A. Introduction and Overview
The aim of the following publication policy is to ensure scientific quality and facilitate the production of novel research contributions based on data collected by RIVUR. A secondary aim of this publication policy is to ensure a fair collaborative effort among RIVUR investigators. The publication policy follows the JAMA guidelines for all issues not explicitly discussed herein.

1. Objectives of Publication Committee
   a. To encourage timely development and submission of high quality publications and presentations from the RIVUR trial.
   b. To provide all collaborating investigators with equitable opportunity to participate in and author publications and presentations.
   c. To prevent premature dissemination of results that might jeopardize the scientific integrity of the study or compromise publication in peer-reviewed journals.

2. Guiding Principles
   a. The data collected by RIVUR study are the joint property of the Principal Investigators and NIDDK.
   b. No data collected as part of the RIVUR study will be presented, published, or otherwise disseminated, except as provided for under these guidelines.
   c. Ultimately, RIVUR data, with appropriate provisions for protection of participant privacy and confidentiality, will be made publicly available, as specified in the NIH policy on data sharing. Use of that version of the database is not controlled by this policy.

All material to be presented orally or submitted for publication or dissemination by individuals associated with the RIVUR and dealing with any aspect of the RIVUR must receive prior review and approval by the Publications Committee (PC) with the following exception:
The PC need not review material prepared for publicity purposes, either nationally, or within the recruitment region of a RIVUR site, or presentations designed to inform professional audiences about the RIVUR study design and objectives. Such material must not include RIVUR data that have not been approved by the PC and presented or published previously.

B. Organization

1. Publications Committee

a. The Publications Committee will be responsible for reviewing proposals for manuscripts and presentations, for managing the development of manuscripts, and for reviewing and approving manuscripts, abstracts and presentations prior to submission. The Committee will be responsible for adjudicating any conflicts that may arise between writing groups.

b. The Publications Committee will be chaired by the Chair of the Steering Committee and will include one member each from the Data Coordinating Center, the NIDDK Project Office, and each of the five core clinical sites.

c. The Steering Committee will monitor the progress of data collection and database closure and will announce the points at which proposals for baseline and outcome manuscripts will be acted on by the PC.

d. The Chair of the PC will review each manuscript proposal for overlap with existing proposals. In such cases, the overlap will be communicated to the proposer and to the lead of the relevant Writing Group. The proposer will then be responsible for contacting the lead of the existing writing group to adjudicate the overlap.

e. The PC will prepare a list of potential publications and presentations and delegate the responsibility for a particular project to the appropriate individual(s).

2. Writing Groups (WG)

Topics suggested for presentation or publication will be discussed by the PC, which will decide on the lead author and the composition of the writing group. This initial WG will suggest and justify names for authors to be reviewed by the PC. If a topic is suggested by a participating investigator in the RIVUR trial, the writing group will be formed as just described except that the person making the suggestion may be considered as the lead author.
The PI of an ancillary study would be the lead author of material derived from that study. Disputes regarding authorship will be settled by the PC Chair after consultation with the members of the PC. All writing groups that require analysis of RIVUR data will be assigned a member from the DCC.

a. In general writing groups should include no more than eight or nine individuals. Where practical, members should be included from a variety of RIVUR sites (i.e., clinical centers, DCC, central laboratory, clinical endpoints committee, reference radiologists, and the NIDDK).

b. Each writing group for a manuscript or presentation that will include RIVUR data must include a statistician from the DCC.

c. The Chair of the writing group is responsible for communicating with the members to develop the manuscript. This ordinarily will involve a series of conference calls, e-mail communications, and perhaps, in-person meetings. The analysis plan provided in the manuscript proposal may be elaborated through a Statistical Analysis Plan developed by the DCC statistician, and will be used to create one or more statistical computing requests. These computing requests will be prepared by the DCC representative on the writing group. The DCC representative will provide the group with statistical reports, including tables, figures, and text with results of those analyses.

d. Membership on a writing group is not sufficient to warrant authorship credit. Each individual listed as a co-author is expected to make significant scientific contributions to the manuscript (see, as an example, the JAMA instructions for authors for definitions of “significant scientific contributions”).

2A. Typical Features of Writing Group

Generally, a writing group consists of four to eight or nine investigators and its composition may vary to include core site investigators, satellite site investigators and ancillary study investigators as well as statisticians from the DCC and NIDDK representatives. The investigator who submits the manuscript proposal may either be the lead or senior author. During its review of the manuscript proposal, voting members of the PC may name study representative co-authors. If none are specified within two weeks of proposal approval, it may result in no co-author from the voting member’s site. Periodically, the Steering Committee may be polled for interest in joining recently approved writing groups. The writing committee for unapproved or withdrawn manuscript proposals is disbanded.
Ancillary or secondary studies do not need to have a co-author from each of the six sites of the study, but should represent the cores that contributed data to the study being reported. In accordance with the responsibility of co-authorship in scientific publications, individuals should only be co-authors if they have substantially contributed to the manuscript. Each voting member of the PC reserves the right of not naming a member of the team as a co-author. Such right is appropriate, for example, not to include authors in specialized methodological papers when there are no individuals with expertise at a particular center (e.g., a new genetics method or radiologic techniques).

The writing group lead is responsible for the completion of the manuscript, as well as the determination of authorship order. The writing group lead is also responsible for communicating significant problems or delays to the PC in a timely manner. Complete draft manuscripts should be submitted to all co-authors for substantive, methodological, and/or statistical review. All members of the writing group must participate in the writing and/or review process, returning edited drafts within a two week period. In the event that a writing group member disagrees with a revised manuscript, an attempt should be made within the writing group to resolve the issue. If such an effort fails, the issue should be brought by the writing group lead to the PC. If a member of the writing group does not actively participate in the preparation of the manuscript including responding to analysis and manuscript drafts, then he/she may be removed from the writing group.

After writing group approval, the draft should be emailed to the Publication Committee for approval prior to journal submission. The DCC representative can facilitate this distribution once the writing group lead indicates the manuscript is ready. A member of the PC will be assigned as the primary reviewer and will have a target date of two weeks to review the draft and bring comments before the PC by meeting, conference call or email for approval. **Manuscripts must be approved by the PC prior to submission.** Primary investigators are responsible for informing PC and DCC about the disposition of submitted manuscripts. If a manuscript is accepted for publication, the primary investigator must send a portable document format (.pdf) version of the published article to the DCC for distribution to the PC.

Prior to or concurrent with the PC review of the final manuscript draft, the DCC will complete a data verification process. During this process, results reported in the manuscript are verified relative to the statistical output generated during data analysis. **All manuscripts must complete the data verification process prior to submission to a journal.**

### 2B. Study Acknowledgment

All manuscripts derived from data collected by RIVUR must include the following acknowledgment:

> The authors thank the RIVUR participants, their families and the participating physicians, investigators and staffs for making this research possible. The Randomized Intervention for Children with Vesicoureteral Reflux trial was
supported by cooperative agreements U01 DK074059 (Carpenter), U01 DK074053 (Hoberman), U01 DK074082 (Mathews), U01 DK074064 (Keren), U01 DK074062 (Mattoo), U01 DK074063 (Greenfield) from the National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services. The trial was also supported by the Children’s Hospital of Philadelphia Clinical and Translational Science Award (UL1TR000003) from the National Center for Research Resources, now at the National Center for Advancing Translational Sciences, National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Diabetes and Digestive and Kidney Diseases or the National Institutes of Health. The RIVUR website is located at http://www.cscc.unc.edu/rivur/.

2C. Categories and Timing of Manuscripts and Presentations

1. Background papers: Manuscripts that describe the justification for the RIVUR study.

2. Methodological papers: Manuscripts describing the design and/or scientific methods used in the RIVUR trial.

3. Baseline papers: Manuscripts that report only data collected at the time of or prior to randomization.

4. Outcome papers: Manuscripts including data collected following randomization of participants.

Development of baseline papers is encouraged as soon as randomization is complete and the baseline database is closed (i.e., while follow-up is on-going). The first baseline paper submitted will be a description of the general characteristics of the overall RIVUR population. Other baseline papers may not be submitted until this first paper has been accepted. Development of outcome manuscripts can begin once collection of follow-up data is complete and the corresponding database is closed. The first outcome paper submitted will be the primary results manuscript. Other outcome manuscripts cannot be submitted until the primary results paper has been accepted. Methodological papers which do not require RIVUR data may be developed at any time. Those methodological papers that include substantial data, particularly outcome data (e.g., results of a quality control program) will follow the timeline required for the data included.

In general, RIVUR manuscripts are expected to include data from all of the relevant participants. Papers that include only a subset of the participants (e.g., first 200 patients randomized, participants from a subset of sites) are strongly discouraged.

2D. Proposal Development for Manuscripts and Presentations: Mechanism of Proposals
1. Any RIVUR Investigator can propose a manuscript or presentation by completing the manuscript proposal form online in the secure area of the RIVUR.net website (Figure 1).

2. Proposals are submitted to the Data Coordinating Center which logs them and forwards them to the Publications Committee for review.

3. After review, the PC may approve the proposal, request revisions, defer, or recommend that the topic not be pursued. In the case of a rejection, the Publications Committee will provide an explanation for the reason that the topic was judged impractical, duplicative, etc. The PC convenes every two months and will attempt to complete this review during the next scheduled call following receipt of a proposal by the DCC.

4. As part of the review process, the PC may suggest additions to the writing group.

5. The PC will indicate if a member of the writing group other than the investigator who submitted the proposal is to serve as the writing group lead. The WG lead will have primary responsibility for communicating with the DCC, making writing assignments, and other tasks necessary to produce a complete draft manuscript. The WG lead will report regularly on the status of the manuscript to the DCC, who will produce a status report for distribution to the PC.

6. The PC will establish general guidelines for the timely completion of manuscripts. The Committee will periodically monitor the progress of manuscripts and take corrective action as needed to insure their timely completion. In extreme cases, this could include replacing the lead of a writing group for a manuscript that is not progressing.

7. When there are more manuscript proposals approved than the DCC has resources to actively work on, the PC will set priorities for the order in which analyses will be conducted.

8. In general, Investigators are discouraged from submitting more than a few manuscript proposals at any one time. In the case of an Investigator with multiple approved proposals, the PC may identify which proposal(s) will receive active attention from the DCC at a particular point in time.

2E. PROCESS FOR RIVUR PROPOSALS

2E.1 Development of Proposals for Analyses of Core RIVUR Study Questions
The PC is responsible for overseeing specific written and oral communications concerning core hypotheses/research questions. To facilitate this process, initial discussion and prioritization of publications or presentations based on the primary research questions will be generated by the PC.

Submissions dealing with the core hypotheses will have priority over ancillary submissions, both in terms of timing and in use of study resources for data analysis. Analyses of hypotheses related to RIVUR shall not be published or presented using individual site data prior to the submission for publication of these hypotheses using pooled (study-wide) data unless approved by the PC.

**2E.2 Submission of Manuscript Proposals**

Requests to use data collected by RIVUR must be completed using the RIVUR study proposal form available online at [http://www.cscc.unc.edu/rivur/](http://www.cscc.unc.edu/rivur/). Following completion of the online manuscript proposal, the submitter should contact the DCC PC liaison. The proposal should be brief (2-3 pages), use the latest version of the submission form:

- a. proposed title, and names of possible investigators
- b. background information, rationale for the analyses
- c. specific aims, hypotheses to be tested
- d. study design (i.e., type of study) and methods
- e. specific inclusion and exclusion criteria
- f. laboratory methods
- g. quality assurance/quality control procedures
- h. statistical approaches to be used and rationale for analyses: this should include power calculations relevant to the proposed study question
- i. identification of variables and description of their role: dependent, independent, effect modifier, etc.
- j. specific timetable for completion of project, including deadlines for submission of abstract, data analyses, and first draft of paper

External investigators submitting a RIVUR manuscript proposal must submit their proposal by email to the DCC PC liaison, who will enter it into the secure online form. External investigators should include a biosketch in NIH format, and are encouraged to team with a RIVUR investigator as a collaborator to facilitate the timely conduct of the proposed initiative and to appropriately place initiatives in the context of the overall study data.

**2E.3 Review and Approval of Proposals**

Manuscript proposals not submitted appropriately will be held and the DCC will provide a request for a revised submission.
If overlapping proposals are submitted to the PC, it is the PC's responsibility to suggest how they may be combined and re-submitted as one proposal potentially involving investigators from more than one research area or how they may be revised and re-submitted as two separate, non-overlapping proposals, or to choose the proposal with the greatest overall merit.

Once submitted, the manuscript proposal will be posted to the "Proposals in Progress" page on the RIVUR private web site. One week prior to the next scheduled PC meeting or call, the DCC will provide all new or revised manuscript proposals to the PC for review. The PC will review all study proposals on the bi-monthly conference call. This process will occur in a timely manner, attempting to provide feedback to the primary investigator within 2 weeks following PC review. The PC will assess the manuscript proposal using various criteria: whether the work is duplicative, whether the manuscript proposal reflects high quality science, whether the manuscript proposal presents a significant use of resources, whether data are available, and whether the concept represents “hot” science and might be eligible for fast-tracked journal submission. The PC can also suggest corrections and revisions. Comments on a particular proposal may be posted as a reply on the secure publication website. The PC will include all comments in their decision. The PC will inform the primary investigator of the status as: approved, rejected or deferred (revisions requested).

The primary investigator will be emailed the final decision and project number (see below), referencing any recent changes to the manuscript proposal, and request their response to any comments.

2F. Authorship Guidelines and Policy

1. Authorship Policy and Guidelines

   a. Selection of persons to be named as authors and the order of authorship will conform to generally accepted standards. In particular, the standards published by the International Committee of Medical Journal Editors (Oct, 2004 which is published in JAMA) will be used to guide decisions on authorship credit.

   b. Authorship for pivotal manuscripts (e.g., primary baseline and outcomes manuscripts) will name authors from the writing group and credit the entire RIVUR Study group, e.g.: “Jones, Smith, and Brown, for the RIVUR Trial Investigators”.

   c. Authors for other manuscripts based on RIVUR data will be individually named from among the members of the writing group, based on the ICMJE guidelines referenced above.

   d. Authorship for manuscripts in which RIVUR data is essential but not the primary focus (e.g., publications from RIVUR ancillary
Specific tasks of the lead author include:

a) Determining authorship order.
b) Obtaining consensus on the authorship order from the writing committee.
c) Notifying DCC within one month of appointment of:
   i. the list and proposed order of the writing group membership;
   ii. proposed analysis target dates for abstract and first draft of paper;
   iii. proposed target date for paper submission. (The timeline should follow the standards set in Section 2E.3)
d) Coordinating with DCC and PC to ensure that data analyses are distributed to writing committee members in a timely fashion.
e) Notifying the PC (or designated committee) of significant problems or delays in completion of analyses or writing of drafts, or the need for changes in authorship.
f) Notifying the writing group of manuscript submission to the PC.
g) Notifying DCC and the PC chair’s assistant of outcomes of journal submission.

2G. Timelines and Milestones for Manuscript Development

At the time of writing group assembly, a biostatistician will be assigned to the project. That individual will contact the investigator as soon as that proposal reaches the top of the queue, or within a week of assignment if there is no queue, to discuss the statistical analysis plan (SAP). Following the SAP, technical specifications for creating the analysis dataset and programming the necessary analyses (statistical computing request) will be prepared and submitted to the DCC programming staff. Programming will be completed in priority order relative to other work in the queue and each manuscript’s priority assigned by the PC. Subsequent milestones and sample time-line would be: Assembly of analytical data set should follow 0.5 to 1 month after receipt of request. Preliminary statistics, data visualization, decryptions, exploration should be complete within 1 to 2 months. A focused statistical analysis aimed at addressing research questions including draft of figures and tables to be included in the paper would follow within a month. The DCC statistician on the writing group will prepare an initial draft of the methods and results sections of the manuscript. Statistical results dissemination and manuscript development activities will take place on the RIVUR Sharepoint site. Each writing group will have a secure space in which to develop the manuscript, and record communications and approvals/comments.

Co-authors should be explicitly informed when a complete draft manuscript is available for substantive, methodological, and/or statistical review. All members of the writing group must participate in the writing and/or review process, making edits to the Sharepoint draft within a two week period. If a writing group member does not actively participate in the writing and/or review process, then he/she may be removed from the
writing committee. Also, in the event that a writing group member disagrees with a revised manuscript, an attempt should be made within the writing group to resolve the issue. If such an effort fails, the issue should be brought by the primary investigator to the PC. Each co-author should indicate in the Announcement section of the writing group page that he/she approves submission of the manuscript.

2I. Review of Manuscripts by Steering Committee

Once the manuscript has been approved by the co-authors, it must be submitted electronically to DCC for distribution and review by the PC prior to submission to any journal. The review version of the manuscript will be posted to the secure PC Sharepoint site. The posting will include the writing group number. The PC Chair will determine if the manuscript should be reviewed by all PC members, or if one member of the PC will be assigned as the primary reviewer. Two weeks is the goal to review the draft and bring comments before the PC by meeting, conference call, or email discussion for approval. If appropriate, at the same time a scientific subject-area expert will be assigned to review the manuscript. Data verification by the DCC is also to be completed during this two week review period.

2H. Preparation of Abstracts and Presentations

All presentations should be developed in coordination with the DCC. Scientific abstracts and presentations typically flow from approved manuscript proposals for which analyses are underway. In rare cases, the PC may approve the preparation of an abstract or presentation in the absence of an active manuscript writing group. In this case, analyses will be expedited by the DCC based on deadline dates, provided the work meets with PC approval and NIH guidelines.

Prepared abstracts and presentations should be submitted online through the secure area of the RIVUR.net web site using the ‘Abstract and Presentation Submission’ Form under the ‘Publications’ section of the site (http://www.cscc.unc.edu/rivur/pubprop/add_proposal_pub_abst.php). An email to the DCC (suitable for forwarding to the PC) should include information on the intended meeting, due date for the abstract, and type of study (core, site-specific, etc.), and associated writing group number. Depending upon the deadline, the abstract will either be distributed immediately to the PC by email or will be held until the packet for the next scheduled call is prepared. The PC should have 1-2 weeks to comment on the abstract and recommend acceptance, rejection or acceptance with revisions. The investigator will receive all comments and have the opportunity to make changes. The core site PI will have the responsibility to review the final abstract to be sure it incorporates critical comments. Investigators will be encouraged to follow the above procedure. Last minute abstracts should be few, and the review/comment/disposition process will occur via email or special PC call.

2I. Review of Abstracts and Presentations
Final abstracts and presentations must be received by the DCC a minimum of 14 days prior to the deadline for submission in order to be reviewed by the PC. All abstracts and presentations must be reviewed and approved by a majority of PC voting members before any presentation at a formal scientific meeting or prior to submission for publication.

2J. Outside Analysis

If data analysis was not carried out at the DCC, the lead author is responsible for preserving and archiving all computer programs and associated data sets associated with the manuscript. The programs and data should be labeled table1.dat, table1.sas (if SAS was used for table1) whereby running table1.sas on table1.dat will produce the statistics presented in table 1 of the paper. RIVUR data will only be provided by the DCC to investigators in conjunction with an approved Data Use Agreement. Use of the received data is confined to the specific aims of the analysis proposed and approved. No further use or distribution of the RIVUR data is permitted.

2K. PROCESS FOR SECONDARY AND ANCILLARY PUBLICATIONS

Secondary publications refer to investigations using data collected as part of the core RIVUR protocol but which are not directly related to the hypotheses of the RIVUR research. (See Section 1 of the Manual of Procedures for the RIVUR core research questions and the list RIVUR Core Manuscripts.) While the primary RIVUR hypotheses shall have priority in terms of data analysis, proposals to study other PC scientific questions using RIVUR data are encouraged. (RIVUR members may propose such studies on their own behalf or on behalf of other qualified investigators from their own or other institutions.) These studies will generally fall into three categories: a) secondary studies among investigators from each of the sites utilizing pooled RIVUR data, b) ancillary studies that use study data in conjunction with data from individuals who are not participants in RIVUR, and c) site-specific data which does not substantively involve the pooled RIVUR data (although some RIVUR-gathered demographic or clinical information relevant to local data might be used). These will be considered separately.

1. Secondary studies require PC approval. The proposing investigator will follow the guidelines outlined in Section 2E3. The PC review of such plans should assure that the study will not interfere with the conduct of the core studies, and that publications arising from the study will not compete with or conflict with similar reports from RIVUR primary investigations (as previously defined). A timetable for analyses of the data by DCC will be approved by the PC, taking into account other analyses and data management priorities.

2. Ancillary investigations that use study data in conjunction with data from individuals who are not participants in the RIVUR must seek approval from the RIVUR PC. The proposing investigator will follow the RIVUR publication guidelines. The PC review of such proposals should assure that publications arising from the ancillary study will not compete or conflict with the reporting of the core or secondary findings of the RIVUR data. A timetable for analysis of the
data by DCC will be approved by the PC, taking into account other analyses and data management priorities.

2N. Complying with NIH Public Access Policy

Award recipients are required to comply with the NIH Public Access Policy. This includes submission to PubMed Central (PMC), upon acceptance for publication, an electronic version of a final peer-reviewed, manuscript resulting from research supported in whole or in part, with direct costs from National Institutes of Health. The author’s final peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. For additional information, please visit http://publicaccess.nih.gov/.
Agreement to Abide by RIVUR Publication and Presentation Policy created on September 14, 2012

I have read the RIVUR Publication Policy above and agree to abide by it. Realizing this policy may be updated during the course of the trial, I also agree to review and adhere to future versions of this Publications Policy that are in place at the time manuscript of presentation activity is on-going.

Name (printed/typed):

Title:

Date:

Signed: _______________________________________________________________
Figure 1.
RIVUR Manuscript Proposal Form Screenshot
7. **Hypothesis / Objective:**

8. **Research Methods (study design, inclusion/exclusion criteria):**

9. a. **Will any non-RIVUR data be analyzed (e.g., ancillary study)?** Yes: ☐ No: ☐  
   b. If so, please document approval or explain data access:

10. a. **Will any outcome (post-randomization) data be utilized?** Yes: ☐ No: ☐  
    b. If so, please review the "Categories and Timing of Manuscripts and Presentations" section of the RIVUR Publication and Presentation Policy:

11. **Data variables to be used in the analysis:**

12. **Statistical Analysis Plan:**

   ☉ Be sure to provide the following details for inclusion/exclusion, outcome and variable definition, other variables of interest (potential confounders), statistical analysis, power considerations, any anticipated challenges if present.

   **Table Shell Title:**

   **Table Shell File:**

   If you desire to provide / attach additional shell tables, provide an illustrative file name. (e.g. Example table for CVD Risk Comparisons), then click "Browse..." and upload a single file from your computer to include in the submission for review.

   (you may need to combine multiple figures, tables etc. into one file to append).
Figure 2.
RIVUR Abstract or Presentation Submission Form Screenshot