

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) is 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 combines 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.

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

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. Specifically, an internal CKiD investigator is a person who is the principal investigator at a local clinical site or a member of one of the scientific working groups/subcommittees.

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. Ancillary investigations are requests to independently perform analyses (i.e., requests for limited datasets), use repository samples, administer new questions or procedures, or collect new samples.

22.3 PROPOSALS

22.3.1 Development of Proposals

The CKiD SC is responsible for overseeing specific written and oral communications concerning hypotheses/research questions. To facilitate this process, initial discussion and prioritization of publications or presentations based on the primary research questions (i.e., CORE hypotheses) will be generated by the CKiD Scientific Area-Based (SAB) Subcommittees with final review by the CKiD SC. The CKiD SC also encourages investigators to submit secondary/ancillary proposals.

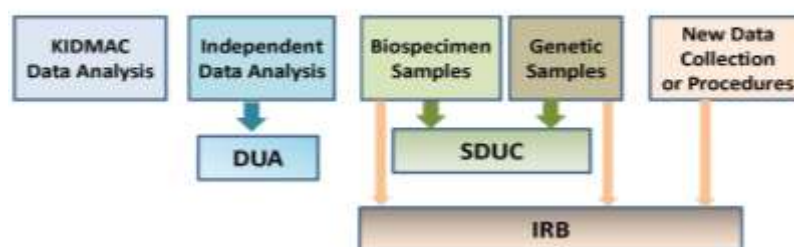
Concept sheet proposals addressing CORE hypotheses will have priority over secondary/ancillary submissions, both in terms of timing and in use of study resources. These CORE concept sheet proposals are expediously reviewed (i.e., expedited review) because these proposals address core CKiD hypotheses and are vetted through the scientific subcommittees prior to submission.

Secondary/ancillary concept sheet proposals dealing with non-CORE hypotheses undergo a scientific review process (see 22.3.3 for details).

There are four basic reasons investigators submit concept sheet proposals. Although the reasons may overlap, the four basic reasons are listed below:

- Investigator is interested in addressing CORE or non-CORE hypotheses in which KIDMAC performs the data analysis
- Investigator is interested in addressing non-CORE hypotheses in which the investigator performs independent analysis (after SC approval, investigator must complete DUA, see Section 22.3.5 for details)
- Investigator is interested in requesting Biospecimen and/or Genetic samples (after SC approval, investigator must complete SDUC, see MOP Section 30 for details)
- Investigator is interested in proposing new data collection or procedures

Types of Concept Sheet Proposals



22.3.2 Submission of Proposals

All investigators must submit proposals by completing the CKiD study proposal form or “concept sheet” available online at <https://statepi.jhsph.edu/ckid/investigator.html>. Completed concept sheets should be emailed to KIDMAC to the attention of Judith Jerry-Flucker (jjerry@jhu.edu) for posting and SC review. The proposal should be brief (2-3 pages), using the most recent version of the submission form. **Concept sheets submitted on the incorrect form version will be returned to the investigator to complete and resubmit on the correct version.**

The concept sheet submission form includes the following:

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

Investigators are encouraged to develop studies in conjunction with one or more of the scientific subcommittee members listed in Section 2 of the Manual of Procedures (MOP). A complete list of participating sites can be found on the CKiD website. The lead investigator on a proposal is encouraged to submit only one concept sheet at a time. Study proposals dealing with CKiD specific aims outlined in Section 1 of the MOP 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.

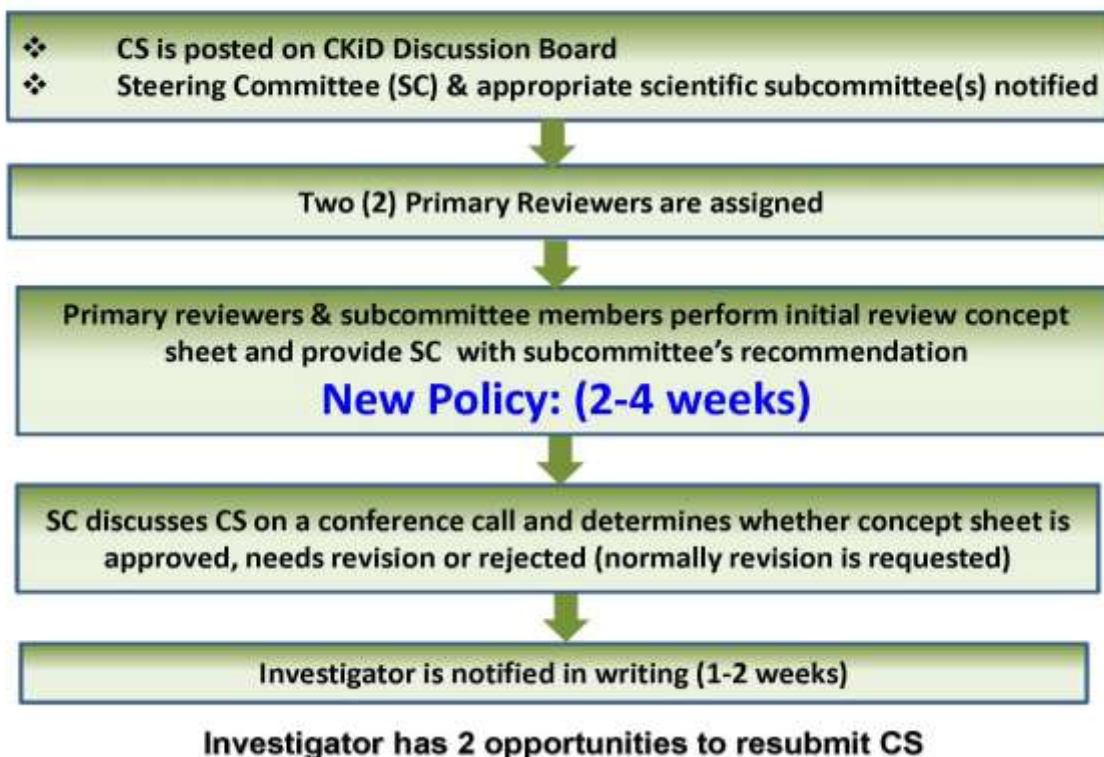
Ethical consideration of human subjects includes a commitment to maintain the confidentiality of enrolled participants. Hence, individually identifiable data may not be released. If the proposed study requires the collection of additional data from participants that are not covered in the original informed consent process, then the information requesting additional data collection must be incorporated into the original concept sheet or 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 site.

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.

22.3.3 Review and Approval of Proposals

The lead investigator will submit a completed concept sheet to Judith Jerry-Fluker at KIDMAC via e-mail (jjerry@jhu.edu) using the most current version of the Concept Sheet Proposal Form. **Concept sheets submitted on the incorrect form version will be returned to the investigator to complete and resubmit on the correct version.**

Review Process Timeline 12-week review process



When a concept sheet is submitted, KIDMAC will assign the concept sheet a study number (i.e., README #) in the form of k-YY-###, where “k” takes values 1, 2, 3 and 9 representing the lead 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 lead 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.**

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 the proposal can 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, the lead investigator of the proposal and the target date for review by the full SC. KIDMAC will also e-mail the SC and appropriate scientific subcommittee members that the information has been posted to the web site. The chairs of the SAB subcommittees will assign **two Primary Reviewers who will prepare a written critique of the concept sheet within 2 (two) weeks**, no later than 4 weeks. The SC will review all study proposals and written critiques on the semi monthly conference call. This process will occur as soon as reasonably possible, attempting to provide feedback to the lead investigator within 8 weeks of initial 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 bulletin board.

The lead investigator will be emailed a letter regarding the SC's final decision and project number (i.e., README #). Specifically, the letter will include all comments and classify the status of the proposal as: approved, deferred (revisions requested) or rejected. If revisions are requested, the lead investigator will be required to address any concerns or questions in writing. 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. When resubmitting the concept sheet, the lead investigator must provide two versions, a tracked version and a clean version. Investigators will have two opportunities to address concerns and resubmit. If the concerns and/or questions are not sufficiently addressed after the 3rd submission (i.e., 2nd revised concept sheet), the concept sheet will be likely rejected. Due to the possibility that the proposal may require at least one resubmission, investigators must submit the initial concept sheet **at least 12 weeks prior to a grant application deadline**.

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.

No data, information, or specimens will be released prior to the lead investigator obtaining a fully executed data use agreement and other NIDDK required paperwork (i.e., SDUC). **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.**

If an investigator plans to submit a grant application, they must indicate the grant application deadline on the concept sheet submission form. Although it is not mandatory, the investigator is encouraged to submit the grant within six months of the submission date indicated on the form or within one year from the date of approval. It is the responsibility of the lead investigator to notify CKiD of the status of the grant. If the grant is not submitted within this time frame or if the investigator decides to submit the grant for a subsequent funding cycle, the investigator must notify CKiD in writing (via email or CKiD Progress Report Form). Also, if grant is not funded upon initial submission and the investigator plans to resubmit, they must notify CKiD. After funding is not secured after two submissions or the investigator fails to submit a grant within the specified time frame or notify CKiD of the status of the grant application, the approved concept sheet's specific aims will no longer be protected for the investigator and open to other investigators and concept sheets from investigators who have indicated interest in submitting a grant with overlapping aims will be considered at that time.

In the event that approval status expires or is revoked, the content area will then be considered to be open to future to other investigators with no consideration of overlap issues related to the proposal.

22.3.4 Amendment/Addendum of Approved Concept Sheet Proposals

Investigators who wish to amend an already-approved CS (either to revise the aims or request additional specimens and/or data) should revise the original CS Submission Form and highlight any changes. The revised CS will be assigned (1) the same README number as the original project, if the amendment requests additional resources (e.g., data or specimens) solely for completion of the initial project or (2) be assigned a new README number if the amendment proposes the addition of data/analyses to the project that will result in publication of an additional manuscript or will significantly expand the scope of concept.

22.3.5 KIDMAC Collaboration and Independent Analysis (Outline of Data Use Agreement, DUA)

Once a project is approved, the investigator will receive a Steering Committee approval letter instructing them to proceed with the research plan outlined in the approved concept sheet. If KIDMAC is performing the analysis, the lead investigator should communicate with KIDMAC to start collaborative efforts, on in study design, creation of analytical datasets, selection of repository specimens, and data analysis. However, if the investigator is approved to perform the analysis independently, then a fully executed data use agreement (DUA) must be obtained between Johns Hopkins University and the investigator's institution. If multiple investigators will have access to the data, the separate DUA must be obtained between Johns Hopkins and each institution prior to receiving CKiD data.

Please note that the data use agreement is submitted after the concept sheet is approved by the Steering Committee. Also, it may take at four (4) weeks or more to obtain a fully executed data use agreement.

Below is an outline of the process to obtain a fully executed DUA (outline is subject to change):

- The investigator completes the DUA:
 - In Section 2 “Authorized Parties” of the DUA, the investigator must include their name and the names of anyone else at your institution who will have access to the dataset.
 - In Section 3 “Permitted Use”, the investigator describes how the data will be used.
- The investigators review the information in the DUA and attach their approved concept sheet submission form.
- The investigator submits the DUA to their institution's research administration to obtain the appropriate signature(s).
- Once a partially executed DUA (meaning the appropriate signatures from the legal department is obtained), the partially executed DUA is emailed to a specified JHU contracts associate. In the event that there are specific questions about the DUA, questions should be directed to JHURA
- JHU personnel will submit the DUA to the JHU Research Administration (JHURA).
- After KIDMAC receives a copy of the fully executed DUA (with all of the appropriate signatures) from JHURA, KIDMAC will prepare the limited dataset and codebook for the variables included in the investigators approved concept.

Prior to submitting a concept sheet, investigators are encouraged to review summaryfile codebooks, contact subcommittee chairs to obtain guidance about the type of data available and (if authorized) review variable names on the password-protected CKiD Data Management System website. **The limited dataset will be restricted to the variables listed in the approved concept sheets.** On the concept sheet, investigators should list the variable name, the form number(s) on which the variables are located, and the visit number(s). Also, if necessary, investigators will be instructed to complete a data request form. KIDMAC will normally require two weeks to create a limited analytic dataset. Longer time may be required for complex data requests or if multiple requests from different investigators are requested.

As previously mentioned, if a KIDMAC team member is performing the analysis, the KIDMAC statistician will communicate with the writing group chair (and perhaps a few others). The writing chair is responsible for updating the other members of the writing committee, if applicable the scientific subcommittee members.

If data analysis is not carried out at KIDMAC, the lead author is responsible for sending computer programs and associated data sets to KIDMAC. **These files should be sent to KIDMAC within one year after the manuscript is accepted for publication.**

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 analysis should be kept confined to the specific aims of the analysis proposed and specified within the DUA.

22.3.6 Request for Repository Specimens (Sample Data Use Certificate Agreement, SDUC)

Similarly to data request, once a project is approved, the lead investigator should communicate with KIDMAC to begin the process to obtain samples.

NOTE: KIDMAC will generate the list of specimens after the investigator has received a fully executed Sample Data Use Certificate (SDUC) agreement. A SDUC is a different agreement than the DUA. A DUA is an agreement between the investigator's institution and Johns Hopkins to receive a CKiD limited dataset from KIDMAC. A SDUC is an agreement between the investigator's institution and NIDDK to receive specimen (and publicly available data). See MOP Section 30: Guidelines for Requesting Repository Samples for details on requesting repository samples.

22.3.7 Formation of Writing Committee

After a CS is approved, requests will be sent out for co-author and senior co-author 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. Senior and co-authors should be in communication with the lead author (i.e., lead investigator) 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 lead investigator is a CKiD-I or a CKiD-E. The lead investigator who is named on the concept sheet may either be the lead or senior author. If the lead 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 lead 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 lead investigator is a CKiD-E, the writing committee must include one investigator from each of the three coordinating centers of the study. Participation as a member of the writing committee is at the discretion of the coordinating center investigators. In addition, the writing committee should also include the following: (a) additional members of the research team of the lead investigator; (b) 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. Completing an annual progress report to update the SC on the status of the concept sheet.
- f. Coordinating with KIDMAC to ensure that data analyses are distributed to writing committee members in a timely fashion.
- g. 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.
- h. Notifying the writing group of manuscript submission to the SC.
- i. Notifying KIDMAC and the SC chair's assistant of outcomes of journal submission.

22.3.8 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 discuss 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 lead investigator to the SC.

22.3.9 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.

22.3.10 Submission of Manuscripts to Steering Committee

Manuscripts are not formally reviewed by the Steering Committee. However, once the manuscript has been approved by the co-authors, the final manuscript should be submitted electronically to Lucy Mulqueen at lmulqueen@jhu.edu.

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.

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.

22.3.11 Study Acknowledgements

All manuscripts should acknowledge that the data were collected through the CKiD Study and credit participating institutions (CKiD representatives, 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 were collected by the Chronic Kidney Disease in children prospective cohort study (CKiD) with clinical coordinating centers (Principal Investigators) at Children's Mercy Hospital and the University of Missouri - Kansas City (Bradley Warady, MD) and Children's Hospital of Philadelphia (Susan Furth, MD, PhD), Central Biochemistry Laboratory (George Schwartz, MD) at the University of Rochester Medical Center, and data coordinating center (Alvaro Muñoz, PhD and Derek Ng, PhD) at the Johns Hopkins Bloomberg School of Public Health. The CKiD Study 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 (U01DK66143, U01DK66174, U24DK082194, U24DK066116). The CKiD website is located at <https://statepi.jhsph.edu/ckid/> and a list of CKiD collaborators can be found at <https://statepi.jhsph.edu/ckid/site-investigators/>.

22.3.12 Annual Progress Report and Deactivation of Concept Sheets

The lead investigator for each approved concept sheet must submit an annual progress report before the annual CKiD meeting (typically in the Spring). A month prior to the meeting, investigators will receive an email notifying them to submit the progress report and then one follow-up reminder. No additional follow-up or reminders will be disseminated. It will be the responsibility of the lead investigator(s) to ensure that the progress report is completed and submitted on time. In the event that the progress report is not submitted within 30 days of due date, approval for the concept sheet will expire. It will also be the lead investigator's responsibility to notify the KIDMAC of changes to their email address and/or contact information.

If a completed progress report indicates that no activity has occurred on the project in the past 6 months or no progress report is received by the due date, the project will be declared inactive.

The online form is available on the Investigator Resources section of the CKiD website: <https://statepi.jhsph.edu/ckid/investigator.html>). Once on the Investigator Resources page, click on "CKiD Concept Sheet Progress Report Form" under the "Concept Sheet Forms" section.

On the Progress Report Form, the investigator must provide the README # for their approved concept sheet. The README # is the number assigned to your concept sheet. For a list of approved concept sheets and README #s, refer to the "List of Approved Concept Sheet" are located on the Investigator Resources page. The number is also listed on the concept sheet approval letter.

CKiD Concept Sheet Progress Report

README #

The "README # is the number assigned to your concept sheet. (Refer to CKiD approval letter for README #)

22.4 PubMed Central Reference Number (PMCID) Requirement

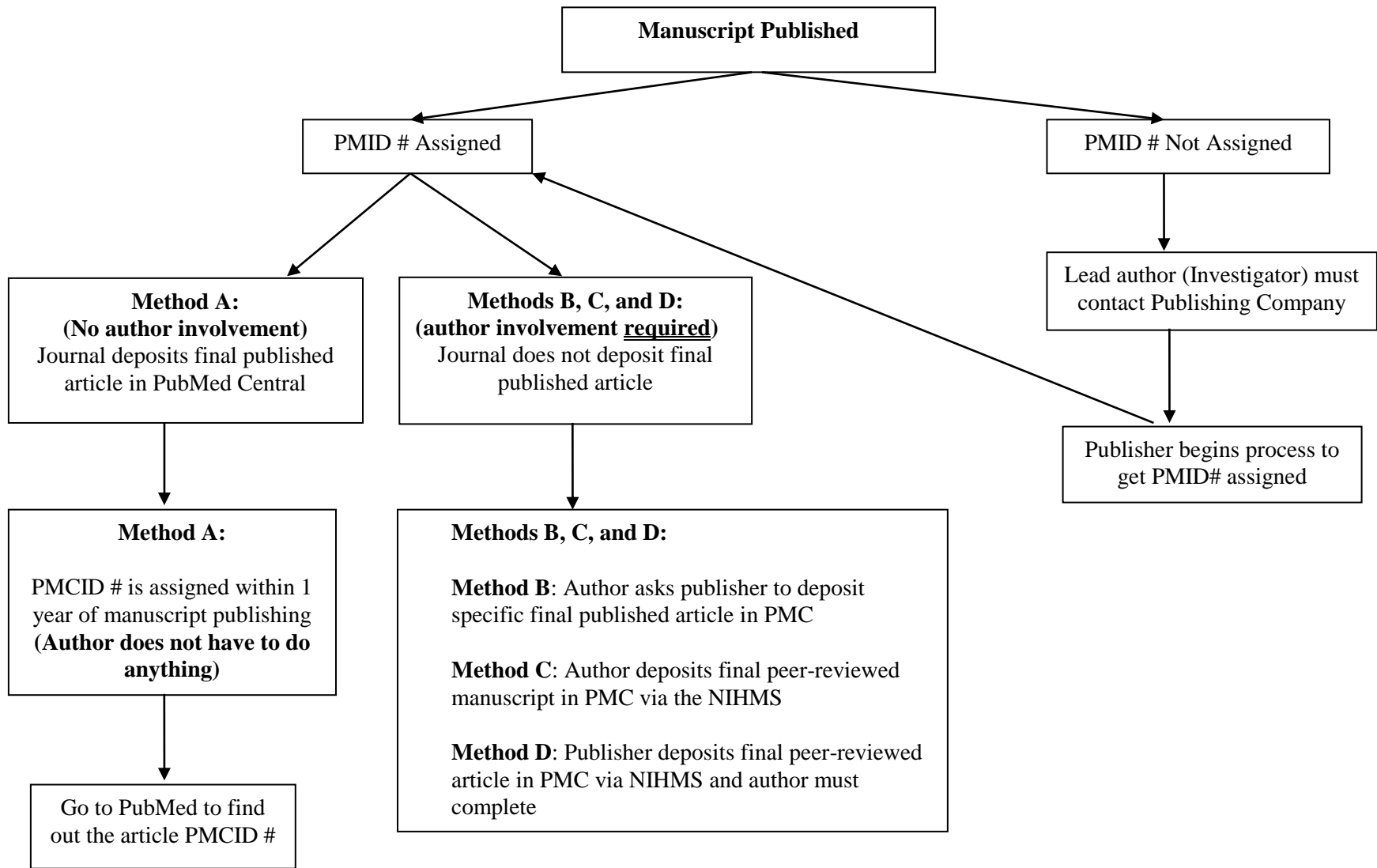
22.4.1 Overview of the National Institutes of Health Public Access Policy

The majority of information contained in Section 22.4.1 was adapted from the National Institutes 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, 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 PMID# for published manuscript



PMID- PubMed reference number

PMCID- PubMed Central reference number

22.4.2 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 22.4.5 on how to identify a submission method.

22.4.3 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.

The screenshot shows the PubMed interface for the article "New equations to estimate GFR in children with CKD". At the top, there is a search bar with "PubMed" selected and the ID "PMC2653687" entered. Below the search bar, the article title "New equations to estimate GFR in children with CKD." is displayed in bold. The authors listed are Schwartz GJ, Muñoz A, Schneider ME, Mak RH, Kaskel F, Warady BA, and Furth SL. The abstract text follows, describing the Schwartz formula and the development of new equations. At the bottom of the abstract, the PMID (19158356) and PMCID (PMC2653687) are shown, with the PMCID circled in red. There are also links for "Free PMC Article", "Publication Types, MeSH Terms, Substances, Grant Support", and "LinkOut - more resources".

22.4.4 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. Any publication that uses CKiD data and does not have a PMCID number is considered to be non-compliant by NIH. It is the responsibility of the lead author of a publication to ensure that it is assigned a PMCID number.

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

22.4.5 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 22.4.3: 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>
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<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>

22.4.6 Steps to Submit a Manuscript to NIHMS to Receive a PMCID Number

If your paper is published in a journal that requires you to deposit the manuscript directly to NIHMS (i.e., method B-D), follow the steps below to upload the manuscript and files.

a. Choose a login route:

- Select eRA Commons if you have this type of an account
- Use a NCBI account if you do not have an eRA Commons log in
 - 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.

Note: Before moving to the next step, please have ready grant numbers, manuscript files (PDF or word document) and figures. You will need to add all the CKiD grant numbers (U24 DK082194 (previously U01 DK082164), U01 DK066174, U24 DK066143, U24 DK066116 (previously U24 DK066116)) and any other grants associated with the manuscript.

b. 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.

Below are the specific steps you will need to complete to upload a manuscript to NIHMS. Go to the NIHMS website:

<https://www.nihms.nih.gov/db/sub.cgi>

1. Click on “Submit New Manuscript.”

There are 3 options to submit the manuscript:

a. “Enter the manuscript and journal titles”

b. “Search for citation in PubMed”

c. “Find citation in my NCBI bibliography”

The screenshot shows the NIH Manuscript Submission System interface. At the top, there is a header with the NIH logo and the text 'Manuscript Submission System'. Below this is a green bar with the text 'New manuscript submission'. Underneath is a navigation bar with five steps: '1. Title Information', '2. Add Funding', '3. Upload Files', '4. Check Files', and '5. Set Reviewer & Embargo'. The first step, '1. Title Information', is currently selected. Below the navigation bar, there is a section titled 'Provide citation information using one of the options below.' There are three options listed: 'Option 1. Enter the manuscript and journal titles', 'Option 2. Search for citation in PubMed', and 'Option 3. Find citation in My NCBI Bibliography'. Option 2 is currently selected and expanded, showing a search box with the text 'brady wady' and a 'Search' button. Below the search box, there is a list of search results with the text 'Last 5 searches: rancy rdyg, Predictors of Rapid Progression of Glomerular and Nonglomerular Kidney Disease in Children and Adolescents; The Chronic Kidney Disease in Children (CKiD) Cohort. Protein energy wasting in children with chronic kidney disease; Protein energy wasting in children with chronic kidney disease; Ceramide and cardiac function in children with chronic kidney disease. Pediatr Nephrol 2014.' At the bottom of the search results, there is a 'Quick search for: MAJeen, MAJeen L'.

2. Choose an option to enter the manuscript title. Then click on “Add funding”

Correlates of leptin in children with chronic kidney disease. <i>J Pediatr</i> 10/01/2014	Already submitted
Duration of chronic kidney disease reduces attention and executive function in pediatric patients. <i>Kidney Int</i> 04/01/2016	Already submitted
⊖ Erratum to: Difficult peritonitis cases in children undergoing chronic peritoneal dialysis ... episodes. <i>Pediatr Nephrol</i>	
Hepcidin and risk of anemia in CKD: a cross-sectional and longitudinal analysis in the CKiD cohort. <i>Pediatr Nephrol</i> 04/01/2015	Already submitted
Progression of Pediatric CKD of Nonglomerular Origin in the CKiD Cohort. <i>Clin J Am Soc Nephrol</i> 04/07/2016	Already in PMC
⊖ Discrepancies in the normative neonatal blood pressure reference ranges. <i>Blood Press Monit</i>	
<input checked="" type="checkbox"/> Predictors of Rapid Progression of Glomerular and Nonglomerular Kidney Disease in Children ... D) Cohort. <i>Am J Kidney Dis</i> 06/01/2015	
⊖ Risk factors for loss of residual renal function in children treated with chronic peritoneal dialysis. <i>Kidney Int</i>	
Genomic imbalances in pediatric patients with chronic kidney disease. <i>J Clin Invest</i> 05/01/2015	Publisher provided

« 1 2 3 4 5 6 7 8 9 ... 16 17 »

Option 3. Find citation in My NCBI Bibliography



3. Add the 4 CKiD grant numbers (U24 DK082194 (previously U01 DK082194), U01 DK066174, U01 DK066143,U24 DK066116 (previously U01 DK066116)) and any other grants associated with the manuscript:
 - a. You can enter the numbers manually
 - b. You can search by PI name

1. Title Information 2. Add Funding 3. Upload Files 4. Check Files 5. Set Reviewer & Embargo

Search by: First Name Last Name

AND/OR Grant/Project ID

How can I add funding support?
 What if I can't find my project or grant?
 What if I'm depositing on an author's behalf and don't know the project or grant?

Search Results:

Grantee/PI	Select	Grant/Project ID	Title
⊕ Alvaro Munoz	<input type="checkbox"/>		
⊕ Susan L. Furth	<input type="checkbox"/>		
⊕ Bradley Warady	<input checked="" type="checkbox"/>	U01 DK066143	Chronic Kidney Disease in Children (CKiD III) Other known titles: Chronic Kidney Disease in Children (CKiD) Chronic Renal Insufficiency in NAPRTCS Patients

4. Next click on “**Upload Files**”

5. Upload manuscript text, figures, tables (if separate from the text), and any supplemental materials. You will need to label any figure or table files. You can add additional figures, as necessary.

1. Title Information 2. Add Funding **3. Upload Files** 4. Check Files 5. Set Reviewer & Embargo

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Manuscript		<input type="button" value="Choose File"/> 1_Predictors of Rapid Pr...INAL clean version.docx			<input type="button" value="X"/>
Figure	<input type="text" value="Figure 1"/>	<input type="button" value="Choose File"/> Predictors of Rapid Progression - Figure 1.docx			<input type="button" value="X"/>
Table	<input type="text"/>	<input type="button" value="Choose File"/> No file chosen			<input type="button" value="X"/>
Supplemental	<input type="text" value="Appendix"/>	<input type="button" value="Choose File"/> Online Supplementary Ap...ssion paper FINAL.docx			<input type="button" value="X"/>
Figure	<input type="text" value="Figure 2"/>	<input type="button" value="Choose File"/> Predictors of Rapid Progression - Figure 2.docx			<input type="button" value="X"/>
Figure	<input type="text" value="Figure 3"/>	<input type="button" value="Choose File"/> Figure3_PredictedProfiles_022215.pdf			<input type="button" value="X"/>

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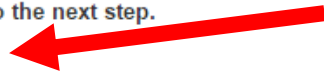
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Journal: [Am J Kidney Dis](#) PubMed # 25799137 NIHMSID 695825 [Provide citation](#)

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Manuscript Information

Journal name: American journal of kidney diseases : the official journal of the National Kidney Foundation
 NIHMS ID: NIHMS695825
 Manuscript Title: Predictors of Rapid Progression of Glomerular and Nonglomerular Kidney Disease in Children and Adolescents: The Chronic Kidney Disease in Children (CKiD) Cohort
 Submitter: Lucy Mulqueen (lmulqueen@jhu.edu)

Manuscript Files

Type	Fig/Table #	Filename	Size	Uploaded
manuscript		1_Predictors of Rapid Progression, Warady et al., FINAL_clean version.docx	167426	2015-05-29 10:51:08
figure	Figure 1	Predictors of Rapid Progression - Figure 1.docx	78024	2015-05-29 10:51:08
figure	Figure 2	Predictors of Rapid Progression - Figure 2.docx	46165	2015-05-29 10:51:09
figure	Figure 3	Figure3_PredictedProfiles_022215.pdf	4255	2015-05-29 10:51:09
supplement	Appendix	Online Supplementary Appendix - CKD Progression paper FINAL.docx	25955	2015-05-29 10:51:09

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<input type="radio"/>	Susan L. Furth
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<input type="radio"/>	George J. Schwartz
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Predictors of Rapid Progression of Glomerular and Nonglomerular Kidney Disease in Children and Adolescents: The Chronic Kidney Disease in Children (CKD) Cohort.
 Journal: [Am J Kidney Dis](#) | PubMed # 25799137 | NIHMSID 695825

Manuscript Summary

Status	Awaiting reviewer's initial approval
Manuscript Title	Predictors of Rapid Progression of Glomerular and Nonglomerular Kidney Disease in Children and Adolescents: The Chronic Kidney Disease in Children (CKD) Cohort.
Journal Title	American journal of kidney diseases : the official journal of the National Kidney Foundation
NIHMSID	695825
PDF Receipt	PDF Receipt [2015-05-29 10:52:13, 454.5 KB]
Reviewer	Bradley Warady

Funding and contacts

Role	Name	Email	Grant/Project #	Grant/Project Title

22.5 PROCESS FOR SECONDARY AND ANCILLARY PUBLICATIONS

22.5.1 Secondary 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 which use central laboratory specimens require review by the Central Biochemistry Laboratory PI. 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 East Coast and Midwest CCC PIs on behalf of the SC before any presentation to a formal scientific meeting or prior to submission for publication. 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.

22.5.2 Ancillary Study publications

In some instances, collaborators who are not members of CKiD SC or partner organizations will be involved in data and/or laboratory analyses. All investigators, either CKiD investigators and outside collaborators (i.e. external investigators) 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. 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 ancillary study 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. A fully executed DUA is required to obtain limited CKiD datasets and a fully executed SDUC must be obtained prior to receiving any repository specimens. When a study is complete, specimen results and other agreed upon deliverables must be returned to CKiD. Unless otherwise specified in the approved concept sheet or SDUC, the remaining samples must be destroyed.
- Ancillary study investigators will forward agreed upon data to KIDMAC as described in section 22.3. **Except for DNA results, all data must be sent to CKiD within 2 years after samples are received by the investigator or within one year after the first publication.** These data will then be entered into the CKiD database and after 1-2 years of embargo (depending on when the results are received) they can be used as part of other analyses. After the embargo, the aims outlined in the approved concept sheet are no longer protected for the investigator and the content area will be considered open to other investigators to publish.

DNA results must be uploaded to dbGAP according to NIH's dbGAP submission guidelines (contact the National Center for Biotechnology Information NCBI for details).

- Ancillary study investigators are required to include CKiD principal investigators as co-authors.
- After embargo, CKiD investigators will have two years to publish. After two years, CKiD will upload the data to the data repository to make it publicly available.
- CKiD investigators or individuals who access publicly available data are not required to include ancillary study investigators (i.e., the investigator(s) who secured funding to analyze repository samples) as co-authors.

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 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.