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.

22.2 DEFINITIONS

The publication policy is designed to address all investigations which may use data collected in this study.

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 22.6.1.

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

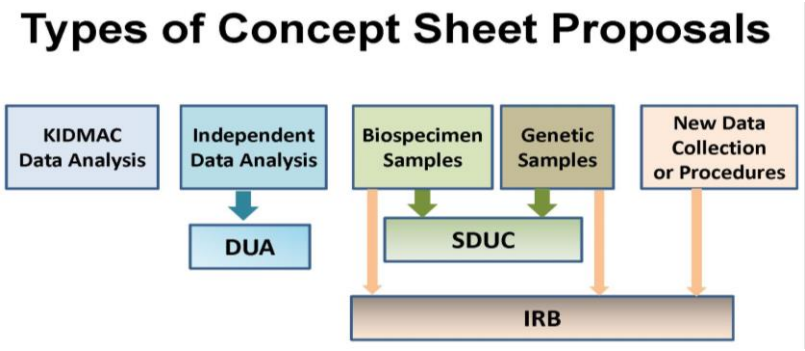
The CKiD SC is responsible for overseeing specific written and oral communications concerning hypotheses/research questions. To facilitate this process, initial discussion and prioritization of publications or presentations based on the primary research questions (i.e., CORE hypotheses) will be generated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

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

Non-CORE (secondary/ancillary) concept sheets undergo a scientific review process (see 22.3.4 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 CSR committee approval, investigator must complete DUA, see Section 22.3.7 for details)
- Investigator is interested in requesting Biospecimen and/or Genetic samples (after CSR committee approval, investigator must complete SDUA, see MOP Section 30 for details about requesting repository samples)
- Investigator is interested in proposing new data collection or procedures



22.3.2 Submission of Proposals - Pre-submission Preparation

1. Review list of approved concept sheets to confirm there is no overlap with previously approved projects.

Investigators should check the list of approved concept sheets to ensure that their concept sheet does not overlap with an approved proposal. If overlapping proposals are submitted, the CSR committee may recommend 1) combining the proposals into one, 2) revising the proposals into two separating non-overlapping proposal, or 3) selecting the proposal with the greatest overall merit. A list of approved concept sheets is available on the CKiD website:
https://airtable.com/appB8FbtpDT3eLsdJ/shrBqbkP7xhGbT8M7

2. Use research template to outline proposal.

The Concept Sheet Research Plan template can be downloaded from the CKiD website. On the Concept Sheet Submission webpage, click on "Research Plan Template."

The research plan includes the following:

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

3. Review data codebooks and data collection forms.

Investigators are encouraged to review summaryfile codebooks located on the CKiD website: https://statepi.jhsph.edu/ckid/data-collection-forms-codebooks/. For investigators requesting data, **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.

4. Ask a CKiD investigator to review their proposal

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: https://statepi.jhsph.edu/ckid/site-investigators/.
Internal CKiD investigators should have their proposal reviewed by another CKiD investigator. External should discuss the research proposal with an internal CKiD investigator (CKiD-I) to determine feasibility. External CKiD investigators investigators must also include a biosketch in NIH format, The CKiD-I will serve as their CKiD liaison on the proposal. If an investigator is not already working with a CKiD liaison, external investigators should contact Bradley Warady (bwarady@cmh.edu) and/or Susan Furth (furths@email.chop.edu). A CKiD liaison is required for all external investigators to facilitate the timely conduct of the proposed initiative and to appropriately place initiatives in the context of the overall study data. CKiD data are complex and CKiD-E are encouraged to have a close collaboration with a CKiD-I.

5. Other considerations

   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 CSR committee will consider whether the proposed study would interfere with, compete or conflict with the conduct of the CKiD core protocol. Use research template to outline proposal.

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 (i.e., new data collection), then information about the new data collection must be incorporated into the study's informed consent form (via protocol amendment) 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.

22.3.3 Online Concept Sheet Submission Process

All investigators must submit proposals "concept sheet" online:
https://statepi.jhsph.edu/ckid/investigator-resources/concept-sheet-submission.
Concept sheets submitted using the incorrect format will be returned to the investigator.

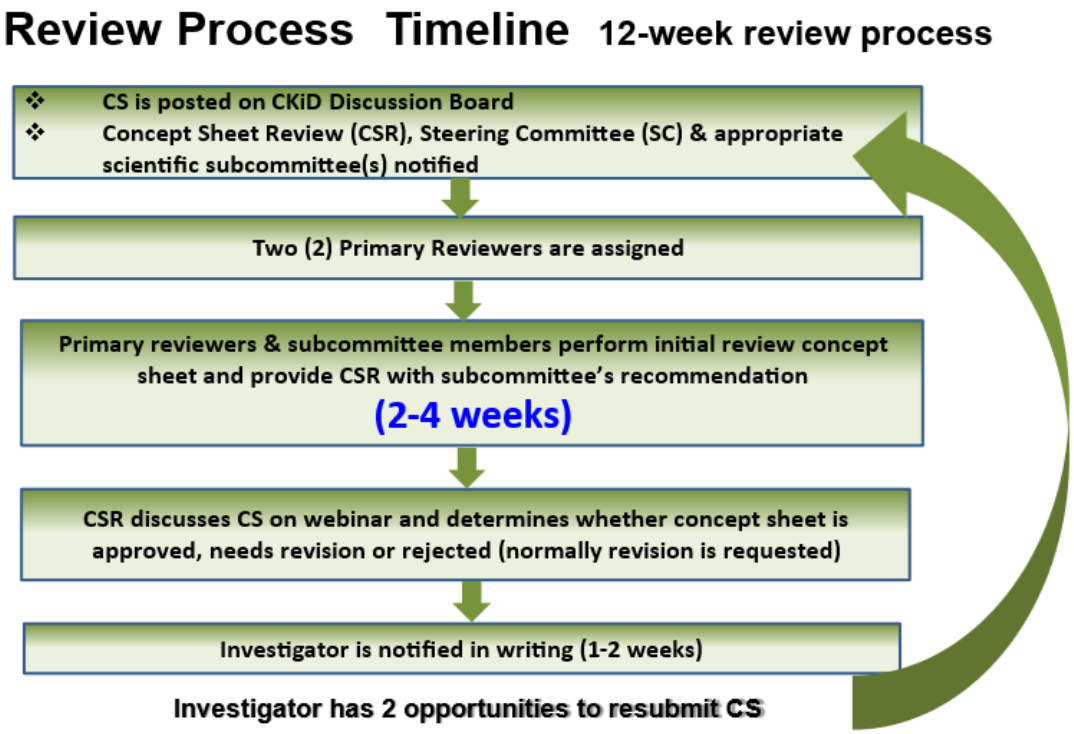
The online submission process is divided into two components:

1) **Information collected via REDcap:** This part gathers necessary details about the investigator and the study proposal through an online form. For details, review the online submission form powerpoint slides on the concept sheet submission webpage: https://statepi.jhsph.edu/ckid/investigator-resources/concept-sheet-submission/

2) **The research plan upload:** This component requires investigators to outline their study proposal in a research plan document, **which must be uploaded.** As specified in Section 22.3.2 (Step 2: Use research template to outline template), investigators use the research template to outline their esearch plan.

22.3.4 Concept Sheet Proposal Review Process

Below is an outline of the concept sheet review process.



When the online 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.

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 Concept Sheet Review (CSR) Committee. KIDMAC will also e-mail the CSR committee, 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 CSR committee 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 CSR committee 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. Comments on a particular proposal may be posted as a reply on the bulletin board.

The CSR committee may 1) approval the proposal, 2) conditionally approval proposal (i.e., no formal review but full approval continguent upon investigator responding to questions, and/or providing minor edits), 3) request revision, responses and resubmission, (i.e., investigator responds to written critique, provides tracked changes and resubmits for full committee review) or 4) reject the proposal.

The lead investigator will be emailed a letter regarding the CSR committee'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 (full or conditional), deferred (revisions requested) or rejected. If revisions are

requested, the lead investigator will be required to address any concerns or questions in writing. 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**.

22.3.5 Key Responsibilities of Lead Investigator after Concept Sheet Approval

After receiving concept sheet approval, 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 data analysis, creation of analytical datasets (if applicable), or selection of repository specimens, and (if applicable); and (3) provision of an annual written progress report to the CKiD SC.

The key responsibilities of the Lead Investigator are outlined below:

- **Lead investigator must demonstrate study productivity** for each approved concept sheet.
    - Within six (6) months of approval, newly approved concept sheet proposals must show productivity. Productivity may be demonstrated by beginning analysis, or submitting paperwork such as a grant submission, sample data use agreement (SDUA), or data use agreement (DUA).
    - Six (6) months after CSR committee approval, the lead investigator can submit a new concept sheet as the lead investigator.
    - Over the course of the project, investigators should have continued progress.
    - Study initiatives that fail to demonstrate *notable* progress within one year after approval (or where scientific misconduct has occurred, as judged by the SC and/or CSR committee) may have approval status revoked by the CSR committee.

- If applicable, **the lead investigator must notify CKiD of the status of the grant.**
    - 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.
    - 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.
    - If 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.

- If applicable, **the lead investigator must obtain fully executed DUA and/or SDUA**.
    - No data will be released prior to the investigator obtaining a fully executed DUA from Johns Hopkins.
    - In addition, no specimens will be released prior to the lead investigator obtaining a fully executed sample and data use agreement from NIDDK (i.e., SDUA).
    - Refer to sections 22.3.5 and 22.3.6 for details on obtaining a DUA and SDUA.

- **Investigators must complete yearly progress reports.**
    - Investigators who do not complete the annual progress report will have 30 days to complete progress report.
        - If progress report is not completed within 30 days, non-compliant projects will be "closed" and other investigators can pursue the specific aims outlined in the closed project.
    - Investigators who have not shown progress since last year's progress report will have 6 months to complete project.
        - After 6 months, the project will be marked as "closed" and other investigators can pursue the specific aims.
    - 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.

- **Lead Investigator of the approved concept sheet is responsibility for ensure that the lead author of any manuscripts associated with thee approved concept sheet adheres to CKiD's manuscript policy** (see Section 22.6 for details). This responsibility includes verifying that all required information, as stipulated by the CKiD guidelines, is properly documented in the manuscript. The lead investigator must fulfill this oversight duty even if they are not the first or senior author on the manuscript. In particular, the lead author must:
    - Submit the final draft of the manuscript to CSR committee for review.
    - Include in the authorship list "for the CKiD study investigator" after the senior auhor.
    - Include the supplemental document with the list of site principal investigators with all manuscript submissions.
    - Include the CKiD publication acknowledgment for manuscipts derived from CKiD data.
    - If appropriate, include the NIDDK publication acknowledgment for manuscripts derived from the use of repository samples (i.e., serum, plasma, urine, DNA).

22.3.6 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.

22.3.7 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 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 investigate completes the DUA:
  - DUA face page – This document outlines the main terms and conditions of the agreement, and **must be signed by the investigator's institution's research administration**.
  - Attachment 1 – This document describes the format of the data you will receive and refers to your approved concept sheet. **The investigator should attach the approved concept sheet as an appendix**.
  - Attachment 2 – This document outlines additional terms and conditions related to receiving the *de-identified limited* data set. Other than reviewing the Terms and Conditions and submitting it to the investigator's research administration, there is no other action is required.
  - Attachment 3 – This document lists the individuals who will have access to the data. If the lead investigator is performing the analysis, then only their name should be listed. Otherwise, the names of any individual at the investigator's institution should be lised (i.e., Authorized Parties). Also, individuals at other institutions (Collaborator Personnel) that will have access to the data should be listed. Individuals not listed in the agreement, should not have access to the data. Collaborator Personnel at the collaborating institution(s) must obtain a separate DUA.
- After reviewing the information, the investigator must submit the DUA face page, Attachments 1-3, and the approved concept sheet to their institution's research administration to obtain the appropriate signature(s) on the DUA face page.
- 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 or if the lead investigator's institution has edits to the DUA, the questions and edits should be directed to JHURA prior to signing the DUA.
- 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. 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.

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.

22.3.8 Request for Repository Specimens (Sample Data Use Certificate Agreement, SDUA)

Similarly to data request, once a project is approved, the lead investigator must communicate with KIDMAC to begin the process to obtain samples. Below are important policies and procedures regarding repository samples:

- A fully executed SDUA must be obtained prior to receiving any repository specimens. KIDMAC will generate the list of specimens after the investigator has received a fully executed Sample Data Use Agreement (SDUA). A SDUA 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 SDUA 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.

- **Except for DNA results, all specimen results data must be sent to KIDMAC 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 sent to CHOP according to guidelines (contact Hannah Derwick at CHOP for details).

- **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.

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 SDUA, the remaining samples must be destroyed.

22.4 ANNUAL PROGRESS REPORT

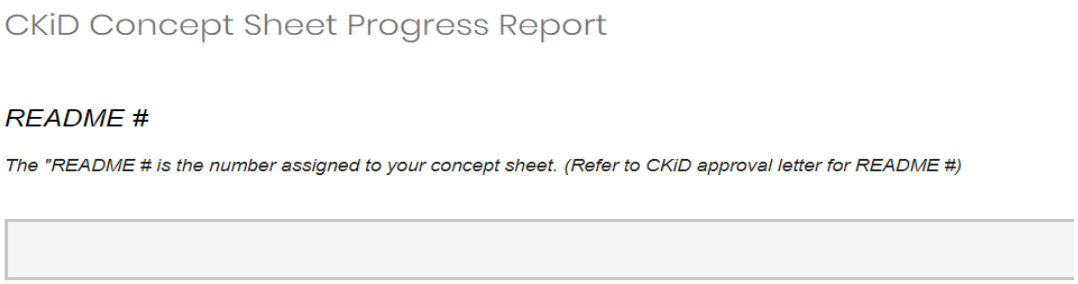
22.4.1 Annual Progress Report and Deactivation of Concept Sheets

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 was 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.



22.5 ABSTRACTS AND PRESENTATIONS

Abstracts and presentations must be reviewed and approved by a SC member before any presentation at a formal scientific meeting or prior to submission for publication (see Section 22.6.1 for writing committee guidelines). Abstract and presentation reviews will be expedited by KIDMAC based on deadline dates and must meet SC and NIH guidelines.

The lead author must share the abstract with their CKiD co-authors. If a SC voting member is not a co-author, the abstract should be submitted electronically to KIDMAC. The abstract should include information on the intended meeting, due date for the abstract, and type of study (core, site-specific, etc.). The investigator will receive all comments and have the opportunity to make changes. The SC voting members and CKiD co-authors will have the responsibility to review the final abstract to ensure 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 lead author who must report the abstract to the SC.

22.6 MANUSCRIPTS

22.6.1 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 are also required to include CKiD investigators as co-authors. 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.

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 CSR committee.

i. Notifying KIDMAC of outcomes of journal submission.

22.6.2 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.

22.6.3 Submission of Manuscripts to Concept Sheet Review Committee

The final draft of the manuscript must be submitted to the Concept Sheet Review (CSR) Committee before journal submission. The CSR committee will verify that the authorship list, supplemental material, and acknowledgments are appropriate. The final manuscript must 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.

22.6.4 Authorship List

ALL manuscripts that result from approved concept sheets that use CKiD data must include "**for the CKiD study investigators**" after the senior author

22.6.5 Supplemental Material

A supplemental document with a list of site principal investigators must be included with all manuscript submissions. The supplemental document can be downloaded as a Word document from this link and may be formatted for the journal.

Link to supplemental document: https://statepi.jhsph.edu/ckid/site-investigators/

22.6.6 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 (Jesse Seegmiller, PhD) at the University of Minnesota, and data coordinating center at the Johns Hopkins Bloomberg School of Public Health (Derek Ng, PhD) (U01 DK066143, U01 DK066174, U24 DK137522, U24 DK066116). The CKiD is funded by the National Institute of Diabetes and Digestive and Kidney Diseases, with additional funding from the National Institute of Child Health and Human Development, and the National Heart, Lung, and Blood Institute. 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/.

All manuscripts derived from CKiD data stored and requested from the NIDDK Data Repository (i.e., publicly archived/repository data) must include the following acknowledgment:

The Chronic Kidney Disease in Children Cohort Study (CKiD) was conducted by the CKiD Investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), with additional funding from the National Institute of Child Health and Human Development, and the National Heart, Lung, and Blood Institute (U01 DK066143, U01 DK066174, U24 DK137522, U24 DK066116). The data and biospecimens from the CKiD study reported here were supplied by the NIDDK Central Repository. This manuscript does not necessarily reflect the opinions or views of the CKiD study, the NIDDK Central Repository, or the NIDDK.

22.7 PubMed Central Reference Number (PMCID) Requirement

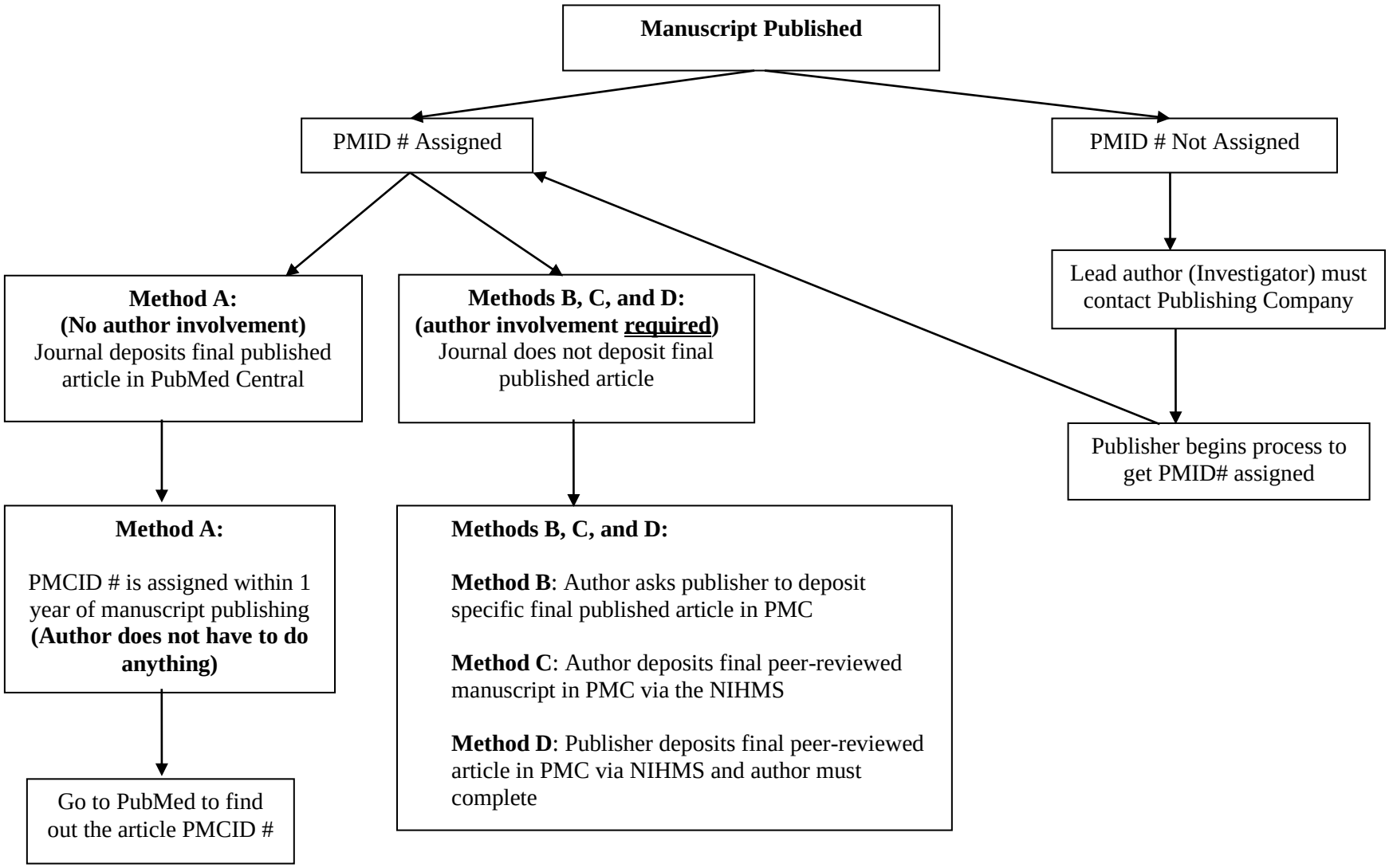
22.7.1 Overview of the National Institutes of Health Public Access Policy

The majority of information contained in Section 22.7.1 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 PMCID# for published manuscript



PMID- PubMed reference number
PMCID- PubMed Central reference number

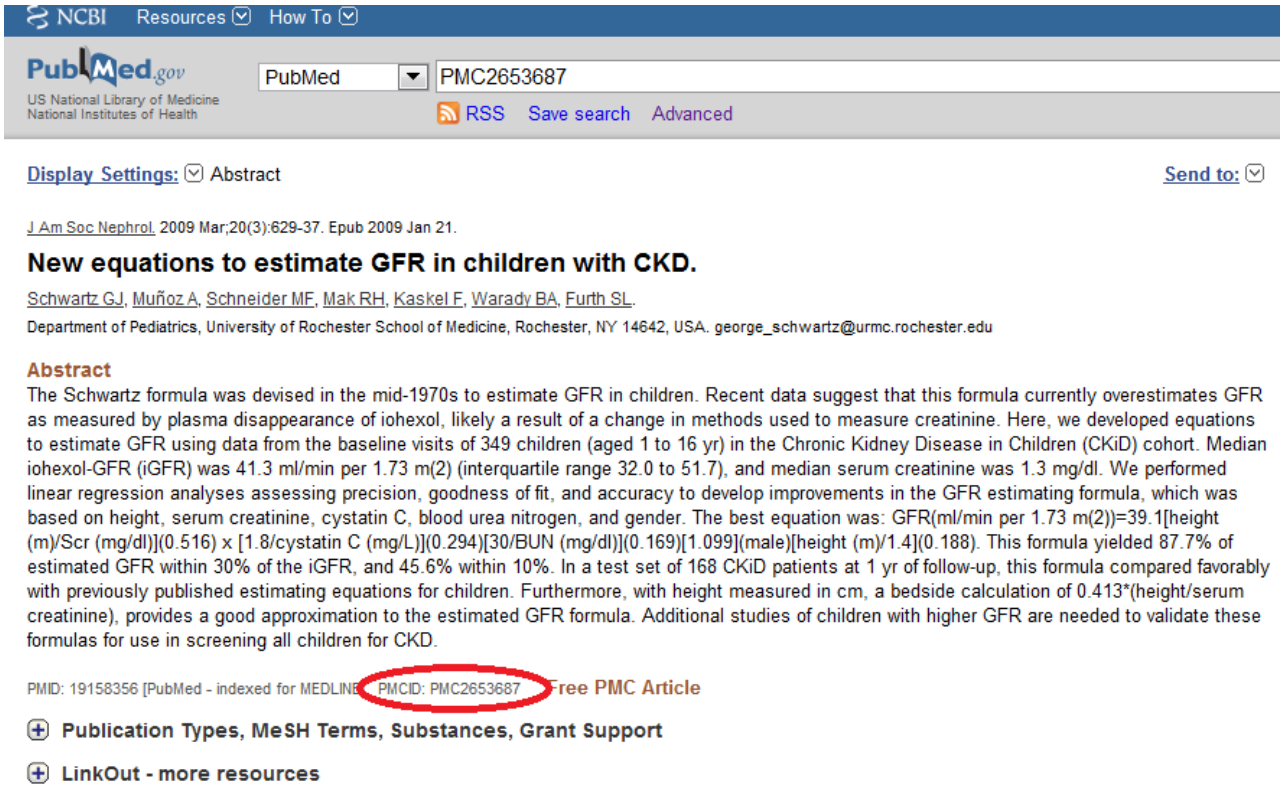
22.7.2 The Difference between a PMCID and a PMID

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 22.7.5 on how to identify a submission method.

22.7.3 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.



22.7.4 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

22.7.5 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 author's 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 22.7.3: 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
- 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

22.7.6 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 NBCI 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 (U01 DK066174, U01 DK066143, U24 DK137522 (previously U01 DK082164), U24 DK066116 (previously U01 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

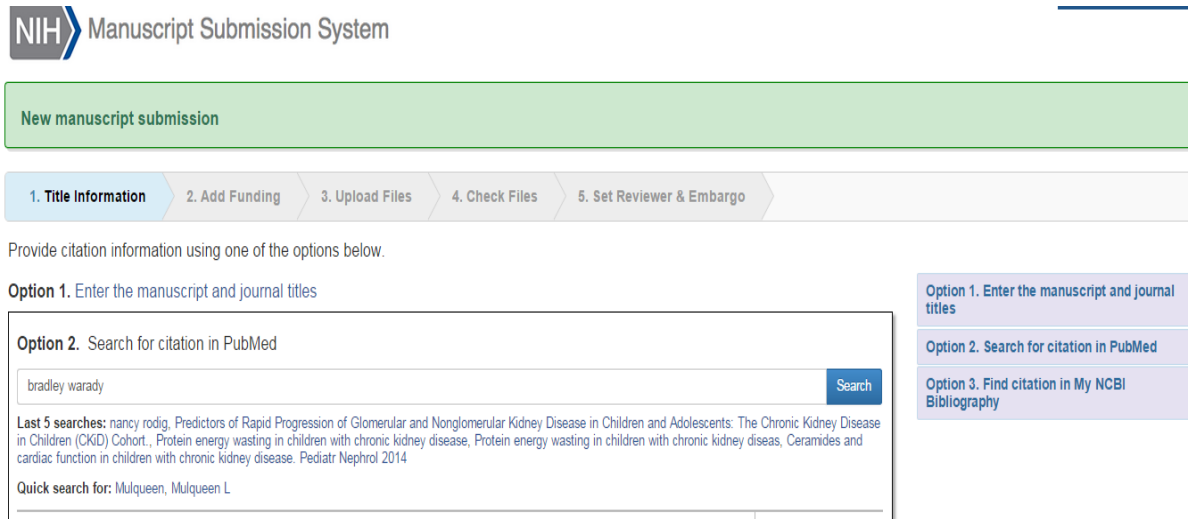
1. Click on "**Submit New Manuscript**."

There are 3 options to submit the manuscript:

a. "Enter the manuscript and journal titles"

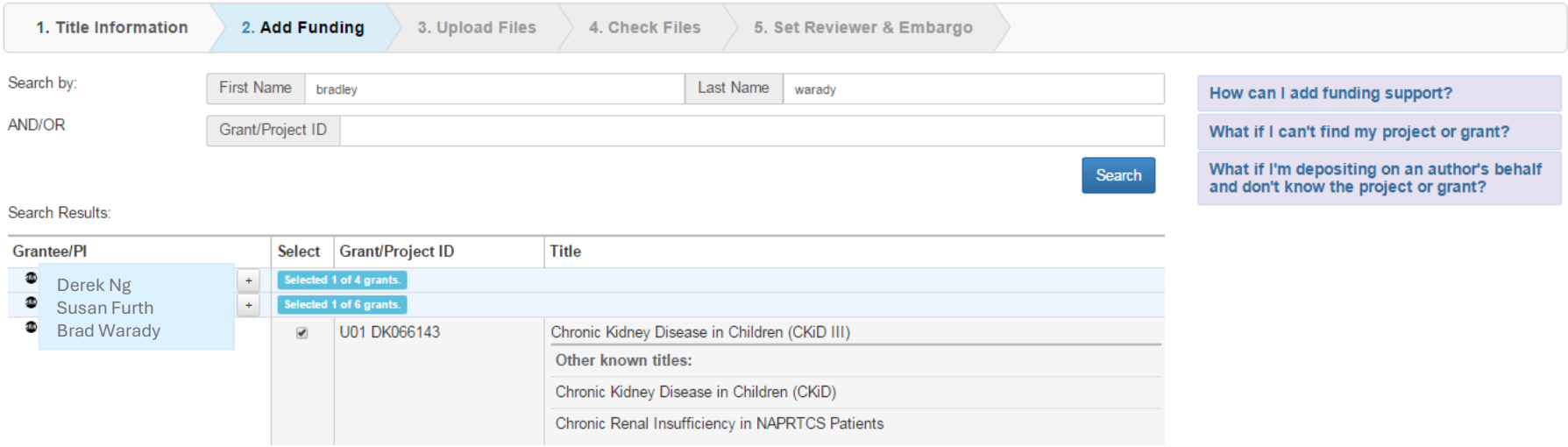
b. "Search for citation in PubMed"

c. "Find citation in my NCBI bibliography"



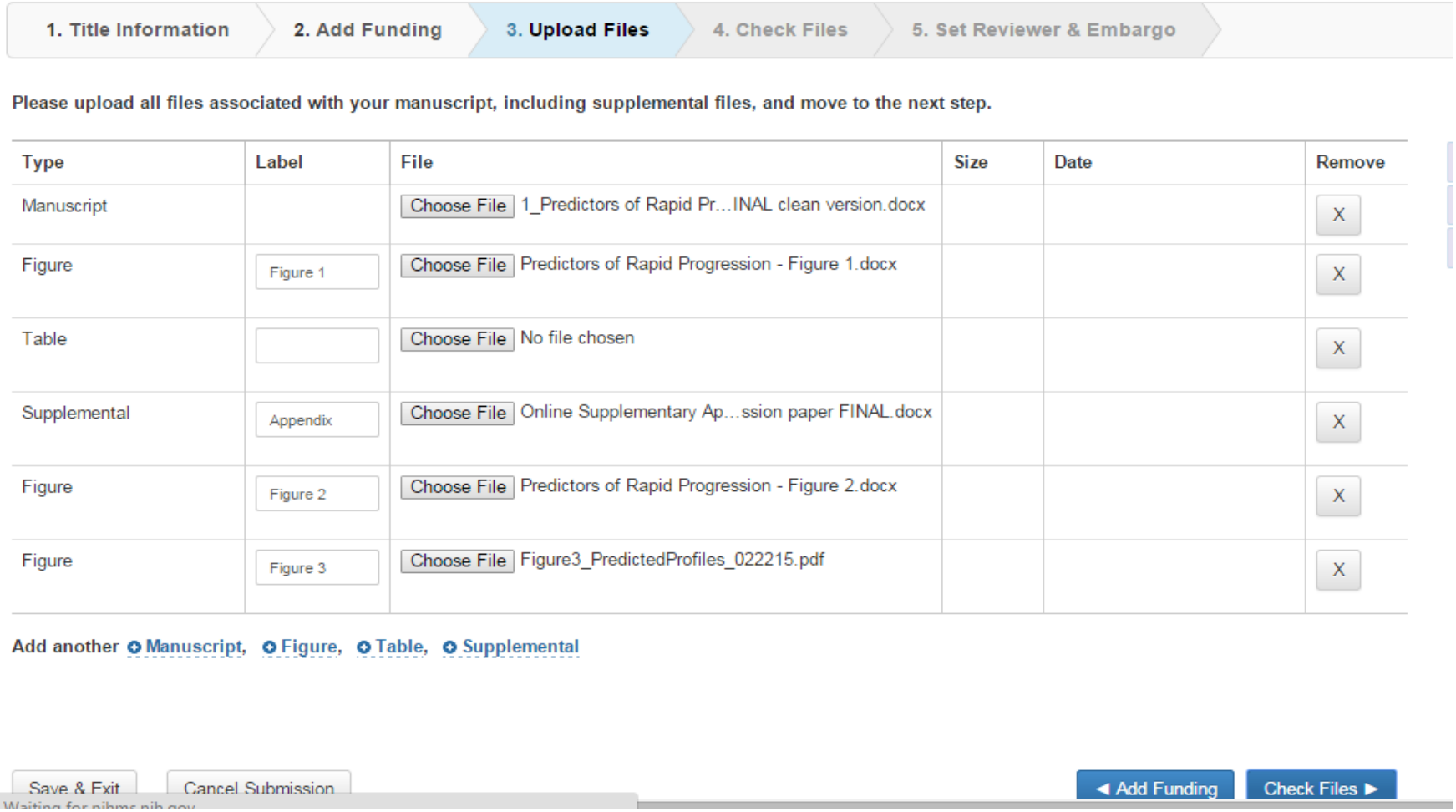
2. Choose an option to enter the manuscript title. Then click on **"Add funding**"

3. Add the 4 CKiD grant numbers (U01 DK066143, U01 DK066174, U24 DK137522 (previously U01 DK082194), 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



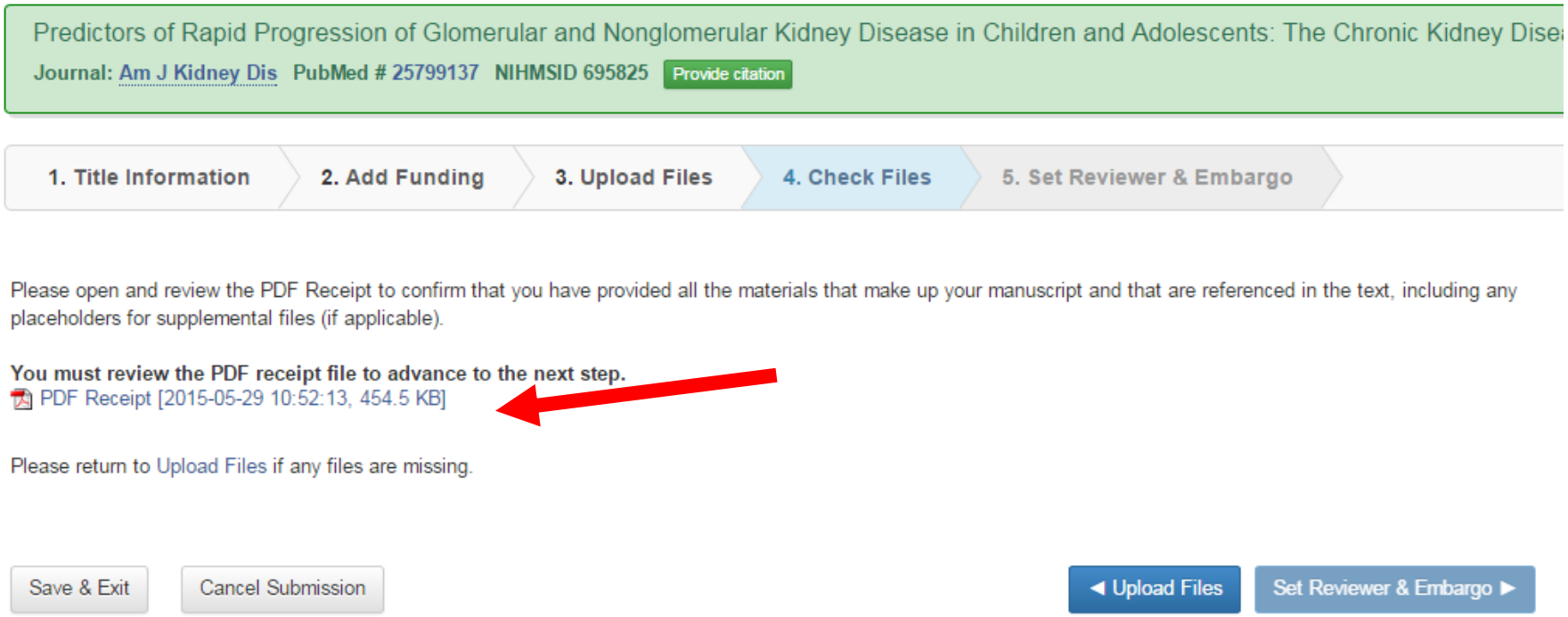
4. Next click on "**Upload Files**"

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.

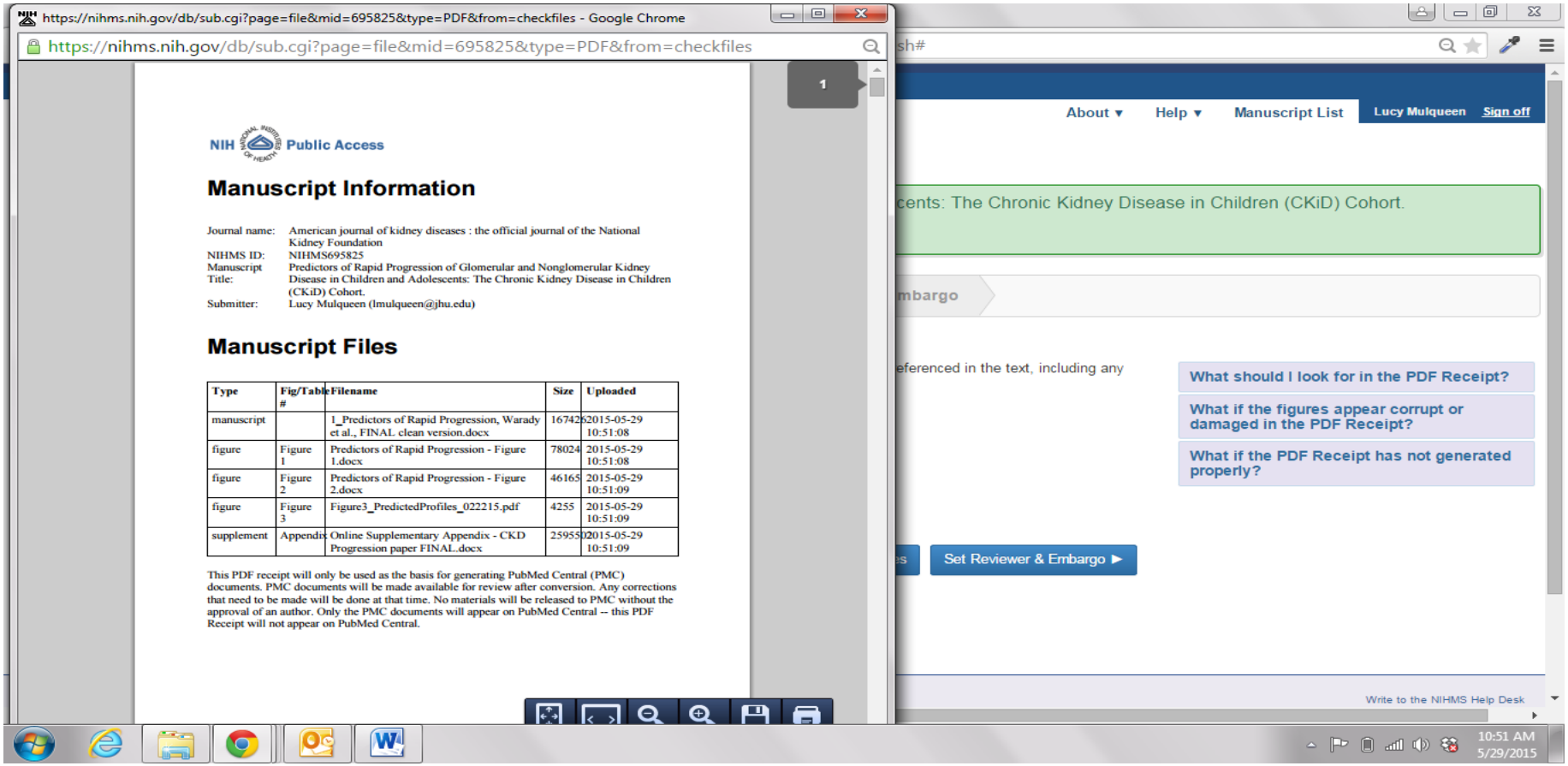


6. Review all the information to make sure it is correct and then click on "**Check Files**."

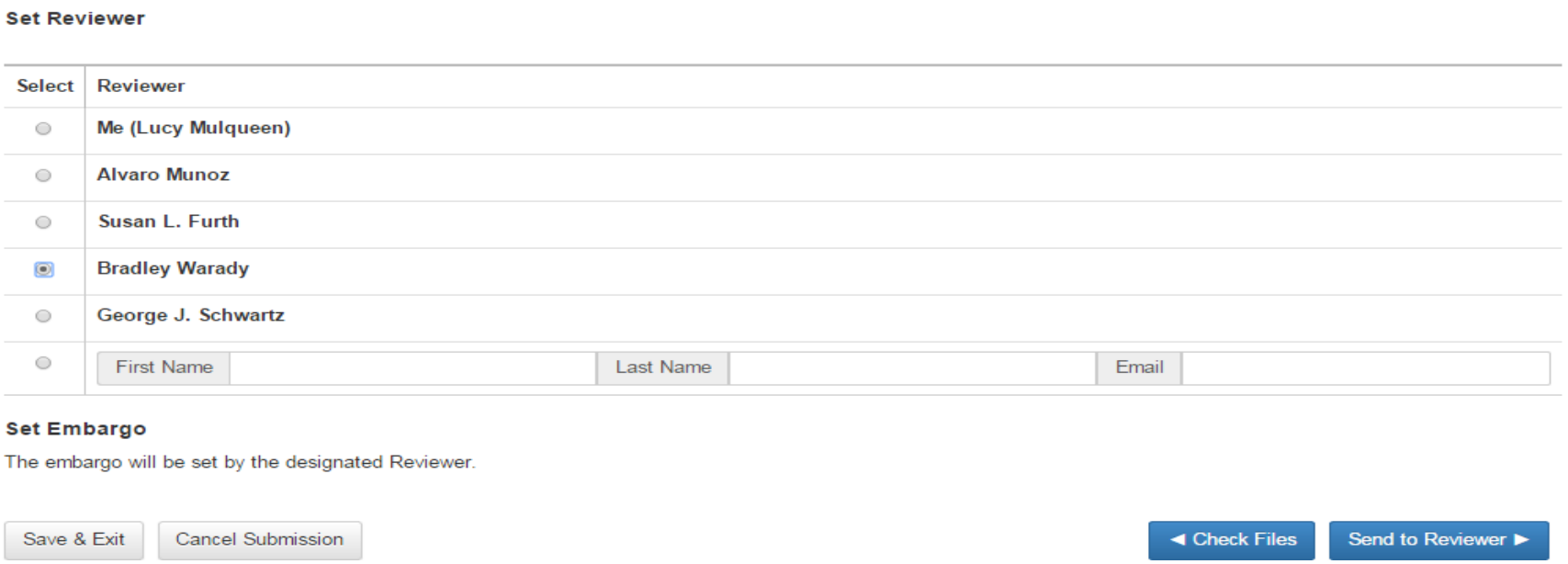
7. After the PDF has generated, you will need to open it up and review the file.



8. Click on the PDF link and review the PDF



9. Click on "**Set Reviewer & Embargo**" You can choose one of the PIs as the reviewer or manually enter the name of the first author. Do not set yourself as a reviewer if you are not an author on the paper. The system will allow you to do this but it won't actually let you approve the PDF in the next step. You will have to start over again and set a new reviewer.



10. Click on "**Send to reviewer.**"

You will see a confirmation page that the manuscript was submitted to the reviewer.

The reviewer will receive an email from NIHMS that they need to approve the initial PDF. The email will include instructions about how to access it and approve it. They should select the shortest time possible to release the article to PubMed Central. At this point, the manuscript status will appear as "in process."

After the reviewer approves the PDF, NIHMS will create a final version that will be deposited to PMC. Once this step is finished, the reviewer will receive another email from NIHMS that they need to approve the final version.

22.8 **PROCESS FOR SECONDARY AND ANCILLARY PUBLICATIONS**

22.8.1 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 22.3.1 for definition) require CSR committee approval. The proposing investigator will follow the guidelines outlined in Section 22.3.2. The CSR committee 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 CSR committee, 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 CSR committee. The proposing investigator will follow the guidelines outlined in Section 22.3.2. The CSR committee 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 CSR committe, taking into account other analyses and data management priorities.

3. Site-specific studies must also be reviewed and approved by the CSR committee. 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 and CSR committee.

4. Final abstracts, presentations, and publications of secondary and ancillary studies must follow the policy outline in MOP Section 22.5 and 22.6 .

22.8.2 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 be approved by the CSR committee.

The expectations and responsibilities of ancillary study investigators are outlined in Sections 22.3 – 22.7:

- Agree to lead investigator key responsibilities (see Section 22.3.5) and Manuscript Policy (see Section 22.6).
- 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 data, obtain a fully executed DUA to receive a limited CKiD dataset (see Section 22.3.7).
- Before receiving CKiD samples, obtain a fully executed SDUA to receive 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 SDUA, the remaining samples must be destroyed.
- Agree to forward agreed upon data to KIDMAC as described in section 22.3.7.

22.9 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.

22.10 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.