**Chronic Kidney Disease in Children Cohort Study**

 **Concept Sheet Submission Form**

**Please fill out all the lettered and numbered sections below**

(*this form will not be accepted unless all of the fields are completed*)

*This form is intended for use for all collaborations. Where* ***“***[ ] **”***appears, click on box to add* “[x] ”*.*

**A. GENERAL INFORMATION**

1. Date of submission: **Click here to enter a date.**
2. Lead investigator(s): **Click here to enter text.**
3. Study Title: **Click here to enter text.**
4. Contact Person (if different from lead investigator): **Click here to enter text.**
5. Institution: **Click here to enter text.**
6. Address:

**Click here to enter text.**

1. Telephone number: **Click here to enter text.**
2. Email address: **Click here to enter text.**
3. Submission Type: [ ]  Initial [ ]  Revised [***Click box to add*** [x] ]

[ ]  Addendum/Expansion of previously approved concept (Readme #\_\_\_\_\_\_\_\_\_)

1. **Summary of Changes:** If submission is an amendment or addendum (to a previously approved) existing concept sheet, please summarize all changes or expansion. **If submission is a revision (to a previously deferred/rejected), investigators must submit a separate document that responds to the reviewers’ questions and/or comments.** (**NOTE:** In addition to the summary and/or responses, please highlight or track all changes to the previously submitted concept sheet.)

**Click here to enter text.**

1. Guidelines (pages 10 – 11) have been reviewed: [ ]  Yes [ ]  No
* By submitting this Concept, you agree to abide by the CKiD Publication Policy (<https://www.statepi.jhsph.edu/ckid/investigator.html> click on “Publication Policy”). The policy includes submitting manuscripts accepted for publications to NIHMS for PMCID number, if not using a NIH-approved PMC journal.
* Productivity (e.g., preliminary data analysis, presentation, and/or publication) of approved Concepts is required within 6 months of approval; otherwise the topic may be reassigned.
* Lead authors are responsible for completing an annual progress report (or as requested) for all approved CKiD concept sheets

|  |
| --- |
| **For Internal Use Only (DO NOT REMOVE)** |

Readme#: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ Processing: [ ] Expedited-Scientific [ ] Regular

**The completed CKiD Concept Sheet Submission Form should be sent electronically to Judith Jerry-Fluker at KIDMAC (****jjerry@jhu.edu****)**

**B. CONCEPT INFORMATION**

1. Please check the scientific subcommittee(s) that should review this concept sheet.

[*Click box to add* [x] *.*]

|  |  |  |
| --- | --- | --- |
| [ ]  | Kidney Disease Progression |[ ]  Cardiovascular |
|[ ]  Neurocognitive |[ ]  Growth |

1. Check whether the specific aims address core or non-core CKiD aims:

|  |
| --- |
|[ ]  Core CKiD specific aims (proposal submitted on behalf of scientific subcommittee) |
|[ ]  Non-core CKiD specific aims/Ancillary  |  |  |

1. Topic (Select all that apply):

|  |  |  |
| --- | --- | --- |
|  | [ ]  *CKD Progression* | [ ]  *Cardiovascular Risk Factors* |
|  | [ ]  *CKD complications* | [ ]  *Hypertension* |
|  | [ ]  *Cognitive Function* | [ ]  *Lipids* |
|  | [ ]  *Behavior* | [ ]  *Inflammatory Markers* |
|  | [ ]  *Neuropsychology* | [ ]  *Genetics* |
|  | [ ]  *Drug Use* | [ ]  *Proteomics,* |
|  | [ ]  *Epidemiology* | [ ]  *Metabolics* |
|  | [ ]  *Immunology* | [ ]  *R01submission,* |
|  | [ ]  *Methodology* | [ ]  *Pharmacology* |
|  | [ ]  *Natural History* |  |
|  | [ ]  *Other:*  |

1. Sites involved in the proposed study:

[ ]  All CKiD Sites

[ ]  Other, please list the clinical sites by name

**Click here to enter text.**

1. Will this project require the withdrawal of specimens from the NIDDK DNA and/or Biological Samples Repository(yes)? [ ]  Yes [ ]  No
2. If “Yes,” the deadline date you will require specimens (mm/dd/yy): **Click here to enter a date.**
* Following approval of the concept, you will need to obtain a fully executed Sample Data Use Certification (SDUC) between your institution and NIDDK. The information regarding how to obtain a SDUC will be sent to you or can be viewed on the CKiD website, under the “Investigator Resources” page.

***Potential Funding Source*** (pending application, planned application or funded effort)

1. Are you planning to submit an application for funding (i.e., R01, K23): [ ]  Yes [ ]  No

If yes, please specify and complete questions **a & b** below:

**Click here to enter text.**

1. Your grant submission deadline: **Click here to enter a date.**
2. Is a letter of support from CKiD needed? [ ]  Yes [ ]  No
* **Please inform Judith Jerry-Fluker (****jjerry@jhu.edu****) and Lucy Mulqueen** (lmulqueen@jhu.edu) **about the outcome of the grant submission within 1 year following approval of concept sheet proposal.**
* **The lead investigator is responsible for notifying KIDMAC.**
1. CKiD Liaison: **Click here to enter text.**
2. Institution: **Click here to enter text.**
3. E-mail Address: **Click here to enter text.**
4. FAX Number: **Click here to enter text.**
5. Mailing Address:

 **Click here to enter text.**

1. KIDMAC Point Person: **Click here to enter text.**

Telephone Number: (410) 614-1277

Mailing Address: Johns Hopkins University

 Bloomberg School of Public Health

 Department of Epidemiology

 Room E7650

 615 North Wolfe Street

 Baltimore, MD 21205-1999

BEFORE SUBMISSION:

* Internal investigators should have the completed Concept Sheet (Concept) reviewed by another CKiD investigator
* External investigators should have the completed Concept reviewed by their co-investigator/CKiD liaison (as indicated on above) to determine that this concept sheet is appropriate
* If no CKiD liaison exists, external investigator should contact Bradley Warady at bwarady@cmh.edu and/or Susan Furth at FurthS@email.chop.edu

**C. STUDY DESIGN (2 – 3 pages)**

Use the following organization to present your study plan and take whatever space is necessary to completely respond to each section. Complete in 12 point font only. Please submit electronic copies in WORD, RTF, or PDF format.

1. **Lay Language Summary** (Please *provide a one paragraph summary of the study and its impact on participants, written for a 10th grade reading level. If this concept results in a publication, CKiD will request an update to this lay summary. )*

**Click here to enter text.**

1. Does this project involve additional participant burden? (*Select all that apply*)

[ ]  Additional specimen collection needed

[ ]  New questionnaire

[ ]  New procedure (i.e., x-ray, biopsy)

[ ]  No additional specimens, questionnaires or procedures needed

1. **BACKGROUND** *(a brief description of the rationale for the sub study including references)*

**Click here to enter text.**

1. **SPECIFIC AIMS AND HYPOTHESES** *(Specimens and data provided by CKiD may only be used to complete the aims described in this concept. Additional testing and use of data, including transfer to another investigator, outside the scope of the stated aims and not explicitly stated in the concept are not allowed. Additional testing and data use require review and approval from the Steering Committee. In addition, upon approval of the proposed CS a Data Use Agreement form will be sent by the CKiD Data Coordinating Center (KIDMAC) and must be completed by the Lead Investigator.)*

**Click here to enter text.**

1. **STUDY DESIGN** (*summarize the type of study, inclusion criteria, and sample size)*

**Click here to enter text.**

1. **SPECIFIC INCLUSION AND EXCLUSION CRITERIA**

**Click here to enter text.**

1. **LABORATORY METHODS** *(Indicate the laboratory that will perform assays and if applicable, summarize how new studies will generate data, etc. If not applicable, check the N/A box.)*

**Click here to enter text.**

[x]  N/A

1. **QA/QC PROCEDURES** *(for studies generating new laboratory data: summarize laboratory QA/QC procedures, participation in recognized program, past publication, etc., relevant to the proposed investigations or testing. If not applicable, check the N/A box.))*

**Click here to enter text.**

[ ]  N/A

1. **STATISTICAL METHODS/ DATA ANALYSIS AND SAMPLE SIZE CALCULATIONS**

*(Include a statement about statistical power. Where appropriate, indicate which variables are needed from the CKiD database and anticipated support needed from CKiD. CKiD questionnaires with variables are available online at* [*http://www.statepi.jhsph.edu/ckid*](http://www.statepi.jhsph.edu/ckid)*. Include how data will be reported: on paper, what database, what file structure)*

**Click here to enter text.**

Primary outcome variables:

Secondary outcome variables:

Other variables:

1. **Expected Visit Numbers:** [ ]  N/A [ ]  ALL visits

[ ]  v1b (baseline) [ ]  v2 [ ]  v3 [ ]  v4

[ ]  v5 [ ]  v6 [ ]  v7 [ ]  v8

[ ]  v9 [ ]  v10 [ ]  v11 [ ]  v12

1. **DATA REQUESTED**

Are you requesting a dataset to perform the analysis at your institution? [ ]  Yes [ ]  No

**Please note that in order to receive CKiD data, a fully executed data use agreement (DUA) must be obtained.** The data use agreement is submitted after the concept sheet is approved by the Steering Committee. Please note that it may take at four (4) weeks or more to obtain a fully executed data use agreement.

1. **PROPOSED TIMETABLE FOR STUDY COMPLETION:**

**Click here to enter text.**

**D. SAMPLE SPECIFICATIONS**

**Effective June 1, 2010,** investigators requesting samples from the NIDDK Repository will have to agree to pay shipping costs before NIDDK will authorize the shipment of samples. As of October 2018, the estimated ancillary shipping fees for samples are listed below. Prices are subject to change. Refer to NIDDK Repository website <https://repository.niddk.nih.gov/pages/costs/> to confirm prices.

**Samples from the Biosample Repository at Precision for Medicine:**

* Per box: Pulling/shipping up to 81 specimens - $235.71 ($2.91 per sample)
* Per box: Pulling/aliquoting/shipping up to 81 specimens - $388.80 ($4.80 per sample)
* Requesting investigator will provide a shipper account number (e.g. FedEx or UPS) so that the repository can bill the shipment using their institutional rates.

|  |
| --- |
| **Samples from the Genetics Repository at Precision for Medicine (All prices include shipping cost):** |
| ***Option 1*** | ***Custom nucleic acid distribution*** | Investigators request specific DNA yields, concentrations, volumes, sample organization, and sample container for their distribution. |
|  | $24.09 per sample |
| ***Option 2*** | ***Fixed volume and concentration*** | DNA will be provided at a FIXED concentration of 100ng/ul in a FIXED volume of 200ul (a yield of 2 or 5 ug per samples in a FIXED sample format with no specific order of samples requested. These samples will be distributed in sealed PCR plates to the requesting investigators. |
|  | $16.14 per sample |
| ***Option 3*** | ***Fixed volume at stock concentration*** | DNA will be provided at a FIXED volume of 20ul of stock DNA (with varied concentrations) in a FIXED sample format with no specific order of samples requested. These samples will be distributed in sealed PCR plates to the requesting investigators. |
|  | $5.00 per sample |

1. Sample Type\*: [ ]  Serum [ ]  Plasma [ ]  DNA/Cells [ ]  N/A

 [ ]  Urine [ ]  Hair [ ]  Nails

1. Are previously thawed sample acceptable? [ ]  Yes [ ]  No (**specify reason below**)

\*Specimens previously thawed for other initiatives will most likely be shipped. **If unacceptable, give a reason below for requiring specimens not previously thawed.**

**Click here to enter text.**

1. Sample Quantity\*\*: Minimum:

 Optimum:

\*\*Please note that due to limited sample quantities stored at the NIDDK Repository, request for serum, plasma and urine should not exceed the following amounts:

Serum no more than 0.1mL Plasma no more than 0.1mL Urine no more than 1.0mL

1. Expected Visit Numbers: [ ]  N/A [ ]  ALL visits

[ ]  v1b (baseline) [ ]  v2 [ ]  v3 [ ]  v4

[ ]  v5 [ ]  v6 [ ]  v7 [ ]  v8

[ ]  v9 [ ]  v10 [ ]  v11 [ ]  v12

1. Expected Number of unique participants: \_\_\_\_\_\_

**NOTE:** Upon Concept Sheet approval, a Repository Request Checklist (available on http://www.statepi.jhsph.edu/ckid) must be submitted to Judith Jerry-Fluker via email at jjerry@jhu.edu.

**E. STATEMENT OF AGREEMENT**

 I hereby acknowledge and agree that:

* All information that I provide in this Concept Sheet is complete and correct as submitted.
* Use of specimens and/or data is restricted to the aims outlined in Section C of the Study Design.
* IRB approval has been, or will be, obtained before any data and/or specimens are received.
* I will complete a CKiD Data Use Agreement, if this proposal receives approval and data is requested.
* Under no circumstances will I make the CKiD study subject ID number and/or ancillary ID number public whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.
* I will provide KIDMAC with a copy of all abstracts and/or manuscripts submitted, and notify KIDMAC when the abstract and/or manuscript is/are accepted.
* My signature below indicates a complete review, acceptance, and adherence to the guidelines for collaboration, publication, acknowledgment as outlined in this concept sheet submission form.

**Investigator Signature** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your signature indicates that you agree with all the above information and (if you are requesting data or specimens) that you have received local IRB approval or will attain approval before data or specimens are released.

NOTE: After your Concept Sheet has been submitted electronically, please sign and email a scanned copy to Judith Jerry-Fluker (jjerry@jhu.edu).

**INSTRUCTIONS FOR SAVING CONCEPT SHEET:**

After completing all of the sections, save the document in the following manner.

Lead Investigator’s last name**\_**title of concept sheet ***Example:*** Fluker\_How to submit a concept sheet

**INSTRUCTIONS FOR SUMBITTING REVISED CONCEPT SHEET:**

Submit a concept sheet with tracked changes and a clean version.

If an investigator is submitting responses to a reviewer’s critique and/or Steering Committee questions, the question/concern must be provided prior to the response.

 Responses must include the README #, lead investigator’s name and study title.

**F. ADDITIONAL SAMPLE AND DATA REQUIREMENTS**

1. **For BIOLOGICAL SAMPLES ONLY:** A data file containing lab results and a codebook of specimen received must be submitted prior to the release of study visit data. NO EXCEPTIONS to this requirement.
2. Use of CKiD specimens require submission of a fully executed SDUC between investigator’s institution and NIDDK.
3. Request for CKiD data require a fully executed data use agreement (DUA) between investigator’s institution and Johns Hopkins University. Separate DUAs are required between all institutions with personnel who will have access to the data and Johns Hopkins University.

**G. Internal Collaborations ONLY**

1. NEW SUBSTUDIES (detail any anticipated additional participant and CKiD staff burden (in terms of amount of time required, additional visits, specimens to be collected, etc.))

**Click here to enter text.**

1. RELEVANCE (to overall CKiD aims and justification for use of CKiD specimens)

**Click here to enter text.**

1. CORE GOALS (Discussion of consistency with CKiD core goals and scope. Proponents of Concepts are encouraged to link with CKiD investigators to avoid overlap with ongoing initiatives. Please review the files listed at http://statepi.jhsph.edu/ckid/ to see active concept sheets by research topic in the CKiD.)

**Click here to enter text.**

**Please read the Guidelines in the following Appendix ➔**

**APPENDIX: Guidelines**

**MANUSCRIPTS**

A CKiD Investigator (CKiD-I) is defined by the CKiD Steering Committee as investigators named by each clinical coordinating center and the data coordinating center (KIDMAC), as well as representatives from each NIH institute supporting the study.

For joint publications with the first author being a CKiD-I, the number of coauthors should be: 1 to 2 additional investigators from the 1st author's coordinating center; 1 to 2 investigators from each of the other two centers; and 1 to 2 members from NIH or other major contributor to the publication (e.g., laboratory collaborator).

For joint publications with the 1st author being someone who does not meet the criteria to be a CKiD-I, the number of co-authors should be: additional members of the research team of the primary author; 1 investigator from each of the three coordinating centers of the study; and 1 to 2 members of NIH or other major collaborating center.

All publications and presentations of studies utilizing samples or data supplied by CKiD **must** include the following acknowledgement:

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 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 (U01-DK-66143, U01-DK-66174, U24-DK-082194, U24-DK-66116). The CKID website is located at <http://www.statepi.jhsph.edu/ckid> **and a list of CKiD collaborators can be found at** [https://statepi.jhsph.edu/ckid/site-investigators/](https://nam02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fstatepi.jhsph.edu%2Fckid%2Fsite-investigators%2F&data=04%7C01%7Clmulqueen%40jhu.edu%7C61c29c80f8874b382dc508d8f8660d84%7C9fa4f438b1e6473b803f86f8aedf0dec%7C0%7C0%7C637532464474587926%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=F6iRz3dIuomCqKeOGp%2FEb4Z5aFMw4D2mbNysY5LmBwM%3D&reserved=0)**.**

**If a CKiD Internal Investigator is not listed as a co-author, the lead investigator must submit a draft of the manuscript to CKiD SC for approval prior to submission. After the co-authors have reviewed the draft manuscripts, manuscripts should be emailed to Judith Jerry-Fluker at KIDMAC (****j****jerry@jhu.edu).** Final revisions must also be available for review before resubmission.

Lead authors are responsible for complying with the NIH Public Access Policy, that peer-reviewed manuscripts arising from NIH funding and accepted for publication on or after April 7, 2008 are deposited in PubMed Central (PMC). The PMCID or NIHMSID should be sent to Lucy Mulqueen (lmulqueen@jhu.edu) at KIDMAC along with notification of accepted for publication or actual publication of a manuscript.

**Lead authors should notify KIDMAC of any and all manuscripts accepted for publication.**

**An electronic copy of all published manuscripts should be sent to Lucy Mulqueen at KIDMAC to provide an archival record of work resulting from the study.**

Lucy Mulqueen

KIDMAC

Johns Hopkins Bloomberg School of Public Health

615 North Wolfe St E7650

Baltimore, MD 21205

(410) 614-1340

lmulqueen@jhu.edu

**If data analysis for the manuscript has not been carried out at KIDMAC**, the first author is responsible for sending the computer programs, final data sets and codebooks that directly relate to tables and figures in the manuscript to KIDMAC. The programs and data should be labeled table1.dat, table1.sas (if SAS was used), etc. and should be sent to Lucy Mulqueen at KIDMAC. Data received from KIDMAC may **only** be used for the specific aims of the analysis proposed in this concept. Additional initiatives should be submitted to the SC via a new Concept Sheet Submission Form.

**Policy on Approved Use of Data and Specimens**

* Specimens or data provided by CKiD are intended for the express purpose of performing SC-approved research. These specimens and data must **not** be provided to other investigators or used for additional projects without the written consent of the CKiD Steering Committee.
* Unauthorized use of data and/or specimens for work not specifically described in the aims of the concept sheet will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data and specimens.

**Internal Investigators submitting proposals for analyses of existing data only:**

Upon approval of a concept sheet, authors are expected to uphold the following time frame:

* Assembly of an analytical data set should follow 0.5 to 1 month after receipt of request. A writing committee will be assembled during this time and you will be notified of the membership. One of the co-authors will be designated to receive copies of all drafts and analytic data sets. That co-author should be prepared to stand in if you are unable to complete the work in a timely fashion.
* Preliminary statistics, data visualization, descriptions and exploration should be complete 1 to 2 months after CS approval.
* A focused statistical analysis aimed at addressing research questions, including drafts of figures and tables to be included in the paper, would proceed during the following month. At this point, co-authors should be solicited for input.
* 2 to 3 months after CS approval, reworking of analyses and writing should be in process. The analyst will be responsible for helping to draft methods and results. The lead author and co-authors are responsible for drafting other components. By the end of 3rd month, a draft should be circulating.
* 3 to 4 months after CS approval the draft should be revised with input from co-authors in preparation of the final draft.
* By the end of month 4, there should be a manuscript ready to submit for publication.This time frame is dependent on many variables but it is a reasonable target. The clearer the concept sheet, the faster the process. Investigators should be willing to be continually engaged with the analyst. Lead authors are expected to keep the KIDMAC Point Person apprised of any delays in testing, analysis, writing, and manuscript submission.

Submission of a concept sheet requires (a) key personnel certified in the NIH OHSR or equivalent training course (b) a signed contract and (c) one CKiD participant enrolled in the main study. Your submission indicates that you agree with all the information on the following page (Internal Investigators only) and that you have received local IRB approval for testing to be performed at the time samples are requested from the repository. The CKiD SC will review your CS via conference call with the Lead Investigator invited to attend. Study specific collaborations will be reviewed by that study SC. You will be notified of the status of your CS via email. After your CS has been reviewed by the CKiD SC, you will be sent an email indicating if it has been approved, approved with comment, revision requested or rejected. In addition, if your CS has been approved, you will be notified of your assigned project number: CKiD k-YY-### (YY = year). You should use this project #s in all correspondence up to and including publication.