit or at last contact, if a participant withdraws. Its purpose is to capture information regarding the coordinator's opinion and the parent/guardian's opinion as to which treatment group the participant had been assigned. The two groups include the group who received active study medication or the group who received an inactive medication (placebo).

This form can be completed on paper or directly entered into the RIVUR DMS. Complete only the appropriate questions. Section A has the questions the study coordinator will answer about his/her opinion. Section B includes the questions to be answered by the participant's parent or guardian. If more than one parent wishes to submit a guess, please record on the form the response of the parent who most frequently administered the study medication. Capture the additional responses in a notelog on items 4 and 5. Be sure to follow the correct skip patterns as instructed on the form.

II. SPECIFIC INSTRUCTIONS

A. STUDY COORDINATOR'S GUESS

1. Select 'A' if study coordinator believes the participant was on active drug.
   Select 'I' if study coordinator believes the participant was on inactive drug.

2. Select 'V' if study coordinator is very certain the participant was randomized to that treatment group.
   Select 'F' if study coordinator is fairly certain the participant was randomized to that treatment group.
   Select 'U' if study coordinator is uncertain the participant was randomized to that treatment group, skip to item 4.

3. Open response for your reasoning in choosing answers to items 1 and 2.

B. PARTICIPANT'S GUESS

4. Select 'A' if parent/guardian believes the participant was on Active Drug.
   Select 'I' if parent/guardian believes the participant was on Inactive Drug.

5. Select 'V' if the parent/guardian is very certain the participant was randomized to that treatment group.
   Select 'F' if the parent/guardian is fairly certain the participant was randomized to that treatment group.
   Select 'U' if the parent/guardian is uncertain the participant was randomized to that treatment group, skip to item 7.

6. Open response for participant's reasoning in choosing answers to items 4 and 5.

C. FUTURE VUR TREATMENT PLANS

7. Select 'Y' if parent/guardian will seek or is considering future VUR treatment for the child.
   Select 'N' parent/guardian will not seek or is not considering future VUR treatment for the child beyond surveillance, skip to item 14.

8a. Select 'Y' if parent/guardian will definitely start child on anti-microbial prophylaxis for child's VUR.
Select 'C' if parent/guardian is considering starting child on anti-microbial prophylaxis for child's VUR.
Select 'N' if parent/guardian will not start child on anti-microbial prophylaxis for child's VUR, skip to item 9a.
Select 'U' if parent/guardian is undecided about child starting anti-microbial prophylaxis for their child's VUR, skip to item 9a.
Select 'X' if starting anti-microbial prophylaxis for child's VUR is not applicable or not an option for treating the child's VUR, skip to item 9a.

8b. If 'Y or 'C' are selected enter the code for the type of anti-microbial prophylaxis (see MOP chapter 4, Appendix 4.3 for the list of Antibiotic/Antimicrobial codes)
.
If the type of anti-microbial prophylaxis is not included in the list enter '500' as the code and insert the type into a notelog.

9a. Select 'Y' if child will definitely have reimplantation surgery, specify procedure details in a notelog.
. Select 'C' if parent/guardian is considering reimplantation surgery for child, specify procedure details in a notelog.
Select 'N' if parent/guardian will not have reimplantation surgery on child, skip to item 10a.
Select 'U' if parent/guardian is undecided about child having reimplantation surgery, skip to item 10a.
Select 'X' if having reimplantation surgery is not applicable or not a treatment option, skip to item 10a.

9b. If reimplantation surgery is scheduled or has been completed, specify date. If date is unknown enter' ==/==/===='.

10a. Select 'Y' if child will definitely have deflux injection, specify procedure details in a notelog.
Select 'C' if parent/guardian is considering deflux injection for child, specify procedure details in a notelog.
Select 'N' if parent/guardian will not have deflux injection on child, skip to item 11
Select 'U' if parent/guardian is undecided about child having surgery deflux injection, skip to item 11.
Select 'X' if deflux injection, is not applicable or not a treatment option, skip to item 11.

10b. If deflux injection is scheduled or has been completed, specify date. If date is unknown enter' ==/==/===='.

11. Select 'Y' if parent/guardian will definitely seek health care for child from another provider, specify provider subspecialty in a notelog.
Select 'C' if parent/guardian is considering seeking health care for child from another provider, specify provider subspecialty in a notelog.
Select 'N' if parent/guardian has decided not to seek health care for child from another provider.
Select 'U' if parent/guardian is undecided about seeking health care for child from another provider.
Select 'X' if seeking health care from another provider is not applicable or not a treatment option.

12a. Select 'Y' if child will definitely have a repeat VCUG in the future, specify procedure details in a notelog.
Select 'C' if parent/guardian is considering having a repeat VCUG in the future, specify procedure details in a notelog.
Select 'N' if parent/guardian will not repeat the VCUG in the future, skip to item 13.
Select 'U' if parent/guardian is undecided about repeating the VCUG in the future, skip to item 13.
Select 'X' if repeating the VCUG in the future is not applicable or not a treatment option, skip to item 13.

12b. If a repeat VCUG is scheduled or has been completed, specify date. If date is unknown enter' ==/==/===='.

13. Select 'Y' if parent/guardian will pursue a treatment option not listed in items 8a-12a, specify what treatment in a notelog.
Select 'N' if no other unlisted treatment option will be considered.

D. ADMINISTRATIVE INFORMATION

14. Record date of consent or modification using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

15. Select 'C' if data from this form was originally captured through the DMS (on a computer).
Select 'P' if data from this form was originally captured on paper.

16. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

Protocol Scheduled Follow-up Form

FUP Version C, 07/18/08

QxQ

I. GENERAL INSTRUCTIONS

The Protocol Scheduled Follow-up contact Form (FUP) should be completed each time a protocol scheduled clinic visit or phone contact occurs (every 2 months from randomization). This form is completed based on an interview with the participant's parent or guardian.

This form is the primary instrument used during follow-up, and will provide instruction about additional data collection and forms needed, based on responses to specific questions. The interviewer should inform the parent or guardian that all information provided in this interview will remain confidential, will be used for study purposed only, and will in no way affect treatment or care of the participating child.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

Prior to a follow-up contact, run the DMS report 'Participant Follow-up Summary Report', which will provide a summary of data collected over time, that can be used as a reference during the parent interview.

II. SPECIFIC INSTRUCTIONS

A. CONTACT INFORMATION

1. This item should be completed by the study coordinator just before initiating the interview. Indicate the type of contact by selecting only one of the following options:

   Select 'A' if this is a regularly scheduled protocol clinic visit.

   Select 'B' if this is a regularly scheduled protocol phone contact.

   Select 'C' if this is a phone contact that will replace a regularly scheduled protocol clinic visit.

   Select 'D' if this is a clinic visit that will replace a regularly scheduled protocol phone contact.

   Select 'E' if the scheduled contact was missed.

   NOTE: If 'A, B, C, or D' then go to Item 3.

2. This item is completed to explain a missed contact, documented as 'E' for item 1. Indicate the main reason the contact was missed by selecting only one of the following options:

   Select 'A' if participant refused.

   Select 'B' if participant was incapacitated.

   Select 'C' if participant withdrew consent.

   Select 'D' if participant location is unknown.

   Select 'E' if contact was missed due to an oversight on the part of the participant.

   Select 'F' if participant died.

   Select 'G' if reason is unknown.

   Select 'H' if **family couldn't be contacted after repeated attempts**

   NOTE: If 'C' then complete ICT form and go to Item 23.

   NOTE: If 'F' then complete AEF, MCA, and MCN forms.

   NOTE: If 'A, B, D, E, G, or H' then proceed to Item 23.

B. ADVERSE EVENTS / SIDE EFFECTS and MEDICAL CARE HISTORY

3a. This question asks about any new side effects that are possibly associated with the study medication, that the parent/guardian or clinic staff feels the child may have experienced since the last study contact (defined as a protocol scheduled call or visit).

A **study medication side effect** is defined as any:
• Known study medication side effect, as documented in Appendix A of the protocol, the drug packaging insert for Sulfamethoxazole and Trimethoprim Oral Suspension. • Considered potential study medication side effects, by the parent/guardian or the clinician.

Please refer to the RIVUR MOP Chapter 9 for more information regarding side effects and serious adverse event reporting.

Select 'Y' if the parent/guardian or a RIVUR clinical staff member reports (or has previously reported) that the child had any new health problems which they believe may be a side effect of the study medication.

Select 'N' if no study medication side effects are being reported.

NOTE: Review Parent Diary for additional information on new health problems and sick visits that might be related to medication side effects since last study contact.

NOTE: Review the Participant Follow-up Summary Report for any previous medication side effects entered, and for a listing of the last study contact dates.

NOTE: If 'Y' then complete and AEF form for each new medication side effect.

NOTE: If 'N' then go to Item 3c.

3b. Select 'P' if a parent or guardian determined a possible side effect.

Select 'C' if a member of the clinical staff determined a possible side effect.

Select 'B' if both a parent or guardian and a member of the clinical staff determined a possible side effect.

3c. This question asks about any new health problems that the child has had since the last study contact (defined as a protocol scheduled call or visit) that fit the study definition for a serious adverse event. This should include those problems that the site has previously been notified about.

A **serious adverse experience or adverse event (SAE)** is any adverse event that results in any of the following outcomes:
• Death • A life-threatening experience • Inpatient hospitalization or prolongation of existing hospitalization • A persistent or significant disability/incapacity • A congenital anomaly/birth defect

Please refer to the RIVUR MOP Chapter 9 for more information regarding side effects and serious adverse event reporting.

Select 'Y' if the child has endured new health problems that fit the study definition of a serious adverse event.

Select 'N' if the child has not endured new health problems that fit the study's definition of a serious adverse event.

NOTE: Review Parent Diary for additional information on new health problems and sick visits since last study contact.

NOTE: Review the Participant Follow-up Summary Report for any previous side effects or serious adverse events, and for a listing of the last study contact dates.

4. This question asks about medical care since the last study contact. Medical care visits that require medical care data collection (MCN, MCA, USR) include any visit where 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. This includes non-sick visits (such as visits for a vaccination or routine physical, but only if urine is collected), sick visits, ER visits and hospitalizations.

   Select 'Y' if the parent/guardian reports (or has previously reported) that their child received medical care that requires medical care data collection since the last study contact.

   Select 'N' if the child's has not received medical care that requires medical care data collection.

   NOTE: Review Parent Diary for additional information on medical care visits since last study contact.

   NOTE: Any surgery to treat the participant's VUR should be collected on an MCN and MCA.

   NOTE: If 'N' then go to Item 7.

5. Record the total number times the child received medical care that requires medical care data collection since last study contact (protocol scheduled call or visit). Record whole numbers only, inserting leading zeros where necessary.

   NOTE: Complete MCN, MCA and USR (if necessary) forms for each occurrence of medical care.

6. This item is designed to capture all MCIDs assigned since the last study contact. Use as many of rows 6a-6j as needed. Beginning with row 6a...

   1. Provide the MCID number associated with a medical care visit.
   2. Indicate whether or nor the MCID number was appropriately assigned.

      Select 'Y' if the MCID was assigned to a confirmed medical care visit.

      Select 'N' if the MCID was assigned in error.

      NOTE: The DMS will pre-fill 'Y' for item 2. To indicate 'N' simply move the cursor back to that field and enter 'N'.

   NOTE: On the paper form, space has been provided for notes to help you keep track of the MCID numbers. Do not enter these notes into the DMS.

   NOTE: If more than 10 medical visits have occurred since the last contact, please enter the additional MCID numbers and corresponding information into a DMS notelog.

7. Select 'Y' if the child has been treated with any other prescription or over-the-counter medications since the last study contact (protocol scheduled call or visit).

   Select 'N' if the child has been *not* been treated with any other prescription or over the counter medications.

   NOTE: Review the Parent Diary and probe for any medications used or prescribed associated with an adverse event or medical care visit.

   NOTE: If 'Y' then add medications to the CMF form.

C. STUDY MEDICATION STATUS

8. This item should be completed by the interviewer and does not need to be incorporated into the interview. Indicate the child's current status of study medication use by selecting from one of the following:

   Select 'A' if the child is currently on study medication.

   Select 'B' if the child will begin a temporary discontinuation today.

   Select 'C' if study medication was temporarily discontinued at a previous study contact.

   Select 'D' if the child will permanently discontinue study medication, beginning today.

   Select 'E' if medication was permanently discontinued at a previous study contact

   NOTE: The participant's study medication status is 'On Study Medication' (response 'A') regardless of compliance, and is only removed from that status by the site's principal investigator. Record medication compliance in items 9-15.
   NOTE: If 'B or D' then complete DDF form.

   NOTE: If 'C' then go to Item 16.

   NOTE: If 'E' then go to Item 17.

D. STUDY MEDICATION INTERVIEW

9. Select 'Y' if the parent/guardian reported child took study medication today.
   Select 'N' if child did not take study medication today.

10. Select 'A' if parent/guardian reports that the child never missed a dose during the past week.
    Select 'B' if parent/guardian reports that the child missed a dose 1-2 times during the past week.
    Select 'C' if parent/guardian reports that the child missed a dose 3-4 times during the past week.
    Select 'D' if parent/guardian reports that the child missed a dose >4 times during the past we
    Select 'E' if the number of missed is unknown.
    Select 'F' if medication was temporarily discontinued.

11. Select 'A' if parent/guardian reports that the child took study medication every day.
    Select 'B' if parent/guardian reports that the child took study medication almost every day.
    Select 'C' if parent/guardian reports that the child took study medication approximately 75-90% of the time.
    Select 'D' if parent/guardian reports that the child took study medication approximately 50-74% of the time.
    Select 'E' if parent/guardian reports that the child took study medication approximately 25-49% of the time.
    Select 'F' if parent/guardian reports that the child took study medication seldom, occasionally, or less than 25% of the time.

Select 'G' if parent/guardian reports that child did not take study medication.

NOTE: If 'A or B' then go to item 14.

12. Based on parent/guardian report of primary reason that child was not given study medication every day or almost every day:

Select 'A' if doses were missed primarily due to forgetfulness.

Select 'B' if doses were missed primarily due to misplacement of medication.

Select 'C' if doses were missed primarily due to the child experiencing side effects.

Select 'D' if doses were missed primarily due to the child refusing to take medication.

Select 'E' if doses were missed primarily due to the parent feeling that medication was unnecessary.

Select 'F' if doses were missed primarily due to a temporary discontinuation of medication.

Select 'G' if doses were missed primarily due to another reason (please specify other reason on the FUP form).

13. This question should be answered by the study coordinator, based discussion arising from items 9-13 of the interview. This question should be answered when a child has stopped taking medication and has done so without being told to do so by study personnel.

Select 'Y' if the parent/guardian can be persuaded to resume giving the child study medication.

Select 'N' if the parent/guardian cannot be persuaded to resume giving the child study medication.

14. Based on parent/guardian response regarding satisfaction/dissatisfaction with medication child is receiving:

Select 'A' if parent/guardian is *very* satisfied with study medication.

Select 'B' if parent/guardian is satisfied with study medication.

Select 'C' if parent/guardian is indifferent about study medication.

Select 'D' if parent/guardian is dissatisfied with study medication.

Select 'E' if parent/guardian is *very* dissatisfied with study medication.

Select 'F' if the child does not take study medication.

15. Based on parent/guardian report of child's response to study medication:

Select 'A' if parent/guardian rates the taste of the medication as *very* pleasant.

Select 'B' if parent/guardian rates the taste of the medication as pleasant.

Select 'C' if parent/guardian rates the taste of the medication as neither pleasant nor unpleasant.

Select 'D' if parent/guardian rates the taste of the medication as unpleasant.

Select 'E' if parent/guardian rates the taste of the medication as *very* unpleasant.

NOTE on recording medication noncompliance: Use the following response set if the family, not the principal investigator, makes the decision to discontinue giving study medication to the participant. The participant's study medication status is 'On Study Medication' (response 'A' to item 8), respond 'N' to item 9 (today's dose), and ask the family to answer items 10-15 accordingly.

E. MEDICATION DISPENSING

16a. This question is answered by the study coordinator.

Select 'Y' if the medication is being returned at this contact.

Select 'N' if the medication is not being returned at this contact.

NOTE: If 'N' then complete MRF form.

16b. This question is answered by the study coordinator.

Select 'Y' if study medication is being dispensed at this contact.

Select 'N' if study medication is *not* being dispensed at this contact.

NOTE: If 'Y' then complete MDD form.

F. INTERIM VOIDING HISTORY

17. For this question, the term 'toilet-trained for urine' means that the child is out of diapers and pull-ups, and is wearing underwear *during the day*. This includes children who urinate in toilet/potty during the day, but still wear pull-ups at night or has occasional bowl movements in underwear during the day.

Select 'T' if child was toilet/potty-trained for urine since last study contact.

Select 'N' if child was is not toilet/potty-trained for urine.

Select 'P' if child was toilet/potty-trained for urine prior to the last study contact.

NOTE: If 'N or P' then go to question 19.

NOTE: The Participant Follow-up Summary Report in the DMS will include previous study report of toilet training.

18. Record the child's age in months when he/she began urinating in the toilet or potty by him/herself during the day. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If parent/guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).

G. INTERIM BOWEL HISTORY

19. For this question, the term 'toilet-trained for bowel movements' means that the child defecates in the toilet/potty during the day.

Select 'T' if child was toilet/potty-trained for bowel movements since last study contact.

Select 'N' if child was is not toilet/potty-trained for bowel movements.

Select 'P' if child was toilet/potty-trained for bowel movements prior to the last study contact.

NOTE: If 'N or P' then go to question 22.

NOTE: The Participant Follow-up Summary Report in the DMS will include previous study report of toilet training.

20. Record the child's age in months when he/she began defecating in the toilet or potty by him/herself during the day. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary. If parent/guardian response includes half a month, record the closest previous month (i.e. if guardian response is "24 and a half months" then record 24).

21. Since the child was toilet/potty trained for bowel movements:

Select 'Y' if the parent/guardian reports child has had multiple episodes of soiling his/her underwear with stool.

Select 'N' if the child does/did not have a history of soiling his/her underwear with stool.

22. Record the average number of times per week the parent/guardian reports child had bowel movements during the past 2 months. Acceptable values include whole numbers greater than 0. Insert leading zeros where necessary.

H. ADMINISTRATIVE INFORMATION

23. Record the date that this data was collected using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

24. Select 'C' if data from this form was originally captured through the DMS (on the computer). Select 'P' if data from this form was originally captured on paper.

25. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank

A	B	C

or

A	-	C

INFORMED CONSENT TRACKING FORM

ICT Version B, 3/18/10

QxQ

I. GENERAL INSTRUCTIONS

The Informed Consent Tracking Form (ICT) is completed during screening prior to randomization into the study. Modifications to consent or withdraw from the study are recorded using this form at any time during the study.

This form is an internal form and is not administered to the participant. The purpose of the form is to document and track in the RIVUR database the initial level of participant consent for the use of study data by the RIVUR investigators.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns as instructed on the form.

II. SPECIFIC INSTRUCTIONS

A. CONSENT STATUS

1. Select 'I' if this is this participant's initial consent.
   Select 'M' if this is a modification to the original consent made during the study.

2. Select 'F' if this is a full consent.
   Select 'P' if this is a partial consent (i.e. if there are restrictions on specimen collection).
   Select 'D' if this is a partial withdrawal of consent (i.e. adding new restrictions on specimen collection).
   Select 'W' if this is a full withdrawal of consent.

   NOTE: If 'W' then please specify other reason.
   NOTE: If 'F' or 'W' then go to item 14.

B. SPECIMEN CONSENT

3. Select 'Y' if there is a restriction on the use or storage of repository archived serum.
   Select 'N' if the parent/guardian consented to the use and storage of repository archived serum.

   NOTE: If 'N' then go to Item 5.

4a. Select 'Y' if there is a date restriction on the use or storage of serum.
   Select 'N' if there is *no* date restriction on the use or storage of serum.

   NOTE: If 'N' then go to Item 5.

4b. If 'Y' selected in item 4a. then provide date by which serum must be used, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

5. Select 'Y' if there is a restriction on the use or storage of genetics repository archived DNA.
   Select 'N' if the parent/guardian consented to the use and storage of genetics repository archived DNA.

NOTE: If 'N' then go to item 7.

6a. Select 'Y' if there is a date restriction on the use or storage of genetics repository archived DNA.
Select 'N' if there is *no* date restriction on the use or storage of genetics repository archived DNA.

NOTE: If 'N' then go to Item 7.

6b. If 'Y' selected in item 6a. then provide date by which DNA specimens must be used, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

7. Select 'Y' if there is a restriction on use or storage of biosample repository archived urine.
Select 'N' if the parent/guardian consented to the use and storage or repository archived urine.

NOTE: If 'N' then go to Item 9.

8a. Select 'Y' if there is a date restriction on the use or storage of repository archived urine.
Select 'N' if there is *no* date restriction on the use or storage of repository archived urine.

NOTE: If 'N' then go to Item 9.

8b. If 'Y' selected in item 8a. then provide date by which urine specimens must be used, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

C. MEDICAL RECORDS CONSENT

9a. Select 'Y' if parent/guardian has given permission to full access to medical records of the child.

Select 'N' if parent/guardian has not given permission to access medical records of the child.

Select 'P' if the parent/guardian has given permission to partial access to medical records of the child.

NOTE: If 'P' then please specify.

9b. Select 'Y' if parent/guardian has given permission to full access to medical records of the child for future research studies.

Select 'N' if parent/guardian has not given permission to access medical records of the child for future research studies.

Select 'P' if the parent/guardian has given permission to partial access to medical records of the child for future research studies.

NOTE: If 'P' then please specify.

10. Select 'Y' if the parent/guardian has given permission to full contact of informants.
    Select 'N' if the parent/guardian has not given permission to contact informants.
    Select 'P' if the parent/guardian has given permission to limited contact of informants.

    NOTE: If 'P' then please specify.

11. Select 'Y' if the parent/guardian has given permission to release study results to participant's physician.

    Select 'N' if the parent/guardian has not given permission to release study results to participant's physician.

    Select 'P' if the parent/guardian has given permission to partial release of study results to participant's physician.

    NOTE: If 'P' then please specify.

12. Select 'Y' if the parent/guardian has given permission to be contacted in the future for imminent research studies

    Select 'N' if the parent/guardian has not given permission to be contacted in the future for imminent research studies.

    Select 'P' if the parent/guardian has given limited permission to be contacted in the future for imminent research studies

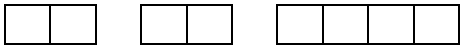
    NOTE: If 'P' then please specify.

13. Select 'Y' if there are restrictions other than those specified in items 3 through 9.
    Select 'N' if there are no other restrictions.

    NOTE: If 'Y' then please specify.

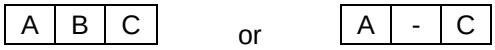
D. ADMINISTRATIVE INFORMATION

14. Record date of consent or modification using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

15. Select 'C' if data from this form was originally captured through the DMS (on a computer).
    Select 'P' if data from this form was originally captured on paper.

16. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

LIA QUESTIONNAIRE

LIQ Version A, 08/31/06

QxQ

I. GENERAL INSTRUCTIONS

This is a self administered questionnaire, to be completed by the parent/guardian at baseline, 12-months, and 24-months (end-of-study) follow-up.

This questionnaire can be administered with help, and must be used with an interpreter for families who do not speak English.

The Coordinator must complete the header information as they would any form, and be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

When completed, the Coordinator should review the questionnaire to make sure that all items have been completed appropriately.

II. SPECIFIC INSTRUCTIONS

The Coordinator should be familiar with MOP Chapter 4.5.3.3 addressing 'Challenges with Self Administered Questionnaires'. The coordinator should instruct the parent/guardian to start at the first question and work down through the form, completing all questions as best they can, reading all questions carefully, and circling their response choice.

Please let the parent/guardian know that you are able to help them if needed. It is acceptable to provide clarifications on words or questions within these forms when necessary. However, parents/guardians should be encouraged to respond based on personal experience and the way they think the answer best applies to themselves or their child. There is no right or wrong answer. Coordinators should remain accessible during their completing the questionnaire, while at the same time providing some confidentiality and privacy.

A. Parent/Guardian Response

1. This question lists a number of ways that parents may describe their child's behavior. For each of items 1a-1n, only one of the following options should be selected:

   Select 'N' if the child behaves this way Never or rarely

   Select 'S' if the child behaves this way Some of the time

   Select 'A' if the child behaves this way Almost always

2. Select the whole number circled (0-10), indicating how the parent/guardian rates the child's health over the last 2 weeks. If more than one number has been circled, urge the parent/guardian to select only one number.

3. Select the whole number circled (0-10), indicating how worried the parent/guardian is about the child's VUR. If more than one number has been circled, urge the parent/guardian to select only one number.

4. Select the whole number circled (0-10), indicating how it has been for the parent/guardian to administer study medication every day. If more than one number has been circled, urge the parent/guardian to select only one number.

NOTE: At the Baseline visit, Coordinators should instruct the parent/guardian to base his/her answer on the administration of medication for the index UTI. For the 12-month and End-of-Study visits, coordinators should instruct the parent/guardian to base his/her answer on the administration of the study medication.

5. Select the whole number circled (0-10), indicating how much of a financial burden the child's VUR has been for the family. If more than one number has been circled, urge the parent/guardian to select only one number.

6. Select the whole number circled (0-10), indicating how bothersome UTI symptoms were for the child. If more than one number has been circled, urge the parent/guardian to select only one number. WHAT IF NO UTI HAS OCCURRED SINCE THE LAST QUESTIONNAIRE? WHICH ONE ARE WE TALKING ABOUT?

7. Select the whole number circled (0-10), indicating how the parent/guardian rates the child's health during the urinary tract infection. If more than one number has been circled, urge the parent/guardian to select only one number.
   WHAT IF NO UTI HAS OCCURRED SINCE THE LAST QUESTIONNAIRE? WHICH ONE ARE WE TALKING ABOUT?

8. Select the whole number circled (0-10), indicating how much discomfort the child experienced during the last ultrasound. If more than one number has been circled, urge the parent/guardian to select only one number.
   WHAT IF NO ULTRASOUND HAS OCCURRED SINCE THE LAST QUESTIONNAIRE? WHICH ONE ARE WE TALKING ABOUT?

9. Select the whole number circled (0-10), indicating how much discomfort the child experienced during the last VCUG. If more than one number has been circled, urge the parent/guardian to select only one number.
   WHAT IF NO VCUG HAS OCCURRED SINCE THE LAST QUESTIONNAIRE? WHICH ONE ARE WE TALKING ABOUT?

10. Select the whole number circled (0-10), indicating how much discomfort the child experienced during the last DMSA. If more than one number has been circled, urge the parent/guardian to select only one number.
    WHAT IF NO DMSA HAS OCCURRED SINCE THE LAST QUESTIONNAIRE? WHICH ONE ARE WE TALKING ABOUT?

B. ADMINISTRATIVE INFORMATION

Questions 11 and 12 are to be completed by the study coordinator or study personnel who reviewed the completed LIQ

11. Record date the LIQ was completed by parent using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Record the initials of the person who reviewed the completed LIQ. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

MEDICAL CARE ABSTRACTION FORM

MCA Version C, 01/21/10

QxQ

I. GENERAL INSTRUCTIONS

The Medical Care Abstraction Form (MCA) is completed as needed throughout the study, based on a the medical records and chart review on the medical care visit documented on the associated MCN form (matching MCID numbers).

This form can be completed on paper first or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS. If any data are permanently unobtainable, fill field entirely with equal signs (=).

II. SPECIFIC INSTRUCTIONS

A. TRACKING / ADMINISTRATIVE

1. Record the MCID number from the associated Medical Care Notification (MCN) form. If completing a paper form, please use the pre-printed MCID label provided by the DCC.

2. Record the date of the medical care visit using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

3. Select 'Y' if this is a follow-up visit to a previously reported medical visit. (A follow-up visit would be a medical care visit that is following up on a previous visit for the same event/diagnosis.)

   Select 'N' if this is not a follow-up visit to a previously reported medical visit.

   NOTE: If 'N' go to item 6.

4. Record the date of the previously reported medical care visit (for which THIS visit is a follow-up) using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

   If this visit is related to multiple previous visits, enter the date of the related visit that occurred most recently prior to this event.

5. Record the MCID number from the previously reported visit (for which THIS visit is a follow-up). If this visit is related to multiple previous visits, enter the MCID of the related visit that occurred most recently prior to this event.

6. Select 'O' if coordinator has obtained access to the medical chart.
   Select 'P' if access to the medical chart is pending.
   Select 'N' if there is no possibility of every accessing the chart.

   NOTE: If 'P' or 'N' then go to item 33.

B. HOSPITALIZATION

7a. Select 'Y' if this is was a hospitalization or an ER visit.
   Select 'N' if this is was neither a hospitalization nor ER visit
   (Admissions for outpatient procedures should not be considered hospitalizations.)

   NOTE: If 'Y' then complete AEF

   NOTE: If 'N' then go to item 12

7b. Select 'E' if the particpant visited the emergency room
   Select 'H' if the participant was hospitalized
   Select 'O' if other
   NOTE: If 'O' then specify (complete notelog in DMS)

8. Record the date of discharge from the hospital or ER (for non-fatal cases), or the date of death using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

   If transferred to another hospital or medical facility, then enter the date the transfer occurred.

9. Select the item that best describes the disposition of the patient at discharge. Select only one of the following:
   Select 'H' if the patient was discharged to home.
   Select 'E' if the patient was admitted to the Hospital from the ER.
   Select 'T' if the patient was transferred to another hospital.
   Select 'M' if the patient was transferred to another medical care facility (e.g. rehab).
   Select 'D' if the patient was deceased.

   NOTE: If 'H' 'E' 'T' or 'M' then go to item 12.

10. Select 'Y' if the discharge summary or medical record lists the cause/causes of death.
   Select 'N' if no cause of death is listed on the discharge summary or medical record.

   NOTE: If 'N' then go to item 12.

11. For items 11a-11f, record the causes of death listed on the discharge summary. Record them in the order that they appear on the discharge summary, beginning with item 11a. Record only one cause per line/field. If there are more than 6 causes listed on the discharge summary, please open a DMS notelog on item 11f and continue listing the reported causes.

C. REASON FOR MEDICAL CARE / DIAGNOSIS (for all medical care abstractions including hospitalizations)

12. Select 'Y' if this medical visit included a work-up for suspected UTI.
    Select 'N' if this medical visit did not include a work-up for suspected UTI.
    NOTE: If 'N' then go to item 14.

13. Record the date that the **first** urine specimen was collected for suspected UTI work-up using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

    This date will be an important date of reference for symptom and fever questions later in the form. This date may also be referred to as the beginning of a work-up for a suspected UTI.

14. Select 'Y' if there are ICD diagnosis codes listed in the medical record.
    Select 'N' if there are no ICD diagnosis codes listed in the medical record.
    NOTE: If 'N' go to item 17.

15. For items 15a-15n, record the diagnosis codes associated with this medical care visit. For hospitalizations, record the hospital discharge diagnosis codes exactly as they appear on the front sheet of the discharge summary. For other visits, list any diagnosis codes provided in the medical record. List one code per item, beginning with item 14a. Leave blank any code fields that you do not need. If more than 14 codes are present, please open a DMS notelog on item 14n and continue listing the diagnosis codes.

16. Indicate the coding system used to code the diagnosis/diagnoses.
    Select 'A' for ICD-9 coding.
    Select 'B' for ICD-10 coding.

17. For items 17a-17n, record the text diagnosis descriptions found in the medical record. (Note: these will not necessarily match one-to-one with the diagnosis codes in item 14, as there are often numerous codes listed for one text description.) Leave blank any descriptor fields that you do not need. If more space is required, please open a DMS notelog on item 17n and continue the descriptors.

D. SYMPTOMS

18. Select 'Y' if the medical record mentions either a patient complaint or a medical finding for any of the symptoms listed in item 19.
    Select 'N' if the medical record does not mention a patient complaint or a medical finding for any of the symptoms listed in item 19.
    NOTE: If 'N,' go to item 22.

19. The purpose of this item is to capture data on study-relevant symptoms recorded in the medical records for this medical care visit. For each of items 19a-19g indicate (1) whether the symptom was documented as a patient complaint, (2) whether the symptom was

documented as a medical finding, (3) the duration of the symptom in days, and (4) if the symptoms occurred within 24 hours of medial visit or work-up for suspected UTI:

For columns 1 and 2:

Select 'Y' if the symptom was documented as occurring.

Select 'N' if the symptom was documented NOT occurring.

Select 'U' if it is unknown whether or not the symptom occurred.

Select 'X' if not applicable (for example, child was aged over 4 months at time of visit)

(Note: if N, U, or X is selected in column 1 and 2, then skip columns 3 and 4.)

For column 3:

Enter the total number of days the child experienced the symptoms:

≤24 hours = 1 day

25-48 hours = 2 days

49-72 hours = 3 days

(etc.)

For column 4:

In this question, we're looking for any symptoms that occurred within 24 hours of the date of first urine collection for suspected UTI (**item 13**), or if no urine collected, then within 24 hours of the medical care visit date (item 2).

Select 'Y' if the symptom occurred within 24 hours of the date specified in **item 13** (or item 2, if not a suspected UTI).

Select 'N' if the symptom did NOT occur within 24 hours of the date specified in **item 13** (or item 2, if not a suspected UTI)**.**

Select 'U' if it is unknown whether or not the symptom occurred with 24 hours of the date specified in **item 13** (or item 2, if not a suspected UTI).

20. Record the date that the medical record indicates the first symptom associated with this event began, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

21. In this question, we're looking for any medications that were administered within 24 hours of the date of first urine collection for suspected UTI (**item 13**), or if not a suspected UTI, then within 24 hours of the medical care visit date (item 2).

Select 'Y' if any medications given to the child for symptoms within 24 hours of the medical visit or work-up for suspected UTI.

Select 'N' no medications were given to the child for symptoms within 24 hours of the medical visit or work-up for suspected UTI.

Select 'U' if medications give to the child for symptoms within 24 hours of the medical visit or work-up for suspected UTI are undocumented.

NOTE: If 'Y,' then list medications in a notelog and remember to also list the medication(s) on the next CMF form.

E. FEVER

22. Select 'Y' if the medical records mention any fever associated with this event.
Select 'N' if the medical records do not mention any fever associated with this event.

NOTE: If 'N' then go to item 26.

23a. Select 'Y' if a temperature was taken during the medical visit.
Select 'N' if a temperature was not taken during the medical visit.

NOTE: If 'N,' go to item 24.

23b. Record the highest temperature measured during the medical visit.

23c. Select corresponding units for temperature recorded in item 23b (select only one).
Select 'F' if °Fahrenheit.
Select 'C' if °Celsius.

23d. Indicate how the temperature captured in item 23b was measured.
Select 'O' if temperature was measured in the mouth (orally).
Select 'A' if temperature was measured under the arm (axillary).
Select 'T' if temperature was measured in the ear (tympanic).
Select 'R' if temperature was measured in the rectum (rectal).
Select 'F' if temperature was measured with a temporal device (forehead).
Select 'U' if measurement route is unknown.

24a. Select 'Y' if the medical record indicates that the child was having a fever of at least 100.4˚F or 38˚ C at any time prior to the medical visit.

Select 'N' if the medical record indicates that the child did NOT have a fever of at least 100.4˚F or 38˚ C at any time prior to the medical visit.

Select 'U' if it is unclear whether or not the child had a fever of at least 100.4˚F or 38˚ C at any time prior to the medical visit.

NOTE: If 'N' or 'U,' go to item 26.

24b. Record the highest temperature measured prior to the medical visit.

24c. Select corresponding units for temperature recorded in item 24b (select only one).
Select 'F' if °Fahrenheit.
Select 'C' if °Celsius.

24d. Indicate how the temperature captured in item 24b was measured.
Select 'O' if temperature was measured in the mouth (orally).
Select 'A' if temperature was measured under the arm (axillary).
Select 'T' if temperature was measured in the ear (tympanic).

Select 'R' if temperature was measured in the rectum (rectal).
Select 'F' if temperature was measured with a temporal device (forehead).
Select 'U' if measurement route is unknown.

24e. Record the date of the highest fever prior to the medical visit using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

25a. Select 'Y' if the medical record indicates that the child had a fever of at least 100.4˚ F or 38˚ C at any time within 24hr prior to the beginning of medical workup (within 24 hours of the date specified in **item 13** [or item 2, if not a suspected UTI]).

Select 'N' if the medical record indicates that the child did NOT have a fever of at least 100.4˚F or 38˚ C at any time within 24hr prior to the beginning of medical workup (within 24 hours of the date specified in **item 13** [or item 2, if not a suspected UTI]).

Select 'U' if it is unclear whether or not the child had a fever of at least 100.4˚F or 38˚ C at any time within 24hr prior to the beginning of medical workup (within 24 hours of the date specified in **item 13** [or item 2, if not a suspected UTI]).

NOTE: If 'N' or 'U,' go to item 26.

25b. Record the highest temperature measured within 24hr prior to the workup.

25c. Select corresponding units for temperature recorded in item 24a (select only one).
Select 'F' if °Fahrenheit.
Select 'C' if °Celsius.

25d. Indicate how the temperature was measured within 24hr prior to the workup.
Select 'O' if temperature was measured in the mouth (orally).
Select 'A' if temperature was measured under the arm (axillary).
Select 'T' if temperature was measured in the ear (tympanic).
Select 'R' if temperature was measured in the rectum (rectal).
Select 'F' if temperature was measured with a temporal device (forehead).
Select 'U' if measurement route is unknown.

25e. Record the date of the highest fever within 24hr prior to the workup using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

26. Select 'Y' if any antipyretics were given to the child within 24 hours of the medical visit or work-up for the suspected UTI.

Select 'N' if antipyretics were not given to the child within 24 hours of the medical visit or work-up for the suspected UTI.

Select 'U' if it is undocumented whether or not the child was given antipyretics within 24 hours of the medical visit or work-up for the suspected UTI.

NOTE: If 'Y,' then list medications in a notelog and remember to also list the medication(s) on the next CMF form.

F. WEIGHT

27. Select 'Y' if a weight measure was recorded.
Select 'N' if a weight measure was not recorded.

NOTE: If 'N' go to item 30.

28a. For item 28a, record the child's weight, inserting leading zeros where necessary

28b. Record the units used to measure the child's weight.
Select 'K' for kilograms.
Select 'P' for pounds.

29. Record the date weight was measured using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

G. URINALYSIS

30. Select 'Y' if a urinalysis or urine culture was performed during the medical care visit.
Select 'N' if neither a urinalysis nor a urine culture was performed during the medical care visit.

NOTE: If 'N' go to item 32.

31. Record the number of urinalysis/urine culture reports that are associated with this medical visit or admission. Whole numbers only, insert leading zeros as necessary.

NOTE: Complete a USR form for each urinalysis or urine culture performed during this medical visit, noting the MCID associated with this form. Report only urinalysis results from urine collected during the medical visit.

H. MEDICAL PROCEDURES / IMAGES:

32a. Select 'Y' if long-term urethral catheterization (such as Foley Cath) was performed at this visit.
Select 'N' if long-term urethral catheterization (such as Foley Cath) NOTE performed during this visit.

NOTE: In this item, we are not talking about short-term catheterization for urine collection.

NOTE: If 'N' then go to item 32d.

32b. Record the date of the urethral catheterization, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

32c. Record the number of days the patient remained catheterized. A day is a 24 hour period. Whole numbers only, round up to the nearest day.

32d. Select 'Y' if renal and/or bladder ultrasound was performed at this visit.
Select 'N' if renal and/or bladder ultrasound was not performed during this visit.
NOTE: If 'N' then go to item 32f.

32e. Record the date of the renal bladder ultrasound, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

32f. Select 'Y' if a VCUG was performed at this visit.
Select 'N' if a VCUG was not performed during this visit.
NOTE: If 'N' then go to item 32h.

32g. Record the date of the VCUG, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

32h. Select 'Y' if DMSA was performed at this visit.
Select 'N' if DMSA was not performed during this visit.
NOTE: If 'N' then go to item 32j.

32i. Record the date of the DMSA, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

32j. Select 'Y' if there was a procedure it correct VUR
Select 'N' if there was not a procedure to correct VUR
NOTE: If 'N' then go to item 33

32k. Record the date of the procedure using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

32l. Record the name of the procedure.

I. Administrative Information

33. Record date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

34. Select 'C' if data from this form was originally captured through the DMS (using a computer). Select 'P' if data from this form was originally captured on paper.

35. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

MEDICAL CARE NOTIFICATION FORM

MCN Version D, 02/23/10

QxQ

I. GENERAL INSTRUCTIONS

The Medical Care Notification Form (MCN) is completed as needed throughout the study whenever medical care is reported or received (including in-clinic RIVUR sick visits). The only medical visit that does not initiate a MCN form is a standard RIVUR protocol follow-up visit where no medical care is provided.

This form is completed based on parent/guardian response to the items as they relate to the event associated with the medical care visit reported. A question has been added to the D version that allows the site to record if another source besides the parent provides information about medical care.

Each MCN form will also have a corresponding MCA form completed based on medical record abstraction associated with the visit being reported in the MCN.

Each individual MCN form is assigned an MCID number from the labels provided by the DCC. This number is used on the corresponding MCA form, as well as any other forms or documents that are associated with the medical care reported in the MCN form (which could include AEF, USR, DDF and/or any source documentation requested by the DCC).

Please review the rules for Contact Occasion and Sequence Number assignment described in the MOP chapter 13.6.2.3, see example on tables 13.2 and 13.3.

This form can be completed on paper first or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. MEDICAL CARE INFORMATION

1. Record the MCID number you are assigning to this medical care visit. Please assign MCIDs in numerical order from lowest to highest number. If completing a paper form, please use the pre-printed MCID label provided by the DCC. Each MCN form is assigned a unique MCID number.

2. Record the date of the medical care visit using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

NOTE: On the paper form only, record the name and address of the physician/clinic that provided the medical care. This is not data entered.

3a. Indicate the type of medical care visit for which this form is being completed.

Select ‘A’ for RIVUR Clinic, skip to item 3c.

Select ‘B’ for other clinic or health care center (such as urgent care) , skip to item 3c.

Select ‘C’ for a private doctor’s office, skip to item 3c.

Select ‘D’ for a hospital outpatient department, skip to item 3c.

Select ‘E’ for an emergency room.

Select ‘F’ for hospitalization.

Select 'G' for other location, skip to item 3c.

NOTE: If 'G' then specify other location in a DMS notelog.

NOTE: If 'E' then complete AEF form.

NOTE: If 'F' then complete AEF form.

3b Indicate if the participant was hospitalized or visited the emergency room. Select only one option.

Select 'E' if the participant visited the emergency room.

Select 'H' if the participant was hospitalized.

Select 'O' if other.
NOTE: If 'O' specify in Notelog

3c. Indicate if it is the family who is providing information about the medical visit.
Select 'Y' if the family is providing information about the medical care visit.
Select 'N' if the family is not providing information about the medical care visit.
NOTE: If 'N,' go to item 8 and 23-25.

4. Select 'Y' if urine was collected at this medical visit.
Select 'N' if urine was not collected at this medical visit.
NOTE: If 'N,' go to item 6.

5. Select 'Y' if the parent/guardian was informed that a UTI was/is suspected or diagnosed at this reported visit.
Select 'N' if the parent/guardian was not informed of a suspected diagnosed UTI during this reported visit.
If unknown, then enter '='.

6. Select 'Y' if the medical visit was a well-child visit (i.e. vaccination visit, routine physical exam) where no symptoms were reported, no fever, and no medication prescribed.
Select 'N' if this was not a well-child visit, or if symptoms were present, fever was present or medication prescribed.

NOTE: If 'Y' then go to item 20.

Remember, if urine and/or blood specimens were collected, you need to complete a matching USR and/or BSR form for this participant/MCID.

7. Select 'Y' if the child was refers to another physician or specialist.
Select 'N' if the child was not referred to another physician or specialist.
NOTE: If 'Y,' record the MD name in a notelog. This will require another MCN to be entered.

8. For this question, please refer to the RIVUR study definition of an adverse event, located in Chapter 9.3.1 of the RIVUR MOP. In this study, a UTI is not considered an adverse event.

Select 'Y' if the illness or reason for the reported visit fits the definition for a RIVUR study adverse event.

Select 'N' if the illness or reason for the reported visit does not fit the definition of a RIVUR study adverse event.

NOTE: If 'Y' then complete an AEF.

B. FEVER

9. Select 'Y' if the parent/guardian reported that the child had experienced a fever at any time during the illness/event that resulted in the reported medical visit.
   Select 'N' if the parent/guardian reported that the child did not experience a fever at any time during the illness/event that resulted in the reported medical visit.

   NOTE: If 'N' then go to item 15.

10a. Record the highest temperature the parent/guardian reported occurring during the event resulting in the reported medical visit, inserting leading zeros where necessary.

10b. Select corresponding units for temperature recorded in item 10a (select only one).
   Select 'F' if °Fahrenheit.
   Select 'C' if °Celsius.

11. Record the date of the highest temperature reported in question 10, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Record the time that the highest temperature was taken, using the 24 hour clock format. The 24-hour clock is a convention of time-keeping in which the day runs from midnight (00:00) to midnight and is divided into 24 hours, numbered from 0 to 23; the last minute of the day is that beginning at 23:59. For example if blood is drawn at 2:34 pm then it would be entered as:

1	4	:	3	4

13. Select the temperature measurement route for the temperature recorded in item 10:
   Select 'O' if temperature was measured in the mouth (orally).
   Select 'A' if temperature was measured under the arm (axillary).
   Select 'T' if temperature was measured in the ear (tympanic).
   Select 'R' if temperature was measured in the rectum (rectal).
   Select 'F' if temperature was measured with a temporal device (forehead).
   Select 'U' if measurement route is unknown.

14a. Record the date the fever started. This should be the date of the very first reported temperature measured during this event, regardless of administration of fever-reducing over-the-counter medicines. Use the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

14b. Record the duration in hours of fever prior to treatment. Duration should be measured from the time of the first reported temperature until antimicrobial treatment was initiated for the cause of the fever. If treatment not yet initiated, then record the time from first reported temperature to time when medical care was reported. Whole numbers only, round to the nearest hour.

15. Select 'Y' if the child was given any antipyretics within 24 hours prior to the medical visit or work-up for suspected UTI.

Select 'N' if the child was not given any antipyretics within 24 hours prior to the medical visit or work-up for suspected UTI.

Select 'U' if it is unknown whether the child was given any antipyretics within 24 hours prior to the medical visit or work-up for suspected UTI.

Note: If 'Y,' list the medications in a notelog. Also remember to list the medications on the CMF for the next scheduled study contact.

C. HISTORY OF SYMPTOMS

16. For this item, ask the parent/guardian about each of the symptoms listed in item 17.

    Select 'Y' if the parent/guardian reported that the child had any of the symptoms listed in Item 17.

    Select 'N' if the parent/guardian does not report that the child had any of the symptoms listed in Item 17.

    Note: If 'N' then go to item 20.

17. The purpose of this item is to capture data about the study-relevant symptoms that the parent/guardian reported occurred during the event which resulted in this medical care visit. For each of items 17a-17g indicate (as described below):

    1. Did the symptom occur?

       Select 'Y' if the symptom was present.

       Select 'N' if the symptom was not present.

       Select 'U' if unknown.

       Select 'X' if not applicable (for example, child was aged over 4 months at time of visit)

       NOTE: If patient was more than 4 months old at the time of the visit, then items 15e-15g should be coded 'X'.

       Note: if N, U, or X selected in column 1, then skip columns 2 and 3.

    2. What was the duration of the symptom?

       Record the duration in DAYS of symptoms prior to treatment. Duration should be measured from the time the first symptom first occurred until antimicrobial treatment was initiated for the cause of the cause of the symptom. If treatment not yet initiated, then record the time from when the symptom first occurred to time when medical care was reported. Whole numbers only, round to the nearest hour.

    3. Did the symptom occur within 24 hours of the medical care visit?

       Select 'Y' if the symptom occurred within 24 hours of the medical visit.

       Select 'N' if the symptom did NOT occur within 24 hours of the medical visit.

       Select 'U' if unknown.

18. Record the date the first symptom started, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

19. Select 'Y' if the parent/guardian reported giving the child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI.

Select 'N' if the parent/guardian did not report giving the child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI.

Select 'U' if the parent/guardian's report of giving the child any medications for symptoms within 24 hours prior to the medical visit or work-up for suspected UTI is undocumented.

Note: If 'Y,' list the medications in a notelog. Also remember to list the medications on the CMF for the next scheduled study contact.

D. STUDY MEDICATION

20a. In this question we want to know if the study medication was discontinued temporarily by ANYONE during this medical care visit. This includes RIVUR Investigators, primary care physicians, etc.

Select 'Y' if the parent/guardian reported study medication was temporarily discontinued during this event.

Select 'N' if the parent/guardian reported study medication was not discontinued during this event.

NOTE: If 'N' then go to item 21a.

20b. Record the number of days that parent/guardian reported study medication was discontinued. Whole numbers only, round up to the nearest whole day.

Note: If a **RIVUR Investigator** discontinued study medication (temporarily or permanently), then a DDF form should be completed. The DDF form is not used for discontinuations instigated by a parent/guardian or other care physician, unless authorized by a study Investigator.

E. RESOURCE UTILIZATION

21a. Select 'Y' if the parent/caregiver reported missing work due to this illness/event.
Select 'N' if the parent/caregiver reports not having to miss work during this illness/event.

NOTE: If 'N' then go to item 22a.

21b. Record the total number of work days missed by all parents/caregivers. Whole numbers only, round up to the nearest whole day.

22a. Select 'Y' if the parent/caregiver reported alternate child care arrangements had to be made during this illness/event.
Select 'N' if no alternate child care arrangements had to be made during this illness/event.

NOTE: If 'N' then go to item 23.

22b. Record the total number of work days that alternate child care was needed. Whole numbers only, round up to the nearest whole day.

F. ADMINISTRATIVE INFORMATION

23. Record date this form was completed using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

24. Select 'C' if data from this form was originally captured through the DMS (using a computer).
Select 'P' if data from this form was originally captured on paper.

25. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

MEDICATION DOSING AND DISPENSING FORM

MDD Version B, 05/11/2010

QxQ

I. GENERAL INSTRUCTIONS

The Medication Dosing and Dispensing Form (MDD) is completed every time study medication is to be dispensed to the participant. The form is used for scheduled and unscheduled dispensing of study medication and will yield the dose of study medication and the codes of the bottles to be dispensed to the participant. The participant's weight must be known to complete the MDD.

The study medication dose should stay the same for 6 months in accordance with the clinic visit schedule. There will be occasions when the participant has not been seen in the clinic and the family needs medication. The best solution for unscheduled dispensing is a clinic visit so that a weight measurement can be done, but in the instance where the family contacts the clinic by telephone and the latest measured weight for the participant was done more than 6 months ago, then adjust the child's weight by either asking the parents for a weight measurement done since the last clinic visit and/or estimate the child's weight from the 2000 CDC Growth Curves (Advance Data No. 314 Dec 4, 2000). See Chapter 6 in the RIVUR Manual of Procedures (MOP) for details on estimating weights.

This form can be completed on paper, but must be entered into the RIVUR DMS to provide the prescribed dose and assigned bottle codes. The recorder must be familiar with Chapter 13 and 14 in the MOP. Complete only the appropriate questions. Be sure to follow the correct skip patterns as instructed on the form.

Recall the following helpful DMS keystrokes:

1. F11 will enlarge the viewing screen. Pushing F11 again will reduce the viewing screen.

2. The DMS screen should say 'Add Mode' for the user to be able to enter data into the MDD. The MDD automatically saves and locks following entry of the user's initials in item 16. There is no way to return to the MDD and edit data after the form is locked.

3. To set an unskipped, empty field to unresolvable, fill the entire field with '=' signs OR cursor to the unresolved field and enter CTRL+U.

4. To confirm a valid value in a field where the number entered failed the edit check, enter the value and then enter CTRL+C. There are many fields in the MDD that will not allow the user to confirm invalid data.

5. To add a note (notelog) to any field, enter CTRL+G, add your note, and then save the notelog by entering ALT+S.

II. SPECIFIC INSTRUCTIONS

A. TIMING OF MEDICATION DISPENSING

1. Select ‘U’ if the participant needs study medication and the contact is unscheduled.
   Select ‘S’ if this is a protocol-scheduled contact and study medication is being dispensed.

   NOTE: If ‘S’ then go to item 9.

B. UNSCHEDULED CONTACT

2. Record the number of months before the next in-clinic follow-up visit. The participant should return to the clinic one time each 6 months.

3. Select ‘T’ if the unscheduled visit is occurring by telephone.

Select 'C' if the unscheduled visit is occurring in the clinic. If the visit is in the clinic, complete and enter the PEF prior to the MDD.

NOTE: If 'C' then go to Item 9.

C. TELEPHONE CONTACT

4a. Record the child's last known measured weight if the DMS has not already filled the data field automatically. The last known measured weight may be retrieved using the Measured Weight of Participant DMS report. Round to the nearest tenth, inserting leading zeros where necessary.

4b. Select corresponding units for the weight recorded in item 4a.

Select 'K' for kilograms.
Select 'P' for pounds.

5. Record the date of the last known measured weight if the DMS has not already pre-filled the data field. Use the mm/dd/yyyy format and insert leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

6. Select 'Y' if the number of months between the last weight measurement and the next clinic visit will exceed 6 months.
Select 'N' if the number of months between the last weight measurement and the next clinic visit is less than 6 months.

NOTE: If 'N' then go to item 10.

7a. Record the child's current weight as reported by the parents OR estimated from the CDC Growth Curve. Round to the nearest tenth, inserting leading zeros where necessary.

7b. Select corresponding units for the weight recorded in item 7a.

Select 'K' for kilograms.
Select 'P' for pounds.

8. Select 'P' if the parent measured the recorded weight.

Select 'G' if the participant's weight was estimated from the CDC Growth Curve. See the Unscheduled Dispensing section in chapter 6 of the RIVUR MOP for instructions on how to estimate weight from the CDC Growth Curve.

NOTE: If 'P' or 'G' then go to Item 10.

D. CLINIC CONTACT

9a. Record the child's measured weight if the DMS has not already filled the data field automatically. This weight must be the same as recorded on the PEF in Item 10a. Round to the nearest tenth, inserting leading zeros where necessary.

9b. Select corresponding units for the weight recorded in item 9a.

Select 'K' for kilograms.

Select 'P' for pounds.

E. DISPENSING

10. Select 'Y' if the beginning items are correct and you are ready to run the dosing algorithm.

    Select 'N' if the beginning items need review or you are not ready to run the dosing algorithm. A no answer will automatically take you to the administrative section of the form.

    NOTE: If 'N' then go to Item 14.

11. The dose that is calculated by the DMS specific for the child's weight will be displayed automatically in the data field.

12. The number of bottles to be dispensed to the participant will be displayed automatically in the data field.

13. The bottle codes assigned to the participant will be displayed automatically in the data fields (a-i). The number of codes displayed will equal the number shown in item 12.

F. ADMINISTRATIVE INFORMATION

14. Record date of drug distribution using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

15. Select 'C' if data from this form was originally captured through the DMS (on a computer). Select 'P' if data from this form was originally captured on paper.

16. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

PHYSICAL EXAM FORM

PEF Version B, 09/18/12

QxQ

I. GENERAL INSTRUCTIONS

The Physical Exam Form is completed at the baseline clinic visit, and all protocol-scheduled clinic follow-up visits. This form is completed based on observations during a brief physical exam of the participant performed by a study MD. For follow-up clinic visits, the DMS Participant Follow-up Summary Report will contain a summary from previous exam data, including status of circumcision (if male), and previous participant weight.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. PHYSICAL EXAM

1. Select 'C' if the child is male and circumcised.

   Select 'U' if the child is male and uncircumcised.

   Select 'R' if the child is male and circumcision was reported at earlier study contact (see DMS follow-up report for this information, provided so you do not have to ask the question).

   Select 'F' if the child is female.

   NOTE: This question must be confirmed by physical examination.

   NOTE: If 'U', 'R', or 'F' then go to item 4.

2 Record date of circumcision using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

3. Record the child's age in months, according to parent/guardian report, at the time of circumcision. Round down to the nearest whole month. For example if child was circumcised at age 1 month and 2 weeks, enter '01'. Enter whole numbers only, inserting leading zeros where necessary.

4a. Record the child's current temperature, inserting leading zeros where necessary.

4b. Select corresponding units for temperature recorded in item 1a.
   Select 'F' if °Fahrenheit.
   Select 'C' if °Celcius.

5. Select the temperature measurement route.
   Select 'O' if temperature was measured in the mouth (orally).
   Select 'A' if temperature was measured under the arm (axillary).
   Select 'T' if temperature was measured in the ear (tympanic).
   Select 'R' if temperature was measured in the rectum (rectal).
   Select 'F' if temperature was measured with a temporal device (forehead).
   Select 'U' if measurement route is unknown.

6. Indicate whether the child showed signs of pain or tenderness during the examination in each area specified. For each of items 3a-3c…

   Select 'Y' if the child showed signs of pain or tenderness in the specified area.
   Select 'N' if the child did not show any signs of pain or tenderness in the specified area.

7. Response to the question "Is the child experiencing dysuria today" is based parental/guardian response, or observation during the study visit. Dysuria is defined as painful or burning sensation making urination difficult.

   Select 'Y' if the child is experiencing dysuria during the day of the exam.
   Select 'N' if the child is not experiencing dysuria during the day of the exam.

8. Response to the question "Does the child have foul-smelling urine today" is based on parental/guardian response, or observation during the study visit.

   Select 'Y' if the child had foul smelling urine during the day of exam.
   Select 'N' if the child did not have foul smelling urine during the day of the exam.

9a. Record the systolic blood pressure (mmHg), inserting leading zeros when necessary.

9b. Record the diastolic blood pressure (mmHg), inserting leading zeros when necessary.

10a. Record the child's weight on day of the physical exam. Round to the nearest tenth, inserting leading zeros where necessary.

10b. Select corresponding units for the weight recorded in item 10a.

   Select 'K' for kilograms.
   Select 'P' for pounds.

11a. Record child's length (infants) or height (toddlers and older) on the day of physical exam. Round to the nearest tenth, inserting leading zeros where necessary.

11b. Select corresponding units for length/height recorded in item 11a.

   Select 'C' for centimeters.
   Select 'I' for inches.

B. ADMINISTRATIVE INFORMATION

12. Record date of the physical exam using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

13. Select 'C' if data from this form was originally captured through the DMS (on the computer).
    Select 'P' if data from this form was originally captured on paper.

14. Record the initials of the person who examined the participant. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

15. Record the initials of the person who recorded the data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

PARTICIPANT SCREENING LOG

PSL Version B, 02/08/08

QxQ

I. GENERAL INSTRUCTIONS

The Participant Screening Log documents the final eligibility determination of patients screened as potential RIVUR participants. A screened patient is defined as a child identified as having had a UTI (not based on the RIVUR protocol definition), and for whom some action and effort occurred at the site to assess further eligibility (i.e. going into a computer system to look at results, talking to primary physician, interacting with radiology, etc…).

Once each participant has completed screening and/or their eligibility and enrollment status has been determined, a row on the PSL should be completed. Note: A participant pending enrollment will have incomplete data on this form, and should not be entered into the DMS until their enrollment status (randomization or determination of ineligibility) is finalized.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures. The PSL form is data entered as a multi-line form. This is described in the DMS User's Guide Chapter 14 of the MOP, in section 14.4.11, page 14-14.

II. SPECIFIC INSTRUCTIONS

Header:

- Site ID: Record clinic site ID number, which is comprised of the two-letter site abbreviation, followed by five zeros. For example: NY00000
- Contact Occasion/Seq#: CO does not associate to a study time period for this form. Use CO='00' and SEQ# ='00' for the first PSL form completed. SEQ# will increase with each new PSL until SEQ# =99. At that time the CO increases to '01' and SEQ# starts at '00' to '99'. This will continue throughout the study.

Special Instructions:

- Since this form enumerates patients who are considered for participation, and who may never be consented or enrolled, no participant identifiers are collected for entry into the study database, and therefore participant confidentiality is kept in compliance with federal and IRB regulations.
- Some IRBs may not allow the collection of age, gender, ethnicity, or race on potential participants prior to consenting. If you site does not allow this collection, please enter these fields as permanently missing "==".
- The PSL forms are to be data entered into the RIVUR DMS at the end of each week, to ensure that all screened patients are counted in study reports.
- You do not need to complete all 10 lines of each PSL page before entering the data, or before beginning a new CO or SEQ#.
- For convenience, we have included up to 3 pages (30 screenings) for each unique (CO and SEQ#).

Data Fields:

1. Line #:

   Line numbers are precoded on the PSL form, but need to be data entered into the DMS. If a line is corrected or skipped, this is okay. The line numbers are there so if a query is made from the DCC, we can refer you to the correct form using the Contact Occasion, Seq # and line number on the form.

2. Referral Source:
   Record the referral source of this potential participant using the codes provided at the bottom of each page. If there is another referral source not listed in the code list, choose other (code=G) and enter the source in the notelog.

3. Gender:
   Record the child's gender. Enter "M" for male, and "F" for female.

4. Race Code:
   Using the codes provided at the bottom left of the form, record the one code that best describes the potential participant's race. If multi-racial, select "F = Other or Mixed" then enter a notelog in the DMS to record the races. Please note: according to NIH guidelines, people of Hispanic ethnicity should be considered "white" unless they are of African descent.

5. Ethnicity Code:
   Record the potential participant's ethnicity (Hispanic or non-Hispanic) using the codes provided at the bottom of the form.

6. UTI per Protocol:
   Enter "Y" if the UTI meets the RIVUR protocol definition for an study index UTI, "N" if the event is a UTI but does not meet RIVUR UTI definitions, enter 'U' if you do not have the information about the UTI to know if it meets the definition or not. Note: Each child recorded as screened on this PSL form must have had a clinical or suspected UTI.

7. (a-b) If not UTI per Protocol, Why?:
   This question is skipped if the answer to # 6 above is "Y" or "U". Otherwise, record up to two reasons from the codes listed at the bottom of the form that explain why the UTI did not meet the RIVUR UTI protocol definition/requirements for eligibility. Codes are listed in a suggested priority. The DCC will occasionally update the code listing as needed for the study.

   If there is another reason that the UTI failed to meet RIVUR protocol criteria, choose other (code=I) and enter a notelog.

   In the DMS, enter '=' for any blank fields.

8. VCUG Result:
   Using the codes provided at the bottom of the form, select the one code that best describes the VCUG result, or, explains the VCUG ineligibility. Codes are presented with a suggested order (listing ineligible reasons first).

9. Other Exclusions:
   Select the one code (from bottom of page) that indicates additional ineligible criteria, codes are presented in a suggested priority order. If this child was eligible select "A" for "None". If there are other exclusion criteria that are not listed in the codes, select "H" and add a notelog in the DMS. The DCC will occasionally update the code listing as needed for the study.

10. Enrolled:
    Select "Y" if the child was enrolled (randomized) into the study and "N" if they were not. Note: A child who is eligible but is still pending will have missing data and a missing date of disposition. Do not enter pending records into the DMS until final disposition is determined.

11. (a-b) If not Enrolled Why?

    This question is skipped if the answer to #10 is "Y". Otherwise, enter the code(s) from the bottom of the form that best describes the reason the child was not enrolled. Up to two codes are allowed if there are multiple reasons. If there is a medical reason not coded, select "F" and add a notelog into the DMS with your reason. The DCC will occasionally update the code listing as needed for the study.

    In the DMS, enter '=' for any blank fields.

12. Date of Final Disposition:

    Record the date each patient is deemed ineligible or is enrolled and randomized into the study. Dates are recorded in MM/DD/20YY format. For example, May 30th 2007 would be: 05/30/2007.

RIVUR Follow-up Form

RFF Version A, 8/30/10

QxQ

I. GENERAL INSTRUCTIONS

This is a one page self administered questionnaire to be completed by the parent/guardian when the participant has missed at least two consecutive follow-up visits. If you are unable to contact the participant for two consecutive visits (i.e., attempted to contact the participant at least twice during the morning, twice during the afternoon, twice at night and at least once on the weekend), then mail the RFF to the parent/guardian. When mailing the RFF form, use the contact occasion for the second missed visit. For example, if a participant misses visit 03 and you are unable to reach them for visit 04, then mail the RFF form to parent/guardian and use the contact number 04 and sequence number 00 on the RFF form.

Once the coordinator mails the form to the participant they should go immediately enter items 0, 00 and 3 into the DMS.

The Coordinator must complete the footer information as they would any form and be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

II. SPECIFIC INSTRUCTIONS

0. As soon as the form is mailed go ahead and record (in the DMS only) the date when the form was mailed to the participant, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, September 1, 2010 would be entered as:

0	9	/	0	1	/	2	0	1	0

00. As soon as the form is mailed, go ahead and record (in the DMS only) the initials of the staff member who mailed the questionnaire.

Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C	or	A	-	C

1. The parent/guardian fills in date that form is completed. The study coordinator will enter this date into the DMS after the form is returned, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, September 1, 2010 would be entered as:

0	9	/	0	1	/	2	0	1	0

2. The parent/guardian circles relationship to participant. For "other," parent/guardian will fill in their relationship to participant. After the form is returned to the clinic site, the study coordinator will enter this information into the DMS as follows:

Select 'A' if the parent/guardian circled 'Mother.'

Select 'B' if the parent/guardian circled 'Father.'

Select 'C' if the parent/guardian circled 'Legal Guardian.'

Select 'D' if the parent/guardian circled 'Other' and enter the specified relationship in a notelog.

3. The study coordinator fills out the date of child's last RIVUR contact on the paper form prior to mailing to the parent/guardian. This date should be the date of the last completed (either phone or clinic) visit. This date can be found on the "Participant Follow-up Report" in the DMS. The date is entered into the DMS, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, September 1, 2010 would be entered as:

0	9	/	0	1	/	2	0	1	0

Questions 4-10 are completed on the paper form by the parent/guardian. After the form is returned to the clinic site, the study coordinator will enter the answers into the DMS as follows:

4. Select 'N' if the parent/guardian circled 'No.'
   Select 'Y' if the parent/guardian circled 'Yes' and enter the side effect(s) in a notelog.

5. Select 'N' if the parent/guardian circled 'No.'
   Select 'Y' if the parent/guardian circled 'Yes.'

6. For items a –f , enter the answers as follows:
   Select 'N' if the parent/guardian circled 'No.'
   Select 'Y' if the parent/guardian circled 'Yes.'

7. Record the number of times listed by the parent/guardian that the participant received medical care for side effects. If the response is '0,' the DMS form will skip to question 9.

8. Record the information listed by the parent/guardian for up to 3 medical care visits:

   Enter the date of each medical care visit using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, September 1, 2010 would be entered as:

0	9	/	0	1	/	2	0	1	0

   Enter the reason of for the medical care visit as listed by parent/guardian. If the response contains more characters than the text box, continue recording the response in a note log.

   Enter the reason of for the medical care provider name or place of treatment as listed by parent/guardian. If the response contains more characters than the text box, continue recording the response in a note log.

   If child had more than 3 medical care visits then enter additional visits in a notelog.

9. The parent/guardian circles the number of time the participant missed their RIVUR medication dose during the past week. After the form is returned to the clinic site, the study coordinator will enter this information into the DMS:
   Select 'A' if the parent/guardian circled 'Never.'
   Select 'B' if the parent/guardian circled '1-2 times.'
   Select 'C' if the parent/guardian circled '3-4 times.'

Select ‘D’ if the parent/guardian circled ‘> 4 times.’
Select ‘E’ if the parent/guardian circled ‘Don’t know.’

10. The parent/guardian answers if the participant is out of study medication. After the form is returned to the clinic site, the study coordinator will enter this information into the DMS:
    Select ‘N’ if the parent/guardian circled ’No.’
    Select ‘Y’ if the parent/guardian circled ‘Yes’ and mail the participant more study medication

RECTAL SWAB RESULTS FORM

RSR Version C, 11/09/07

QxQ

I. GENERAL INSTRUCTIONS

The Rectal Swab Results Form (RSRF) is used to verify eligibility criteria so that randomization may occur. It is important that this form be entered into the DMS while the participant is present at the randomization visit. The ICT must be entered prior to completion of this form. It is recommended to have filled out the PEF prior to completion of the RSRF so that the possibility of a UTI at randomization has been eliminated. Collect urine for dipstick prior to beginning ERF form.

This form is completed based on an interview with the participant's parent or guardian. The interview should be conducted in a comfortable and confidential location. Interviewer should inform the parent or guardian that all information provided in this interview will remain confidential.

Interviewers and data entry personnel should understand and be familiar with chapters 13 and 14 in the Manual of Procedures, prior to completing this form. Complete only the appropriate items. Be sure to follow the correct skip patterns.

Recall the following helpful DMS keystrokes:

1. F11 will enlarge the viewing screen. Pushing F11 again will reduce the viewing screen.
2. The DMS screen should say 'Add Mode' for the user to be able to enter data into the RSRF. The RSRF automatically saves and locks following entry of the user's initials in item B12. There is no way to return to the RSRF and edit data after the form is locked.
3. To set an unskipped, empty field to unresolvable, fill the entire field with ' =' signs OR cursor to the unresolved field and enter CTRL+U.
4. To confirm a valid value in a field where the number entered failed the edit check, enter the value and then enter CTRL+C. There are many fields in the RSRF that will not allow the user to confirm invalid data.
5. To add a note (notelog) to any field, enter CTRL+G, add your note, and then save the notelog by entering ALT+S.
6. Press F1 to retrieve the lists of bacteria codes and antimicrobial codes used on the RSRF (Q24 and Q26-29a).

II. SPECIFIC INSTRUCTIONS

A. E Coli (Lactose positive and indole positive colonies on Maconkey agar)

1. Record dates of rectal swab received by the central lab and date the results were read by the central lab's personnel in respective sections.

a. Record the date the rectal swab was received in the central lab using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

b. Record the date on which the results were read by the central lab's personnel using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Select 'P' if E Coli growth was present.
Select 'A' if E Coli growth was absent.

NOTE: If 'A' then go to item 11

3. Select 'A' if the density of E Coli growth was +1.
Select 'B' if the density of E Coli growth was +2.
Select 'C' if the density of E Coli growth was +3.
Select 'D' if the density of E Coli growth was +4.

4. Select 'P' if E Coli growth was present on TMP-SMZ agar.
Select 'A' if E Coli growth was absent on TMP-SMZ agar.

5. Select 'P' if E Coli growth was present on Ceftazidime agar.
Select 'A' if E Coli growth was absent on Ceftazidime agar.

6. Select 'P' if E Coli growth was present on Ciprofloxacin agar.
Select 'A' if E Coli growth was absent on Ciprofloxacin agar.

NOTE: If items 4-6 are all 'A' go to item 11

7. Record the data type and E Coli sensitivity indicated by **TMP-SMZ** E- test in respective sections.

a. Write 'A' if the data type is = (equal to) recorded E Coli sensitivity.
Write 'B' if the data type is > (greater than) recorded E Coli sensitivity.
Write 'C' if the data type is ≥ (greater than or equal to) recorded E Coli sensitivity.
Write 'D' if the data type is < (less than) recorded E Coli sensitivity.
Write 'E' if the data type is ≤ (less than or equal to) recorded E Coli sensitivity.

b. Record E Coli sensitivity, inserting leading and decimal zeros where necessary. When recording numerical values, enter the number so that the last digit appears in the rightmost box. For example, the value 96.5 would be entered as:

0	9	6	.	5	0	0

NOTE: You will need to enter the "." into the DMS.

8. Record the data type and E Coli sensitivity indicated by **Ceftazidime** E- test in respective sections.

a. Write 'A' if the data type is = (equal to) recorded E Coli sensitivity.
Write 'B' if the data type is > (greater than) recorded E Coli sensitivity.
Write 'C' if the data type is ≥ (greater than or equal to) recorded E Coli sensitivity.
Write 'D' if the data type is < (less than) recorded E Coli sensitivity.
Write 'E' if the data type is ≤ (less than or equal to) recorded E Coli sensitivity.

b. Record E Coli sensitivity, inserting leading and decimal zeros where necessary. When recording numerical values, enter the number so that the last digit appears in the rightmost box. For example, the value 96.5 would be entered as:

0	9	6	.	5	0	0

NOTE: You will need to enter the "." into the DMS.

9. Record the data type and E Coli sensitivity indicated by **Ciprofloxacin** E- test in respective sections.

a. Write 'A' if the data type is = (equal to) recorded E Coli sensitivity.
Write 'B' if the data type is > (greater than) recorded E Coli sensitivity.
Write 'C' if the data type is ≥ (greater than or equal to) recorded E Coli sensitivity.
Write 'D' if the data type is < (less than) recorded E Coli sensitivity.
Write 'E' if the data type is ≤ (less than or equal to) recorded E Coli sensitivity.

b. Record E Coli sensitivity, inserting leading and decimal zeros where necessary. When recording numerical values, enter the number so that the last digit appears in the rightmost box. For example, the value 96.5 would be entered as:

0	9	6	.	5	0	0

NOTE: You will need to enter the "." into the DMS.

10. Select 'P' if ESBL production is determined by double disk synergy test.
Select 'N' if ESBL production is not determined by double disk synergy test.

B. Administrative Information

11. Record the date of data collection using the mm/ddd/yyyy format , and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

12. Select 'C' if data from this form was originally captured electronically (on the computer).
Select 'P' if data from this form was originally captured on paper.

13. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

SPECIMEN COLLECITON FORM

SCF Version A, 04/11/07

QxQ

I. GENERAL INSTRUCTIONS

The Specimen Collection Form provides an inventory of blood, urine and rectal swab specimens collected during the study, as well as shipping dates for specimens sent to central labs and repositories. It also serves to identify quality control replicate specimens for QC analysis.

Note: For specimens that are batch shipped on date after the date of collection, the shipping dates will need to be updated on the form and in the DMS.

Note: if the specimen is a QC specimen that has been requested by the CSCC, the form header ID is completed using the ID number for the specimen. The link to the original participant is made in question #2, where the participant ID or ID label is recorded. In the event that a QC specimen is collected, a separate SCF form is completed only for the QC specimen collected. The skip patterns embedded into the form will provide the way out for specimens not collected.

This form can be completed on paper or directly entered into the RIVUR DMS. Either way, the Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns instructed on the form or in the DMS.

II. SPECIFIC INSTRUCTIONS

A. QC SPECIMEN

1. Select 'Y' if the specimen's documented in this form are QC specimens.
   Select 'N' if this is a standard participant specimen collection (not for QC).

   NOTE: If 'N' then go to item 3.

2. Record the ID of the participant providing the QC specimen (or attach appropriate participant ID label).

B. BLOOD SPECIMEN

3. Select 'Y' if any blood specimens were collected.
   Select 'N' if no blood specimens were collected.

   NOTE: If 'N' then specify reason in a notelog and go to item 9.

4. Record date of blood specimen collection, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

5. Record the time of blood draw using the 24 hour clock format. The 24-hour clock is a convention of time-keeping in which the day runs from midnight (00:00) to midnight and is divided into 24 hours, numbered from 0 to 23, the last minute of the day is that beginning at 23:59. For example if blood is drawn at 2:34 pm then it would be entered as:

1	4	:	3	4

6. Record the total volume of blood drawn (mL). Round to the nearest tenth, and insert leading zeros where necessary.

7. Record the initials of the phlebotomist who drew the blood. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C	or	A	-	C

8a. Select 'Y' if any blood was collected for local lab CBC.
Select 'N' if blood was not collected for local lab CBC.

NOTE: If 'N' then specify reason in a notelog.

8b. Select 'Y' if any blood was collected for local lab metabolic/electrolyte analytes.
Select 'N' if blood was not collected for local lab metabolic/electrolyte analytes.

NOTE: If 'N' then specify reason in a notelog.

8c. Select 'Y' if any blood was collected for central lab serum.
Select 'N' if blood was not collected for central lab serum.

NOTE: If 'N' then specify reason in a notelog and go to item 8d.

8c1. If collected, indicate shipping date of serum, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

Note: This blood is shipped in batches, and you will have to go back at shipping time to update this form/DMS for this field.

8d. Select 'Y' if any blood was collected for repository blood collection.
Select 'N' if blood was not collected for repository blood collection.

NOTE: If 'N' then specify reason in a notelog and go to item 9.

8d1. Select 'Y' if repository whole blood was collected.
Select 'N' if repository whole blood was not collected

NOTE: If 'N' then specify reason in a notelog and go to item 8d4.

8d2. Record volume of repository whole blood collected (mL). Round to the nearest tenth, and insert leading zeros where necessary.

8d3. If collected, indicate the shipping date of repository whole blood using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

8d4. Select 'Y' if repository serum specimen was collected.
Select 'N' if repository serum specimen was not collected.

NOTE: If 'N' then specify reason in a notelog and go to item 9.

8d5. Record volume of repository serum specimen collected in mL. Round to the nearest tenth, and insert leading zeros where necessary.

8d6. If collected, indicate the shipping date of repository serum specimen, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

C. URINE SPECIMEN

9. Select 'Y' if urine was collected.
Select 'N' if no urine was collected.

NOTE: If 'N' then specify reason in a notelog and go to item 15.

10. Record the date of urine specimen collection, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

11. Select 'A' if urine was collected by catheterization.
Select 'B' if urine was collected by suprapubic aspiration.
Select 'C' if urine was collected using clean voiding technique.
Select 'D' if urine was collected using bag collection (only allowed if dipstick negative for pyuria)

12a. Select 'Y' if urine was collected for local lab culture.
Select 'N' if urine was not collected for local lab culture.

NOTE: If 'N' then specify reason in a notelog.

12b. Select 'Y' if urine was collected for repository.
Select 'N' if urine was not collected for repository.

NOTE: If 'N' then specify reason in a notelog and go to item 15.

13. Record volume of urine specimen for repository (mL). Round to the nearest tenth, and insert leading zeros where necessary.

14. Indicate the shipping date of repository urine specimen, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

D. RECTAL SWAB SPECIMEN

15. Select 'Y' if rectal swab was collected.
Select 'N' if no rectal swab was collected.

NOTE: If 'N' then specify reason in a notelog and go to item 18.

16. Record the date of rectal swab collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

17. Record the shipping date of the rectal swab, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

E. ADMINISTRATIVE INFORMATION

18. Record the date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

19. Select ‘C’ if data from this form was originally captured through DMS (on a computer).
Select ‘P’ if data from this form was originally captured on paper.

20. Record the initials of the person recording and completing this form. Enter one letter per box. If initials include only 2 letters, enter a ‘-‘ in the box that is to be left blank. For example:

A	B	C

or

A	-	C

ULTRASOUND RESULTS FORM
URF Version C, 5/08/07
QxQ

I. GENERAL INSTRUCTIONS

The Ultrasound Results Form should be completed by the reference radiologist each time an ultrasound image is received. On paper forms affix the participant ID label at the top of the form where indicated. When recording numerical values, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. For example, the value 365 would be entered as:

0	0	3	6	5

Recorder should be familiar with the RIVUR Form Completion and Data Entry Guidelines, found in Chapters 13 of the Manual of Procedures. Complete only the appropriate questions. Be sure to follow the correct skip patterns.

II. SPECIFIC INSTRUCTIONS

A. IMAGING RESULTS

1. Record the date of the ultrasound, using the mm/dd/yyyy format and inserting leading zeros when necessary. For example, May 3, 2006 would be entered:

0	5	/	0	3	/	2	0	0	6

2. Describe the right kidney as follows:

   a. Record the length in centimeters of the right kidney, using leading zeros as necessary. Round to the nearest tenth.

   b. Record the width in centimeters of the right kidney, using leading zeros as necessary. Round to the nearest tenth.

   c. Select ‘Y’ if there is duplication.
   Select ‘N’ if there is no duplication.
   Select ‘U’ if duplication is unevaluated.

   d. Select ‘Y’ if hydronephrosis is present in the right kidney.
   Select ‘N’ if hydronephrosis is not present in the right kidney.

   NOTE: If N, then go to item 3.

   e. Record the SFU grade of hydronephrosis. Whole numbers only, 0-5.

   f. Record the renal pelvis A-P diameter in centimeters. Round to the nearest tenth.

3. Describe the left kidney as follows:

   a. Record the length in centimeters of the left kidney. Round to the nearest tenth.

   b. Record the width in centimeters of the left kidney. Round to the nearest tenth.

   c. Select ‘Y’ if there is duplication.
   Select ‘N’ if there is duplication.
   Select ‘U’ if duplication is unevaluated.

d. Select 'Y' if hydronephrosis is present in the left kidney.
Select 'N' if hydronephrosis is not present in the left kidney.
NOTE: If N, then go to item 3.

e. Record the grade of hydronephrosis. Whole numbers only, 0-5.

f. Record the renal pelvis A-P diameter in centimeters. Round to the nearest tenth.

4. Describe the right ureter as follows:

a. Select 'Y' if the right ureter was dilated.
Select 'N' if the right ureter was not dilated.

b. Select 'Y' if the right ureter was proximal.
Select 'N' if the right ureter was not proximal.

c. Select 'Y' if the right ureter was distal.
Select 'N' if the right ureter was not distal.

5. Describe the left ureter as follows:

a. Select 'Y' if the left ureter was dilated.
Select 'N' if the left ureter was not dilated.

b. Select 'Y' if the left ureter was proximal.
Select 'N' if the left ureter was not proximal.

c. Select 'Y' if the left ureter was distal.
Select 'N' if the left ureter was not distal.

6. Select 'Y' if the bladder post-void volume was assesed.
Select 'N' if the bladder post-void volume was not assessed.
NOTE: If N, then go to item 8.

7. Indicated the post void residual by selecting only one of the following:
Select 'A' for none, bladder is empty, post void.
Select 'B' for small, nearly empty, post void.
Select 'C' for moderate, volume less, still distended post void.
Select 'D' for large, volume similar pre and post void.
Select' E' for not assessed, no comparable pre/post images.

8. Select 'Y' if the bladder wall is qualitatively thickened.
Select 'N' if the bladder wall is not qualitatively thickened.

9. Select 'Y' if the posterior bladder wall was measured.
Select 'N' if the posterior bladder wall was not measured.
NOTE: If N, then go to item 11.

10. Record the posterior bladder wall measurement (mm). Insert leading zeros where necessary. Round to the nearest tenth.

11. Select 'Y' if bladder diverticulum present.
    Select 'N' if bladder diverticulum not present.
    Select 'U' if unknown.

12. Select 'Y' if bladder masses present.
    Select 'N' if bladder masses not present.
    Select 'U' if unknown.

13. Select 'Y' if you have any additional comments.
    Select 'N' if you do not have any additional comments.
    NOTE: If 'Y' then enter comments into the blank or DMS note log provided.

14. Based on your experience, would you say that the image quality was adequate or inadequate?
    Select 'A' if the image quality is adequate.
    Select 'I' if the image quality is inadequate.

B. ADMINISTRATIVE INFORMATION

15. Record date of data collection, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

16. Select 'C' if data from this form was originally captured through the DMS (on a computer). Select 'P' if data from this form was originally captured on paper.

17. Record the initials of the reference radiologist who reviewed the Ultrasound results data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

URINE SPECIMEN RESULTS FORM

USR Version E, 02/18/2013

QxQ

I. GENERAL INSTRUCTIONS

The Urine Specimen Results Form (USR) is used to record all urinalysis results at any time throughout the study including baseline when urinalysis or urine culture is performed. This form is completed from medical records abstraction.

Interviewers and data entry personnel should understand and be familiar with chapters 13 and 14 in the Manual of Procedures, prior to completing this form. The USR is a multi-line form, which means that when multiple urinalyses are performed during one event or time frame, the line number may be incremented instead of incrementing the sequence number of the form.

Complete only the appropriate items. Be sure to follow the correct skip patterns.

Recall the following helpful DMS keystrokes:

1. F11 will enlarge the viewing screen. Pushing F11 again will reduce the viewing screen.

2. The DMS screen should say 'Add Mode' for the user to be able to enter data into the USR.

3. To set an unskipped, empty field to unresolvable, fill the entire field with '=' signs OR cursor to the unresolved field and enter CTRL+U.

4. To confirm a valid value in a field where the number entered failed the edit check, enter the value and then enter CTRL+C.

5. To add a note (notelog) to any field, enter CTRL+G, add your note, and then save the notelog by entering ALT+S.

6. Press F1 to retrieve the lists of bacteria codes and antimicrobial codes used on the USR (Q13a through Q16a, Q18a through Q39a, and Q42a through Q45a).

II. SPECIFIC INSTRUCTIONS

A. Dipstick Results

1. Select ‘Y’ if urine dipstick is performed.
   Select ‘N’ if urine dipstick is not performed.
   NOTE: If N, then go to Item 6.

2. Record date the urine dipstick is performed using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

3. Select ‘A’ if method if urine collection for dipstick is catheterization.
   Select ‘B’ if method if urine collection for dipstick is suprapubic aspiration.
   Select ‘C’ if method if urine collection for dipstick is clean voided.
   Select ‘D’ if method if urine collection for dipstick is bag collected.
   Select ‘E’ if method of urine collection for dipstick is unknown.

4. Select ‘Y’ if dipstick results were based on urine collected at home.
   Select ‘N’ if dipstick results are not based on urine collected at home.

5a. Select 'A' if leukocyte esterase is negative in dipstick results.
Select 'B' if there is trace amount of leukocyte esterase in dipstick results.
Select 'C' if there is a small (+) amount of leukocyte esterase in dipstick results.
Select 'D' if there is moderate (++) amount of leukocyte esterase in dipstick results.
Select 'E' if there is a large (+++) amount of leukocyte esterase in dipstick results.

5b. Select 'N' if dipstick is negative for nitrites.
Select 'P' if dipstick is positive for nitrites.

B. Microscopy Results

6a. Select 'Y' if the urine microscopy results are available.
Select 'N' if the urine microscopy is not performed.
Select 'O' if there is another reason that the urine microscopy is not performed and specify the reason in the notelog.

NOTE: If N, then skip to item 8.

6b. Record date the urine sample collection for microscopy is performed using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

6c. Select 'A' if method of urine collection for microscopy is catheterization.
Select 'B' if method of urine collection for microscopy is suprapubic aspiration.
Select 'C' if method of urine collection for microscopy is clean voided.
Select 'D' if method of urine collection for microscopy is bag collected.
Select 'E' if method of urine collection for microscopy is unknown.

6d. Select 'Y' if microscopy results are based on urine collected at home.
Select 'N' if microscopy results are not based on urine collected at home.

7a. Record the value of the white blood cell count. Use 999.999 for values $\geq$ 999.999.

7b. Select 'A' if the urine microscopy count is WBC per cubic millimeter (WBC/mm^3).
Select 'B' if the urine microscopy count is WBC per high power field (WBC/hpf).

C. Urine Culture Results

8. Select 'Y' if urine culture results are available.
Select 'N' if urine culture is not performed.
Select 'C' if the sample is contaminated.
Select 'O' if the sample for urine culture is not collected and specify the reason in a notelog.

NOTE: If N, then go to item 40.
NOTE: If C, then complete items 9-11, then go to item 40.
NOTE: If O, then go to item 40.

9. Record the date of the urine sample collection for culture using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

10. Select 'A' if method of urine collection for urine culture is catheterization.
    Select 'B' if method of urine collection for urine culture is suprapubic aspiration.
    Select 'C' if method of urine collection for urine culture is clean voided.
    Select 'D' if method of urine collection for urine culture is bag collected.
    Select 'E' if method of urine collection for urine culture is unknown.

11. Select 'Y' if the urine culture report is based on urine collected at home.
    Select 'N' if the urine culture report is not based on urine collected at home.

12. Indicate how many different organisms are isolated on culture.

    NOTE: If no organisms are isolated on culture, enter 0, then go to item 40.
    NOTE: Up to 4 organisms isolated on culture may be recorded on the USR.

13-16.

a. Enter the two-digit code of the organism. For a complete listing of codes, refer to the 'RIVUR Organism/Species Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. If the organism is not listed, use 'other' code '99' and record the name of the organism in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b. Select 'A' if the organism colony count from the culture results equals the value reported.
   Select 'B' if the organism colony count from the culture results is greater than the value reported.
   Select 'C' if the organism colony count from the culture results is greater than or equal to the value reported.
   Select 'D' if the organism colony count from the culture results is less than the value reported.
   Select 'E' if the organism colony count from the culture results is less than or equal to the value reported.
   Select 'F' if the organism colony count from the culture results is reported as a range.

   NOTE: If A, B, C, D, or E are selected then skip c2 in Items 13-16.

c. Record the colony count of the isolated organism (CFU/ml), inserting leading zeros where necessary. Where a range of values are reported on the culture results, use item c1 for the bottom range value and item c2 for the top range value.

d.. Enter the three-digit code of up to three species(d1, d2, d3) for each organism listed. For a complete listing of codes, refer to the 'RIVUR Organism/Species Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. If the species is not listed, use 'other' code '300' and record the name of the species in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

D. Drug Sensitivity Results

17. Indicate how many different antimicrobials were tested for sensitivity against the organisms isolated on culture.

    NOTE: If no antimicrobials are tested for sensitivity then enter 00 and go to Item 40.
    NOTE: Up to 21 antimicrobials tested for sensitivity may be recorded on the USR.

18-39.

a. Enter the three-digit code of the antimicrobial tested for sensitivity. Refer to the 'Antibiotic-Antimicrobial Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. Additional information, such as brand and/or alternate names, has been added to the 'Antibiotic - Antimicrobial Code List.' This additional information will not appear on the DMS list due to limited space available on the online form. If the antimicrobial is not listed, use 'other' code '500' and record the name of the antimicrobial in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b-e. Record results from the first isolated organism in column b. Record the results from the second isolated organism in column c. Record results from the third isolated organism in column d. Record the results from the fourth isolated organism in column e.

Select 'S' if the organism(s) is sensitive to the antimicrobial listed in column a. Record results in b through e for up to the 4 isolated organisms.
Select 'I' if the organism(s) has intermediate sensitivity to the antimicrobial listed in column a. Record results in b through e for up to the 4 isolated organisms.
Select 'R' if the organism(s) is resistant to the antimicrobial listed in column a. Record results in b through e for up to the 4 isolated organisms.
Select 'N' if the organism(s) is not tested for sensitivity to the antimicrobial listed in column a. Record results in b through e for up to the 4 isolated organisms.

NOTE: There will be skips in some columns if less than 4 organisms are isolated on culture.

E. UTI Treatment

40. Select 'Y' if UTI treatment is prescribed.
Select 'N' if UTI treatment is not prescribed.

NOTE: If 'N', go to item 46.

41. Indicate how many different antimicrobials were prescribed to treat the UTI.

NOTE: Up to 4 different antimicrobials prescribed for UTI may be recorded on the USR.

42-45.

a. Record the antimicrobial code associated with the treatment from the 'Antibiotic -Antimicrobial Code List' following this QxQ, or in the DMS, click on this item and hit the F1 key. Additional information, such as brand and/or alternate names, has been added to the 'Antibiotic - Antimicrobial Code List.' This additional information will not appear on the DMS list due to limited space available on the online form. If the antimicrobial is not listed, use 'other' code '500' and record the name of the antimicrobial in a notelog. (See Section I for instructions on adding a notelog.) Press ESC to exit the reference table and proceed with data entry.

b. Record the date this antimicrobial was prescribed using the mm/dd/yyyy convention and inserting leading zeros if necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

c. Record the total number of days the participant was taking the prescribed antimicrobial, whole numbers only.

d. Indicate the sensitivity of the pathogen to the treatment prescribed as reported on the sensitivity report.

Select 'Y' if organism is reported sensitive to antimicrobial listed in a.

Select 'N' if organism is reported not sensitive to antimicrobial listed in a.

Select 'U' if there are no sensitivity results for the antimicrobial listed in a to the organism that was isolated on the culture.

F. Urine Chemistry Results

46. Select 'Y' if urine chemistry results are available.
Select 'N' if urine chemistry is not performed.
Select 'I' if the sample is inadequate.
Select 'O' if the sample for urine chemistry is not collected specify the reason in a notelog.

NOTE: If N, then go to item 54.
NOTE: If I, then complete Item 47, then go to item 54.
NOTE: If O, then go to item 54.

47. Record the date of the urine sample collection for chemistry using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

48. a. Select 'A' if method of urine collection for urine chemistry is catheterization.
Select 'B' if method of urine collection for urine chemistry is suprapubic aspiration.
Select 'C' if method of urine collection for urine chemistry is clean voided.
Select 'D' if method of urine collection for urine chemistry is bag collected.
Select 'E' if method of urine collection for urine chemistry is unknown.

b. Select 'Y' if the urine chemistry results are based on urine collected at home.
Select 'N' if the urine chemistry results are not based on urine collected at home.

49. a. Record the urine creatinine value inserting leading zeros where necessary.

b. Select 'A' if the urine creatinine value from the urine chemistry results equals the value reported.
Select 'B' if the urine creatinine value from the urine chemistry results is greater than the value reported.
Select 'C' if the urine creatinine value from the urine chemistry results is greater than or equal to the value reported.
Select 'D' if the urine creatinine value from the urine chemistry results is less than the value reported.
Select 'E' if the urine creatinine value from the urine chemistry results is less than or equal to the value reported.

c. Select 'A' if the urine creatinine value units were reported as mg/dl.
Select 'B' if the urine creatinine value units were reported as mg/L.
Select 'C' if the urine creatinine value units were reported as mcg/mL.
Select 'D' if the urine creatinine value units were reported as mcg/mg.
Select 'E' if the urine creatinine value units were reported as mg/g.
Select 'F' if the urine creatinine value units were not reported or other specify in a notelog.

d. Record the reference range for the creatinine value in d1 and d2 inserting leading zeros where necessary. If reference range units are different than the measured creatinine units please enter units in a notelog.

50. Select 'Y' if the laboratory provided results for microalbumin.
Select 'N' if the laboratory did not provide results for microalbumin.

NOTE: If N, then go to item 52.

51. a. Record the microalbumin value inserting leading zeros where necessary.

b. Select 'A' if the microalbumin value from the urine chemistry results equals the value reported.
Select 'B' if the microalbumin value from the urine chemistry results is greater than the value reported.
Select 'C' if the microalbumin value from the urine chemistry results is greater than or equal to the value reported.
Select 'D' if the microalbumin value from the urine chemistry results is less than the value reported.
Select 'E' if the microalbumin value from the urine chemistry results is less than or equal to the value reported.

c. Select 'A' if the microalbumin value units were reported as mg/dl.
Select 'B' if the microalbumin value units were reported as mg/L.
Select 'C' if the microalbumin value units were reported as mcg/mL.
Select 'D' if the microalbumin value units were reported as mcg/mg.
Select 'E' if the microalbumin value units were reported as mg/g.
Select 'F' if the microalbumin value units were not reported or other specify in a notelog.

d. Record the reference range for the microalbumin value in d1 and d2 inserting leading zeros where necessary. If reference range units are different than the measured microalbumin units please enter units in a notelog

52. Select 'Y' if the laboratory provided results for the microalbumin/creatinine ratio.
Select 'N' if the laboratory did not provide results for the microalbumin/creatinine ratio.

NOTE: If N, then go to item 54.

53. a. Record the microalbumin/creatinine ratio inserting leading zeros where necessary.

b. Select 'A' if the microalbumin/creatinine ratio from the urine chemistry results equals the value reported.
Select 'B' if the microalbumin/creatinine ratio from the urine chemistry results is greater than the value reported.
Select 'C' if the microalbumin/creatinine ratio from the urine chemistry results is greater than or equal to the value reported.
Select 'D' if the microalbumin/creatinine ratio from the urine chemistry results is less than the value reported.
Select 'E' if the microalbumin/creatinine ratio from the urine chemistry results is less than or equal to the value reported.

c. Select 'A' if the microalbumin/creatinine ratio units were reported as mg/dl.
Select 'B' if the microalbumin/creatinine ratio units were reported as mg/L.

Select 'C' if the microalbumin/creatinine ratio units were reported as mcg/mL.
Select 'D' if the microalbumin/creatinine ratio units were reported as mcg/mg.
Select 'E' if the microalbumin/creatinine ratio units were reported as mg/g.
Select 'F' if the microalbumin/creatinine ratio units were not reported or other units then specify in a notelog.

d. Record the reference range for the microalbumin/creatinine ratio in d1 and d2 inserting leading zeros where necessary. If reference range units are different than the measured microalbumin/creatinine ratio units please enter units in a notelog

G. Administrative Information

54. Select 'P' if the source of the urine results is for either the protocol-scheduled baseline or end-of-study clinic visit.
Select 'M' if the source of the urine results is abstracted from the medical record for a medical event for the participant.
Select 'O' if the urine results come from a routine clinic visit other than baseline and end-of-study, but not a visit that has an associated MCN or MCA.

NOTE: If 'P', then go to item 56.
NOTE: If 'O', then go to item 56.

55. Enter or record the 7-character medical care ID (MCID) that matches the MCID from the Medical Care Notification (MCN) form where the details of the medical care notice are recorded.

56. Record the date of data entry using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2009 would be entered as:

0	5	/	0	3	/	2	0	0	9

57. Select 'C' if data from this form was originally captured electronically (on the computer).
Select 'P' if data from this form was originally captured on paper.

58. Record the initials of the person who collected this data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank.

A	B	C

or

A	-	C

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
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

ORGANISM/SPECIES CODE LIST

RIVUR Organism Code	Organism	Species	RIVUR Species Code
10	Aerobic Gram Negative Enterobacteriaceae		
11	Escherichia	coli	111
		fergusonii	112
12	Klebsiella	oxytoca	121
		pneumoniae	122
13	Enterobacter	aerogenes	131
		cloacae	132
14	Citrobacter	amalonaticus	141
		braakii	142
		farmeri	143
		freundii	144
		gillenii	145
		koseri (diversus)	146
		murliniae	147
		rodentium	148
		sedlakii	149
15	Proteus	mirabilis	151
		penneri	152
		vulgaris	153
16	Providencia	alcalifaciens	161
		friedericiana	162
		heimbachae	163
		rettgeri	164
		rustigianii	165
		stuartii	166
		vermicola	167
17	Morganella	morganii	171
18	Serratia	grimesii	181
		liquefaciens	182
		marcescens	183

ORGANISM/SPECIES CODE LIST

RIVUR Organism Code	Organism	Species	RIVUR Species Code
19	Salmonella	bongori	191
		choleraesuis	192
		enterica	193
20	Pseudomonas	aeruginosa	201
21	Staphylococcus aureus	aureus	211
22	Staphylococcus--coagulase negative	saprophyticus	221
		hominis	222
		coagulase negative	223
23	Staphylococcus epidermidis	epidermidis	231
24	Enterococcus	faecalis	241
		faecium	242
		gallinarum	243
25	Gardnerella	vaginalis	251
26	Lactobacillus	delbrueckii	261
		gasseri	262
27	Candida	albicans	271
		glabrata	272
		rugosa	273
28	Streptococcus	agalactiae	281
		anginosus	282
		bovis	283
		pneumoniae	284
		pyogenes	285
29	Corynebacterium	aquaticum	291
		pseudogenitalium	292
		urealyticum	293
		Other	300
80	Mixed		
99	Other		

VCUG RESULTS FORM
VRF Version C, 5/8/07
QxQ

I. GENERAL INSTRUCTIONS

The Ultrasound Results Form should be completed by the reference radiologist each time a VCUG image is received.

On paper forms affix the participant ID label at the top of the form where indicated. When recording numerical values, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. For example, the value 365 would be entered as:

0	0	3	6	5

Recorder should be familiar with the RIVUR Form Completion and Data Entry Guidelines, found in Chapters 13 of the Manual of Procedures. Complete only the appropriate questions. Be sure to follow the correct skip patterns.

II. SPECIFIC INSTRUCTIONS

A. IMAGING RESULTS

1. Record the date of the VCUG, using the mm/dd/yyyy format and inserting leading zeros when necessary. For example, May 3, 2006 would be entered:

0	5	/	0	3	/	2	0	0	6

2. Select ‘Y’ if the child voided during the study.
   Select ‘N’ if the child did not void during the study.
   Select ‘U’ if it is unknown whether or not the child voided during the study.

3. For each of items 3a-3b, indicate the highest grade of reflux for each ureter as follows:
   Select ‘0’ for no reflux.
   Select ‘1’ for Grade I reflux.
   Select ‘2’ for Grade II reflux.
   Select ‘3’ for Grade III reflux.
   Select ‘4’ for Grade IV reflux.
   Select ‘5’ for Grade V reflux.

   NOTE: If ‘0’ for 3a then skip item 4a - 4d.
   If ‘0’ for 3b then skip item 5a - 5d.

4. Describe the RIGHT ureter as follows:
   a. Select ‘Y’ if there was complete duplication.
      Select ‘N’ if there was not completed duplication.
      NOTE: If N, then go to item 4e.

   b. Select ‘U’ if reflux is located in the upper pole alone.
      Select ‘L’ if reflux is located in the lower pole alone.
      Select B if reflux is located in both poles
      NOTE: If U or L then go to item 4e.

c. Record the upper pole grade of reflux.
   Enter '1' for Grade I reflux.
   Enter '2' for Grade II reflux.
   Enter '3' for Grade III reflux.
   Enter '4' for Grade IV reflux.
   Enter '5' for Grade V reflux.

d. Record the lower pole grade of reflux.
   Enter '1' for Grade I reflux.
   Enter '2' for Grade II reflux.
   Enter '3' for Grade III reflux.
   Enter '4' for Grade IV reflux.
   Enter '5' for Grade V reflux.

e. Select Y if paraureteral diverticulum present.
   Select N if paraureteral diverticulum not present.
   NOTE: If N, then go to item 5a.

f. Indicate the diameter of the diverticulum as follows:
   Select A if less than 1 cm.
   Select B if 1-2 cm.
   Select C if greater than or equal to 2 cm.
   Select D if not measured.

5. Describe the LEFT ureter as follows:
   a. Select 'Y' if there was complete duplication.
      Select 'N' if there was not completed duplication.
      NOTE: If N, then go to item 5e.

   b. Select 'U' if reflux is located in the upper pole alone.
      Select 'L' if reflux is located in the lower pole alone.
      Select B if reflux is located in both poles
      NOTE: If U or L then go to item 5e.

   c. Record the upper pole grade of reflux.
      Enter '1' for Grade I reflux.
      Enter '2' for Grade II reflux.
      Enter '3' for Grade III reflux.
      Enter '4' for Grade IV reflux.
      Enter '5' for Grade V reflux.

   d. Record the lower pole grade of reflux.
      Enter '1' for Grade I reflux.
      Enter '2' for Grade II reflux.
      Enter '3' for Grade III reflux.
      Enter '4' for Grade IV reflux.
      Enter '5' for Grade V reflux.

e. Select Y if paraureteral diverticulum present.
Select N if paraureteral diverticulum not present.

NOTE: If N, then go to item 6.

f. Indicate the diameter of the diverticulum as follows:
Select A if less than 1 cm.
Select B if 1-2 cm.
Select C if greater than or equal to 2 cm.
Select D if not measured.

6. Indicate the bladder shape as follows (select only one):
Select 'A' if smooth / round.
Select 'B' if triangular / elongated.
Select 'C' if not reported.

7-12. For each of items 7-12, indicate whether the abnormality is present on the VCUG image:
Select 'Y' if abnormality is present.
Select 'N' if abnormality is not present.
Select 'U' if not reported or unknown.

13. Select 'Y' if you have any additional comments.
Select 'N' if you do not have any additional comments.

NOTE: If Y then enter comments into the blank or DMS notelog provided.

14. Based on your experience, would you say that the image quality was good, adequate or poor?

Select 'A' if the image quality is adequate.
Select 'I' if the image quality is inadequate.

B. ADMINISTRATIVE INFORMATION

15. Record date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

16. Select 'C' if data from this form was originally captured through the DMS (on the computer).
Select 'P' if data from this form was originally captured on paper.

17. Record the initials of the reference radiologist who reviewed the Ultrasound results data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C

or

A	-	C

VCUG SEDATION FORM

VSF Version A, 02/07/07

QxQ

I. GENERAL INSTRUCTIONS

The VCUG Sedation Form should be completed by the study coordinator, based on information they obtain when requesting participant VCUG images.

Interviewer/recorder must be familiar with Chapter 13 of the RIVUR MOP on Data Management and Administrative Procedures.

Complete only the appropriate questions. Be sure to follow the correct skip patterns.

If any data is missing and unavailable, fill all spaces provided for that response with '='.

II. SPECIFIC INSTRUCTIONS

A. Radiology Procedure

1. Record the date of the VCUG scan, using the mm/dd/yyyy format and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

2. Select 'Y' if sedation was used during this VCUG scan.
   Select 'N' if sedation was not used during this VCUG scan.
   Select 'U' if you cannot determine whether or not sedation was used during this VCUG scan.
   NOTE: If 'N' or 'U' then go to item 9.

B. Sedation

3-7. Items 3 through 7 list some types of medication commonly used for sedation during VCUG scans. For each item answer of the following;

   a. Select 'Y' if the listed medication was used during the VCUG scan.
      Select 'N' if the medication was not used during the VCUG scan.

   b. Provide the dose of the medication (mg/kg). Round to the nearest tenth, and enter leading zeros as necessary.

   c. Select 'Y' if medication was administered as general anesthesia.
      Select 'N' if medication was not administered as general anesthesia.
      Select 'U' if unknown.

8. In this item, please specify whether or not any sedation medication was used during the VCUG other than those listed in items 3 -7 Answer each of the following:

   a. Select 'Y' if another medication was used during the VCUG scan.
      Select 'N' if another medication was not used during the VCUG scan.

   b. Provide the dose of the medication (mg/kg). Round to the nearest tenth, and enter leading zeros as necessary.

   c. Select 'Y' if medication was administered as general anesthesia.
      Select 'N' if medication was not administered as general anesthesia.
      Select 'U' if unknown.

d. Specify the name of the medication.

C. ADMINISTRATIVE INFORMATION

9. Record date of data collection using the mm/dd/yyyy format, and inserting leading zeros where necessary. For example, May 3, 2006 would be entered as:

0	5	/	0	3	/	2	0	0	6

10. Select 'C' if data from this form was originally captured through DMS (on a computer). Select 'P' if data from this form was originally captured on paper.

11. Record the initials of the reference radiologist who reviewed the DMSA scan data. Enter one letter per box. If initials include only 2 letters, enter a '-' in the box that is to be left blank. For example:

A	B	C	or	A	-	C