CHRONIC KIDNEY DISEASE IN CHILDREN COHORT STUDY

SECTION 22: PUBLICATION POLICY AND ANCILLARY STUDIES

22.1 BACKGROUND AND PURPOSE

The Chronic Kidney Disease in Children Cohort Study (CKiD) will use a multi-site, prospective study design to determine the risk factors for decline in kidney function and to define how a progressive decline in kidney function impacts neurocognitive function and behavior; the risk factors for cardiovascular disease, and growth failure and its associated morbidity. When deemed appropriate and beneficial, the CKiD Steering Committee (SC) also intends to combine CKiD data with other homologous cohort data to address research questions common to both studies. The CKiD SC, consisting of the principal investigators from each CKiD clinical coordinating centers, the National Institutes of Health (NIH), the CKiD Data Management and Coordinating Center (KIDMAC), the CKiD Central Biochemistry Laboratory (CBL) and Principal Investigators from some clinical sites, intend that key findings from this multicenter study be presented and published widely, promptly, and be of the highest quality.

The purpose of this publication policy is to ensure that these important multicenter research findings from the Chronic Kidney Disease in Children Cohort Study be developed collaboratively, efficiently and fairly among the collaborators from each of the participating sites, the NIH and KIDMAC. Additionally, it is the purpose of this policy to ensure an efficient, fair and coordinated collaboration with other outside investigators or other cohort studies on all research questions deemed appropriate for joint analysis.

22.2 DEFINITIONS

The publication policy is designed to address all investigations which may use data collected in this study. The basis for determination of these definitions will over time fall to the SC voting members, a subcommittee of the Steering Committee.

The CKiD SC recognizes two categories of investigators and two categories of investigations:

1. CKiD INVESTIGATORS (CKiD-I)
   CKiD-I are defined by the SC as investigators named by each clinical coordinating center and the data coordinating center, as well as a representative from each NIH institute supporting the cooperative agreement.

2. CKiD EXTERNAL INVESTIGATORS (CKiD-E)
   CKiD-E are defined as any investigator who does not meet the criteria to be a CKiD-I. In addition, CKiD-I who cease to meet the definition of CKiD-I will be external investigators. Such departing CKiD-I must submit a letter to the SC within six months of departure, requesting authorship on any papers in process at the date of departure. This letter must detail how the departing CKiD-I meets authorship criteria, as outlined in section 22.3.4 below.

3. CORE INVESTIGATIONS
   Core investigations are those designed to accomplish the study objectives that are common to all CKiD sites. Analyses and publications or presentations resulting from this data will be developed by a writing committee formed by the CKiD collaborators and confirmed by the Steering Committee. As shared data, these investigations and publications will have priority over secondary or ancillary investigations.

4. SECONDARY/ANCILLARY INVESTIGATIONS
   Secondary investigations are those that rely upon data collected as part of this study but which are unrelated to study-wide hypotheses. CKiD investigators may propose such investigations on their or their consortium's behalf.

22.3 PROCESS FOR CORE CKID PROPOSALS

22.3.1 Development of Proposals for Analyses of Core CKiD Study Questions

The CKiD SC is responsible for overseeing specific written and oral communications concerning core hypotheses/research questions described in the CKiD research models for publication and presentation at scientific meetings. To facilitate this process, initial discussion and prioritization of publications or presentations based on the primary research questions will be generated by the CKiD Scientific Area-Based (SAB) Subcommittees with final review by the CKiD SC.

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 the CKiD research models shall not be published or presented using individual site data prior to the submission for publication of studies of these hypotheses using pooled (study-wide) data unless approved by the SC.

22.3.2 Submission of Proposals

Requests to use data collected by CKiD must be completed using the CKiD study proposal form or "concept sheet" available online at www.statepi.jhsph.edu/ckid. Completed concept sheets should be emailed to KIDMAC to the attention of Judith Jerry-Fluker (jjerry@jhsph.edu) for posting and SC review. The proposal should be brief (2-3 pages), using 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. numbers, types and volume of specimens needed, if applicable

k. timetable for completion of project, including deadlines for submission of abstract, data analyses, and first draft of paper

Investigators are encouraged to develop studies in conjunction with one or more of the scientific subcommittee members listed in Section 2. Study proposals dealing with CKiD specific aims outlined in Section 1 of the Manual of Procedures will have priority in terms of study resources. In evaluating proposed studies, the SC will consider whether the proposed study would interfere with, compete or

conflict with the conduct of the CKiD core protocol. Proposed studies may require external funding to cover costs incurred by the CKiD clinical coordinating centers, sites, central laboratories, and KIDMAC.

Ethical consideration of human subjects includes a commitment to maintain the confidentiality of enrolled participants. Hence, individually identifiable data may not be released. If the proposed study requires the collection of additional data from participants that are not covered in the original informed consent process, then a supplemental written informed consent must be obtained from every participant in the proposed study. If a separate consent form is required for the proposed study, a copy of a signed ancillary study consent form for each study participant must be included in the CKiD record. A data file tracking all signed ancillary consent forms must be maintained by the primary investigator and an electronic copy of that file must be delivered to KIDMAC.

External investigators submitting a CKiD concept sheet must include a biosketch in NIH format, and are encouraged to team with a CKiD-I 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. Data from cohort studies are complex and CKiD-E are encouraged to have a close liaison with a CKiD-I. Submission of a concept sheet requires (a) key personnel certified in the NIH OHSR or equivalent training course (b) a signed contract and (c) inclusion of at least one CKiD participant enrolled in the main study.

22.3.3 Review and Approval of Proposals

The primary investigator will submit his/her concept sheet to KIDMAC via e-mail using the most current version of the Concept Sheet Proposal Form. Concept sheets submitted on the wrong form will be returned with a request for resubmission on the correct form.

If overlapping proposals are submitted to the SC, it is the SC'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 to KIDMAC, KIDMAC will post the concept sheet (CS) to the "Submitted Concept Sheets" bulletin board on the CKiD private web site. The posting will include the title and the lead author of the proposal and the target date for review by the full SC. KIDMAC will also e-mail the SC members when this information has been posted to the web site. The SC will assign a Primary Reviewer (often referring to the appropriate scientific subcommittee) who will prepare a written critique of the concept sheet within two weeks, when possible. The SC will review all study proposals and written critiques on the semi monthly conference call, inviting the Primary Investigator and Primary Reviewer. This process will occur in a timely manner, attempting to provide feedback to the primary investigator within 4 weeks of submission. The SC will assess the CS using various criteria: whether the work is duplicative, whether the CS reflects high quality science, whether the CS presents a significant use of resources, whether data is available, and whether the concept represents “hot” science and might be eligible for fast-tracked journal submission. The SC can also suggest corrections and revisions. Comments on a particular proposal may be posted as a reply on the bulletion board. The SC will include all comments in their decision. The SC 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 SC changes to the CS, and request their response to any comments via posting. The author of the proposal will have approximately one week to address any concerns that may have been voiced on the discussion board. Significant changes in a concept or in the variables to be analyzed will require resubmission of the proposal as outlined above in Section 22.3.2.

Removal of CKiD specimens from the NIDDK repository for analysis requires prior approval by the SC,

and prior authorization by both KIDMAC and the Repository Project Officers before KIDMAC will request samples. The process for requesting CKiD repository samples is outlined in Section 30 of the Manual of Procedures.

If approved, KIDMAC will assign the concept sheet a study number in the form of k-YY-###, where "k" takes values 1, 2, 3 and 9 representing the primary investigator affiliated with the mid-west CCC, east-coast CCC, KIDMAC and external investigator, respectively; YY will represent the year; and ### will represent the sequential ID of the concept sheet. This study number will accompany any communications regarding the approved study. The primary investigator named on the concept sheet is responsible for: (1) successful and timely completion of the proposed study; (2) communicating with KIDMAC to initiate creation of analytical datasets, selection of repository specimens, and (if necessary) data analysis; and (3) provision of an annual written progress report to the CKiD SC. No data, information, or specimens will be released prior to the primary investigator providing a copy of local IRB approval to KIDMAC. Studies that have failed to demonstrate notable progress within one year from the date of approval, or where scientific misconduct has occurred, as judged by the SC, may have approval status revoked by the SC.

22.3.4 Formation of Writing Committee

After a CS is approved, requests will be sent out for co-author and senior co-author (MNJ) assignment to principal investigators. Principal investigators carefully select their sites' representative on the paper. Failure to name an author, who must be willing to be an active participant, within 2 weeks will result in the site having no author. MNJ authors should be in communication with the lead author and receive all data sets and manuscript versions.

The number and composition of the people in a writing committee may vary according to whether the primary investigator is a CKiD-I or a CKiD-E. The primary investigator who is named on the concept sheet may either be the lead or senior author. If the primary investigator is a CKiD-I, the writing committee for the publication may include a total of up to nine members as follows: (a) up to two additional investigators from the coordinating center of the primary investigator whom also must be named on the concept sheet; (b) up to two investigators from each of the other two centers; and (c) up to two members from NIH or other major contributor to the publication (e.g., a laboratory collaborator). Failure of a SC voting member to name a study representative co-author within two weeks of study approval results in no co-author from the voting member's center. The writing committee for a revoked study is disbanded.

If the primary investigator is a CKiD-E, the writing committee may include the following: (a) additional members of the research team of the primary investigator; (b) up to one investigator from each of the three coordinating centers of the study; and (c) up to two members from NIH or other major collaborating centers. In any case, studies reporting data at the core of the specific aims of the study should have at least one representative from each of the three coordinating centers of the study. Ancillary or secondary studies do not need to have a co-author from each of the three coordinating centers of the study. 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 SC 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).

The lead author is responsible for the completion of the manuscript, as well as the determination of authorship order. The lead author of the writing committee will be responsible for requesting and facilitating a conference call early in the planning of the analysis. Writing assignments should be given to those interested committee members at this time. A proposed order of authorship should also be considered at the time writing assignments are distributed.

Specific tasks of the lead author include:

a. Determining authorship order.

b. Obtaining consensus on the authorship order from the writing committee.

c. Notifying KIDMAC within one month of appointment of:

   i. the list and proposed order of the writing committee membership;

   ii. proposed analysis target dates for abstract and first draft of paper; and

   iii. proposed target date for paper submission.

   (The above timeline should follow the standards set in Section 22.3.5)

e. Coordinating with KIDMAC to ensure that data analyses are distributed to writing committee members in a timely fashion.

f. Notifying the SC (or designated committee) of significant problems or delays in completion of analyses or writing of drafts, or the need for changes in authorship.

g. Notifying the writing group of Manuscript submission to the SC.

h. Notifying KIDMAC and the SC chair's assistant of outcomes of journal submission.

22.3.5 Timelines for Manuscript Development

At the time of writing committee assembly a biostatistician will be assigned to the project. That individual will contact the investigator within a week of assignment to discuses the optimal format for analytic data set requests. The analytic request should then follow within 2 weeks. As a proposed subsequent time-line: Assembly of analytical data set should follow 0.5 to 1 month after receipt of request. Preliminary statistics, data visualization, descriptions, exploration should be complete 1 to 2 months after CS prioritization. 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.

Complete draft manuscripts should be submitted to the co-authors for substantive, methodological, and/or statistical review. All members of the writing committee must participate in the writing and/or review process, returning edited drafts within a two week period. If a writing committee 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 committee member disagrees with a revised manuscript, an attempt should be made within the writing committee to resolve the issue. If such an effort fails, the issue should be brought by the primary investigator to the SC.

22.3.6 Data Specimens and Analysis Requests

Once a project is approved, the lead author should communicate with KIDMAC to start collaboration in study design, creation of analytical datasets, selection of repository specimens, and data analysis.

Data requests should be submitted to KIDMAC as a list including each CKiD variable name for which data are needed, the form number(s) on which the variables are located, and the visit number(s) and/or calendar dates for which data are needed. Variable names can be obtained from the private CKiD Data Management System website. A KIDMAC repository coordinator (KRC) will be assigned to the project once a data request has been made. If a request for data analysis is made but it is not to be done by KIDMAC, then KIDMAC will normally require two weeks for the production of an analytic database. Longer time may be required for complex data requests.

Once the list of specimens has been generated, a request for obtaining the specimens is forwarded to the NIH Repository Officer for sign-off. Once approval is obtained, KIDMAC will contact the repository to arrange shipment of the specimens.

NOTE: Requests for specimens will not be processed until verification of local IRB approval has been provided.

It is anticipated that, during the analysis phase, KIDMAC team members will primarily and intensively communicate with the writing group chair (and perhaps a few others). The writing chair is responsible for updating working groups and other members of the writing committee.

Once abstracts and manuscripts are written and finalized among members of the writing committee, they should be sent to the SC for review and approval.

22.3.7 Review of Abstracts, Presentations

Final abstracts and presentations must be reviewed and approved by a SC voting member before any presentation at a formal scientific meeting or prior to submission for publication. These requests will be expedited by KIDMAC based on deadline dates and must meet SC and NIH guidelines.

Abstracts will be submitted electronically to KIDMAC and should include information on the intended meeting, due date for the abstract, and type of study (core, site-specific, etc.). Abstracts will be posted on the CKiD private website and PIs will have one week 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 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 responsibility for review and recommendation will fall to the site PI who will report to the SC on the subsequent scientific call.

22.3.8 Review of Manuscripts by Steering Committee

Once the manuscript has been approved by the co-authors, it should be submitted electronically to KIDMAC prior to submission to journals. Manuscripts will be posted to the "Manuscripts" bulletin board. The posting will include the title and lead author of the proposal. A member of the SC 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 SC by meeting or conference call for approval. If appropriate, at the same time a Scientific Area-Based Subcommittee chair will assign an expert in the field to review the manuscript.

Manuscripts are processed in much the same manner as CS. The primary reviewer (PR) will review the manuscript and use co-author and SC members' comments to decide the outcome of the manuscript. Co-authors are required to post their approval/disapproval of the manuscript version. Anyone with comments on a particular manuscript may post them as a reply on the web site.

KIDMAC will e-mail SC members indicating when a manuscript is posted to the web site and when it will be due for review on the full SC call.

If a co-author disagrees with a manuscript or finds the manuscript to be misleading about CKiD data they need to first attempt to resolve the issue with the writing group/co-authors before submitting to the SC. If a co-author still finds fault with the version submitted to the SC, they should indicate that on the discussion board. The PR will review the comments and the full SC can eventually be asked to review the manuscript and discuss any concerns.

Lead authors are responsible for informing KIDMAC regarding the outcome of any journal submissions. If a manuscript is accepted for publication, lead authors must also send a Portable Document Format (.pdf) version of the published article.

Presentations or manuscript submissions which do not have prior SC approval and NIH notification are inconsistent with the spirit of collaborative research. Disregard of this policy may result in a denial of access to data and a cessation of collaborative support. In addition, presentation or submission of unapproved manuscripts puts the investigator at risk of disciplinary proceedings by the CKiD SC and/or

funding agencies.

Publications and presentations shall be in compliance with the rules and procedures of the disclosure set forth in the Privacy Act. Confidential or proprietary information shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the paper/presentation.

22.3.9 Study Acknowledgements

All manuscripts should acknowledge that the data were collected through the CKiD Study and credit participating institutions (CKiD representatives plus KIDMAC and the NIH). NIH support contract numbers are to be on the front page of the manuscript. All manuscripts derived from data collected by CKiD must include the following acknowledgment:

> Data in this manuscript was collected by the Chronic Kidney Disease in children prospective cohort study (CKiD) with clinical coordinating centers at Children's Mercy Hospital and the University of Missouri – Kansas City (Bradley Warady, MD) and Children's Hospital of Philadelphia (Susan Furth, MD, Ph.D.), Central Biochemistry Laboratory (George Schwartz, MD) at the University of Rochester Medical Center, and data coordinating center at the Johns Hopkins Bloomberg School of Public Health (Alvaro Muñoz, Ph.D.) (U01-DK-66143, U01-DK-66174, U01-DK-82194, U01-DK-66116). The CKiD is supported by grants from the National Institute of Diabetes and Digestive and Kidney Diseases, with additional funding from, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Heart, Lung, and Blood Institute. The CKiD website is located at http://www.statepi.jhsph.edu/ckid.

22.3.10 Outside Analysis

If data analysis was not carried out at KIDMAC, the lead author is responsible for sending computer programs and associated data sets to KIDMAC.

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. Data received from KIDMAC should be kept confined to the specific aims of the analysis proposed.

22.3.11 PubMed Central Reference Number (PMCID) Requirement

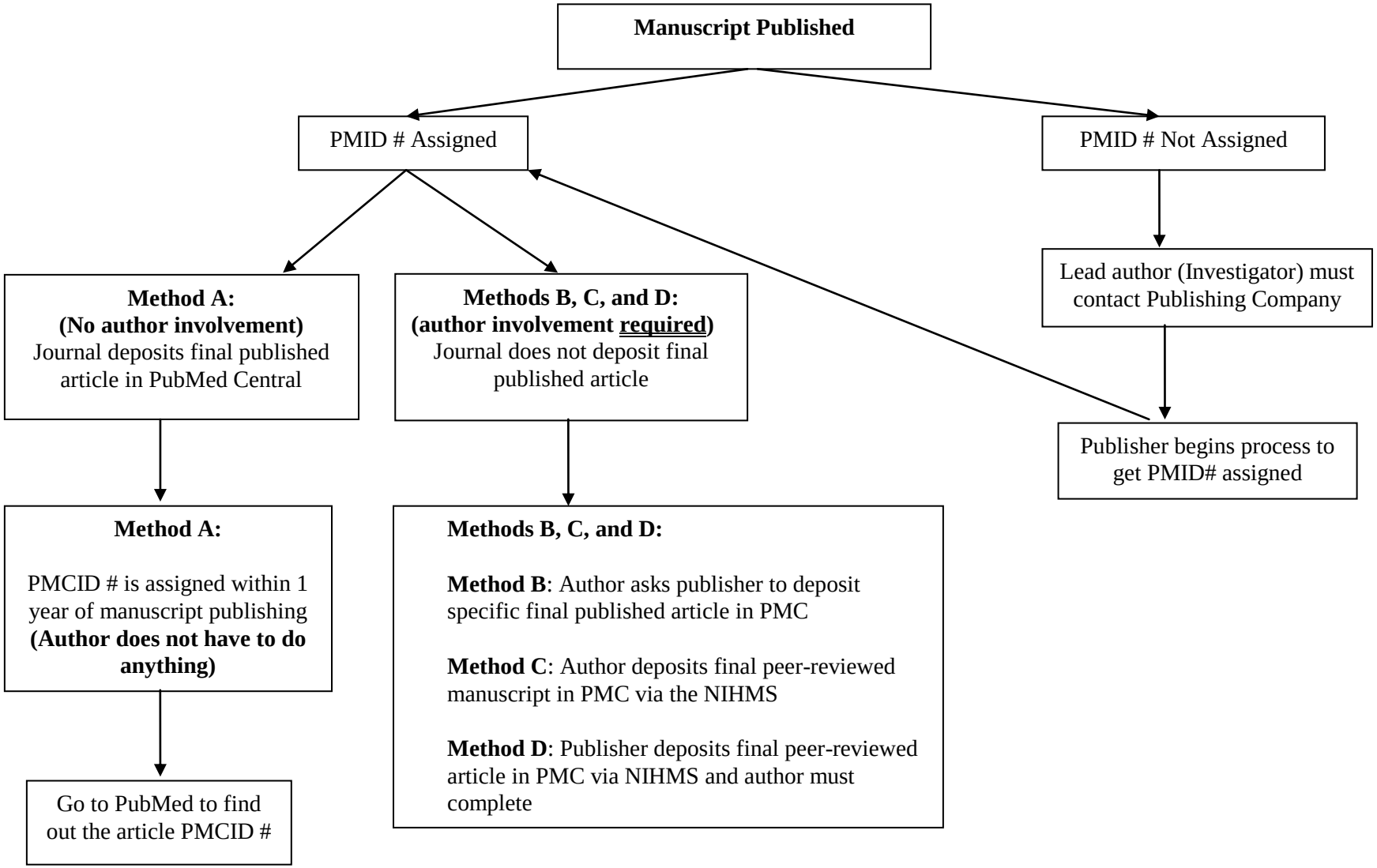
22.3.11.1 Overview of the National Institutes of Health Public Access Policy

The majority of information contained in Section 22.3.11 was adapted from the National Institiutes of Health (NIH) Public Access website: http://publicaccess.nih.gov/.

NIH implemented the Public Access Policy on January 11, 2008. As of April 7, 2008, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central (PMC) upon acceptance for publication. As of May 25, 2008, NIH applications, proposals, and progress reports must include the PubMed Central reference number when citing a paper that falls under the policy and is authored or co-authored by the investigator, or arose from the investigator's NIH award.

There are four submission methods, methods A-D as outlined in Diagram 1 and described in Section 22.3.11.2, to ensure that an applicable paper is submitted to PubMed Central in compliance with the NIH Public Access Policy. **It is the sole responsibility of the author and/or the publishing company to follow the steps to obtain a PMCID #.**

Diagram 1: Process to obtain PMCID# for published manuscript



PMID- PubMed reference number
PMCID- PubMed Central reference number

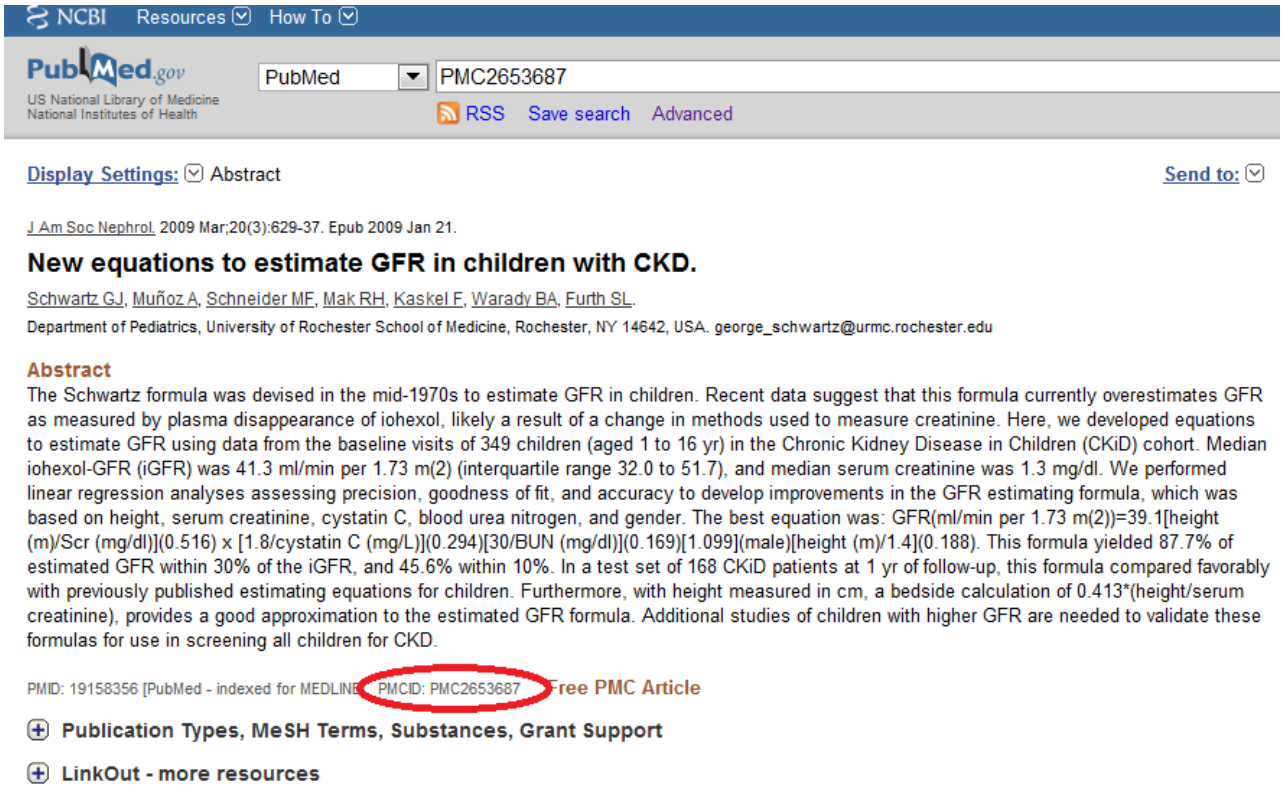
22.3.11.1.1 The Difference between a PMCID and a PMID

The PubMed Central reference number (PMCID) is different from the PubMed reference number (PMID). PubMed Central is an index of full-text papers, while PubMed is an index of abstracts. All CKiD publications should have both numbers. The PMCID number indicates compliance with NIH's Public Access Policy.

In order for a manuscript to be deposited in PMC, **a PMID # must be assigned by the publisher**. In most cases, the PMID # is automatically assigned by the publisher; however, in some cases, the lead author must contact the publisher and request that the PMID # is assigned. See section 22.3.11.1.4 on how to identify a submission method.

22.3.11.1.2 Locate the PMCID

The PMCID is posted in PubMed when an article has been processed by PubMed Central. PMCIDs are listed in the lower right hand corner of the Abstract View in www.pubmed.gov.



22.3.11.1.3 Include PMCID in Citation

When submitting an application, proposal, or report to the NIH, CKiD papers must include the PMCID number at the end of the citation. Below is an example of how to cite a paper with a PMCID number.

Schwartz GJ, Muñoz A, Schneider MF, Mak RH, Kaskel F, Warady BA, Furth SL. New Equations to Estimate GFR in Children with Chronic Kidney Disease. J Am Soc Nephrol 2009;20:629-37. (Commentary by Lemley, KV in Nature Reviews Nephrology 2009;5:310-1). PMCID: PMC2653687

22.3.11.1.4 Identify a Submission Method

The NIH Public Access website http://publicaccess.nih.gov/submit_process_journals.htm provides a list of journals that make the final published version of all NIH-funded articles available in PubMed Central (PMC) no later than 12 months after publication. The listed journals deposit these articles in PMC at the time of final publication, which fulfills the submission requirement of the NIH policy without author involvement. The start date shown for each journal is the earliest publication date that meets this requirement. For any journal that is not on the Public Access website's list, see the other submission options outlined under http://publicaccess.nih.gov/submit_process.htm.

The four journals listed below, in which the CKiD study has published articles, follow method A. Specifically, these journals deposit all final published articles to PMC without the authors involvement.

- American Journal of Epidemiology (AJE)
- Clinical Journal of the American Society of Nephrology (CJASN)
- Journal of the American Society of Nephrology (JASN)
- Pediatrics

The journals listed below, in which the CKiD study has published articles, use **other submission options (i.e., method B-D).** Details about each method is described in Section 22.3.11.2: Submission Methods. Below the name of each journal is a link to the journal's submission method. For examples of copyright agreement forms for each journal is also provided the appendices.

- American Journal of Kidney Disease (see Appendix A for example of copyright agreement)
  http://www.ajkd.org/content/edpolicies#nih
- Epidemiology (see Appendix B for example of copyright agreement)
  http://journals.lww.com/epidem/_layouts/oaks.journals/nih.aspx
- Hypertension (see Appendix C for example of copyright agreement)
  http://journals.lww.com/jhypertension/_layouts/oaks.journals/nih.aspx
- Journal of Urology (see Appendix E for example of copyright agreement)
  http://www.elsevier.com/wps/find/journaldescription.cws_home/706695/authorinstructions
- Kidney International (see Appendix F for example of copyright agreement)
  http://www.nature.com/authors/policies/license.html
- Mental Retardation Developmental Disabilities Research Reviews (see Appendix G for example of copyright agreement)
  http://www.wiley.com/WileyCDA/Section/id-321171.html
  http://media.wiley.com/assets/1540/86/ctaaglobal.pdf
- Pediatric Nephrology (see Appendix H for example of copyright agreement)
  http://www.springer.com/open+access/authors+rights?SGWID=0-176704-2-994122-0&changeHeader

22.3.11.2 PMCID Submission Methods

There are four methods to ensure that an applicable paper is submitted to PubMed Central in compliance with the NIH Public Access Policy. Authors may use whichever method is most appropriate for them and consistent with their publishing agreement. Click on the method in the table for details.

	Method A Journal deposits final published articles in PubMed Central without author involvement	**Method B** Author asks publisher to deposit specific final published article in PMC	**Method C** Author deposits final peer-reviewed manuscript in PMC via the NIHMS	**Method D** Author completes submission of final peer-reviewed manuscript deposited by publisher in the NIHMS
Example of Journal that follows method	**AJE** **CJASN** **JASN** **Pediatrics**	**Pediatric Nephrology** **(B or D)**	**Kidney International** **Journal of Urology**	**Am J of Kidney Disease** **Epidemiology** **Hypertension** **Journal of Pediatrics** **Men Ret Dev. Dis Res Rev** **Pediatric Nephrology (B or D)**
Version of Paper Submitted	Final Published Article	Final Published Article	Final Peer-Reviewed Manuscript	Final Peer-Reviewed Manuscript
Task 1: Who starts the deposit process?	Publisher	Publisher	Author or designee, via NIHMS	Publisher
Task 2: Who approves paper for processing?	Publisher	Publisher	Author, via NIHMS	Author, via NIHMS
Task 3: Who approves paper for Pub Med Central display?	Publisher	Publisher	Author, via NIHMS	Author, via NIHMS
Participating journal/publisher	Method A Journals	Make arrangements with these publishers	Check publishing agreement	Check publishing agreement
Who is Responsible?	NIH Awardee	NIH Awardee	NIH Awardee	NIH Awardee
To cite papers, from acceptance for publication to 3 months post publication	PMCID or "PMC Journal- In Process"	PMCID or "PMC Journal-In Process"	PMCID or NIHMSID	PMCID or NIHMSID
To cite papers, 3 months post publication and beyond	PMCID	PMCID	PMCID	PMCID

Method A: Publish in a journal that deposits *all* final published articles in PubMed Central (PMC) without author involvement.

Some journals automatically deposit all NIH-funded final published articles in PubMed Central, to be made publicly available within 12 months of publication, without author involvement. For a list of journals that automatically deposits final published articles to go: http://publicaccess.nih.gov/submit_process_journals.htm.

Method B: Make arrangements to have the publisher deposit a *specific* final published article in PubMed Central.

Some publishers will deposit an individual final published article in PubMed Central upon author request, and generally for a fee. For the list of publishers that will deposit published article after author's request go to: http://publicaccess.nih.gov/select_deposit_publishers.htm.

Method C: Lead author deposits the final peer-reviewed manuscript in PubMed Central himself/herself via the NIH Manuscript Submission System (NIHMS).

Submitting a final peer-reviewed manuscript to PMC via the NIHMS involves three tasks, as explained below. ***Task 1*** may be done by an author or by someone in the author's organization (e.g., an assistant or a librarian). ***Tasks 2 and 3*** **must by done by the author.**

A Note on Timing: NIH awardees are responsible for ensuring that manuscripts are submitted to the NIHMS upon acceptance for publication and that all NIHMS tasks are complete within three months of publication.

A video of this process is posted on the NIH Public Access website, click on "Submitting an Article to PubMed Central (WMV Video - 12:01)" at http://publicaccess.nih.gov/submit_process.htm#c.

***Task 1*: Deposit Manuscript Files and Link to NIH Funding**

Upload a copy of the accepted final peer-reviewed manuscript and associated files (e.g., Microsoft Word document and figures) via the NIHMS (www.nihms.nih.gov). At the same time, identify the NIH funding associated with the manuscript. It usually takes less than 10 minutes to complete this task.

Please note that in order to electronically upload a copy of the accepted manuscript and associated files, the author must have one of the following accounts:

- eRA Commons (for NIH Extramural principal investigators, grantees or applicants)
- NIH Login (for Intrmural NIH scientists and staff)
- HHMI Login (for HHMI-funded investigators)
- My NCBI (for third party submitters)

In most cases, the CKiD authors will log in to NIHMS using their eRA Commons login or their NIH login. The eRA Commons is an online interface where signing officials, principal investigators, trainees and post-docs at institutions/organizations can access and share administrative information relating to research grants.

Using eRA Commons, follow the steps below to upload the manuscript and files.

Step 1: Choose a login route:

- Select eRA Commons
- Log in with your NIH Commons user ID and password. Once logged in, you will be able to upload your manuscript to the NIH Manuscript Submission System.
- If you need to create a new account, contact your central grants administration within your institution/department.

Note: Before moving to Step 2, please have ready budget #s, manuscript (in any electronic word-processing format) and figures.

Step 2: Upload manuscript

After providing basic information about the manuscript and contact information, users can upload their manuscript file(s). The system will generate a receipt of the uploaded files in PDF format. The PDF Receipt summarizes the information entered into the system, and merges the manuscript's files into one viewable document. Submitters confirm that the manuscript and any additional supporting documents have been successfully received by NIHMS.

***Task 2*: Authorize NIH to Process the Manuscript**

If the person who uploaded the manuscript is not the lead author/principal investigator (PI), an email will be sent to the author/PI to approve the PDF and indicate the release date when the manuscript will be made publicly available on PMC. Specifically, the author designates the number of months after publication when the manuscript may be made publicly available in PMC. The author then confirms, via the NIHMS, a statement that the deposit of the manuscript is consistent with any publication and copyright agreements, and that NIH may begin processing the manuscript for use in PMC.

***Task 3*: Approve the PMC-formatted Manuscript for Public Display**

The NIHMS will convert the deposited files into a standard PMC format (i.e., XML-standardized digital format used by PMC). After the conversion process, a preview of the article as it will appear in PubMed Central is emailed to the author, allowing the author to correct any errors if necessary. After final approval, the article will be publicly accessible through PubMed Central (after the time-delay specified by the author.)

Following completion of Task 3:

- The NIHMS will email the author and all PIs the citation with the PMCID once it is assigned;
- PMC will automatically make the paper publicly available after the designated delay period has expired.

For further questions or comments regarding the NIHMS System, please contact the NIHMS Help Desk.

Additional information regarding the NIH Public Access policy can be found at the NIH website, or contact PublicAccess@nih.gov.

Method D: Complete the submission process for a final peer-reviewed manuscript that the publisher has deposited in the NIH Manuscript Submission System (NIHMS).

In a variation of Method C, some publishers deposit the manuscript files in the NIHMS, provide contact information for a corresponding author, and designate the number of months after publication when the paper may be made publicly available in PMC.

A Note on Timing: Though a publisher may make the initial deposit of files under Method D, NIH awardees are responsible for ensuring that manuscripts are submitted to the NIHMS upon acceptance for publication and that all NIHMS tasks are complete within three months of publication.
The NIHMS will notify the author when the manuscript files are received from the publisher. At that point, the author must complete Task 2 (Authorize NIH to process the manuscript) and Task 3 (Approve the PMC-formatted manuscript for public display) as outlined above.

Following completion of Task 3:

- The NIHMS will email the author and all PIs the citation with the PMCID once it is assigned;
- PMC will automatically make the paper publicly available after the designated delay period has expired.

For a video demonstrating author tasks on the NIHMS for Method D, click on "Approving Submission of an Article to PubMed Central (WMV Video - 6:26)" at http://publicaccess.nih.gov/submit_process.htm#c.

22.4 PROCESS FOR SECONDARY AND ANCILLARY PUBLICATIONS

Secondary publications refer to investigations using data collected as part of the core CKiD protocol but which are not directly related to the hypotheses of the CKiD research. (See Section 1 of the Manual of Procedures for the CKiD core research questions.) While the primary CKiD hypotheses shall have priority in terms of data analysis, proposals to study other scientific questions using CKiD data are encouraged. (CKiD members and Institute staff 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 CKiD data, b) ancillary studies that use study data in conjunction with data from individuals who are not participants in CKiD, and c) site-specific data which does not substantively involve the pooled CKiD data (although some CKiD-gathered demographic or clinical information relevant to local data might be used). These will be considered separately.

1. Secondary studies (see 22.4 for definition) require SC approval. The proposing investigator will follow the guidelines outlined in Section 22.3.2. The SC 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 CKiD primary investigations (as previously defined). A timetable for analyses of the data by KIDMAC will be approved by the SC, 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 CKiD must seek approval from the CKiD SC. The proposing investigator will follow the guidelines outlined in Section 22.3.2. The SC review of such plans should assure that the ancillary study will not interfere with the conduct of the primary or secondary studies, and that publications arising from the ancillary study will not compete or conflict with the reporting of the core or secondary findings of the CKiD data. A timetable for analysis of the data by KIDMAC will be approved by the SC, taking into account other analyses and data management priorities.

3. Site-specific studies must also be reviewed and approved by the SC. Site-specific proposals must have the approval of the principal investigator of the site(s) at the time of submission of the concept sheet. Site-specific proposals which use central laboratory specimens require review by the chair of the Laboratory/Specimen Working Group. In addition, those proposals which require analyses at KIDMAC will require the approval of the KIDMAC PI.

   The results of the analysis of specific aims (see Section 1 of the Manual of Procedures) using site-specific data shall not be presented or published prior to their analysis and publication for the entire CKiD cohort, unless approved by the SC.

4. Final abstracts, presentations, and publications of secondary and ancillary studies must also be approved by the SC and receive NIH notification before any presentation to a formal scientific meeting or prior to submission for publication. These requests will follow the same approval process as outlined in Sections 22.3.7 and 22.3.8, and will be accomplished in a timely fashion. The review will focus on the accuracy of the description of the methods and on the conclusions as consistent with the spirit of the CKiD.

22.5 OUTSIDE COLLABORATORS

In some instances, collaborators who are not members of CKiD SC or partner organizations will be involved in data and/or laboratory analyses. These collaborators will be required to acknowledge that CKiD specimens and laboratory data are the property of CKiD. Collaborating scientists will be encouraged to raise relevant scientific questions beyond the data analysis as contracted by the CKiD study; however these requests for approval for data analysis, presentation, or publication must follow the principles outlined in the Publication Policy. Outside investigators should name a CKiD contact person whose responsibility is to ensure the lead investigator has had the opportunity to share his/her ideas with the working groups. Proposals will be submitted electronically to KIDMAC for posting and review. Proposals will follow the same review process as outlined in Section 22.3. Assignment of the writing chair and authorship will follow similar guidelines. For reports resulting from methodological work that exclusively utilizes laboratory data, the collaborating laboratory scientist will have significant input into the assignment of the writing committee and of authorship. However, reports which utilize clinical and laboratory data will likely include authorship of investigators based in CKiD. Analysis of laboratory data from CKiD participants limited to an individual site shall not be published or presented prior to the submission for publication of studies of the core research questions using pooled data.

The expectations and responsibilities of outside investigators are:

- Review and sign response indicating agreement to follow the CKiD Publication Policy.
- Disseminate results to CKiD collaborators in a timely manner. Even though not all studies will result in publication or presentation, all studies from outside investigators should be summarized and presented to CKiD in a written form.
- Before receiving CKiD samples or data, sign a document indicating that the samples and data will only be used as agreed upon in the collaboration. This will be documented at completion of the study. When a study is complete, remaining samples and other agreed upon deliverables must be returned to CKiD.
- Outside investigators will forward agreed upon data to KIDMAC as described in section 22.3. These data will then be entered into the CKiD database where they can be used as part of other analyses after the initial collaborative analyses are completed.
- CKiD investigators have the option to publish results of the analyses if the outside investigator does not wish to write up the study, but agrees that a publication is worthwhile.

22.6 DEPARTING INVESTIGATORS

Departing investigators or staff from KIDMAC or Institute Program Offices shall submit a proposal for authorship role on abstracts and/or papers to CKiD for approval, based on the following guidelines:

- There will be a maximum time limit of two years from separation from the institution to submission of abstract/paper;
- The departing individual can only petition for authorship on abstracts and/or papers in process at the time of separation;
- The departing individual must meet all reasonable criteria for authorship as outlined in the requirement of the journal and as judged by the CKiD SC; and
- A current individual and a departing individual from the same institution may, if appropriate, co-author a single abstract or paper.

22.7 REVISIONS TO PUBLICATION POLICY

Review of the Publication Policy is periodically done by the voting members of the CKiD Steering Committee.

II. PUBLICITY POLICY

A. LOCAL PUBLICITY

Local publicity refers to media distributed primarily to each site's city, metropolitan area, or state. This would include local TV stations, radio stations, and newspapers; city, county, or state health department newsletters; hospital publications; and local university publications not available by general public subscription.

1. Each site can independently release to local media general information about the CKiD study as well as specific information about the conduct of the CKiD study at that site.

2. No disclosures of single- or multi-site study data or analyses should occur without prior clearance by the SC.

B. REGIONAL/NATIONAL PUBLICITY

National publicity refers to media distributed widely outside each site's city, metropolitan area, or state. This includes network television (including "superstations"), network radio, major newspapers, national newsletters (e.g., Nephrology Newsletter), and widely disseminated university publications.

Because such national publicity is likely to impact other sites and the overall reputation of the CKiD study, any site contacted by national media must notify at least one principal investigator at each CKiD site and cooperating federal agencies.

No disclosure of single- or multi-site study data or analyses should occur without prior clearance by the SC.

C. GENERAL GUIDELINES

1. If significant questions arise about other sites or funding agencies ("How much is XIX agency spending overall on the CKiD study?"), refer the reporter to the appropriate agency (i.e., investigators at those sites or agencies).

2. When answering questions, make clear distinctions between personal opinions and positions which have been arrived at jointly by the CKiD collaborators.