

## **Section 1: ANCILLARY STUDIES POLICY**

Revised July 2022

### **I. General Policy and Process Overview**

To enhance the value of the CRIC Study, the SC welcomes proposals from individual investigators to carry out ancillary studies.

To protect the integrity of the CRIC Study, ancillary study proposals must be reviewed and approved by the Ancillary Studies (AS) Committee and the SC before submission for external funding consideration.

The ancillary study proposal template is appended to this document. See Section XII for instructions on the submission process.

### **II. Definition of Ancillary Study**

An ancillary study is one based on information and/or biosamples from CRIC Study participants, which includes hypotheses, specific aims, anticipated publications and sufficient non-CRIC Study funding to support an investigation or analysis which is relevant to, yet not described in, the CRIC Study protocol. It is anticipated that a typical ancillary study will propose the collection of additional data not collected or analyzed as part of the routine CRIC Study data set. Ancillary studies may be submitted by investigators within the CRIC Study network or by investigators without a prior relationship to the CRIC Study. Investigators who are not part of the core CRIC Study are encouraged to collaborate with a CRIC investigator but this is not a requirement.

Ancillary studies require external funding; there are no funds available for these purposes within the CRIC Study. Examples include studies funded by investigator-initiated NIH research awards (e.g. R01), grants from academic institutions or private sources (e.g. private foundations, pharmaceutical companies). Ancillary studies must have sufficient funding to cover the costs that may be incurred by the CRIC Study Clinical Centers, laboratories (e.g., to process, test or ship samples), and the Scientific and Data Coordinating Center (for tasks such as sample selection, preparing and documenting analysis files, participating in statistical analysis, and integrating the new ancillary data into the combined CRIC Study database).

### **III. Requirements and Procedures for Approval of an Ancillary Study**

#### IIIa. Overview

Participation in, and approval of an ancillary study is subject to review by the CRIC AS Committee, and formal approval by the CRIC SC. The role of the AS Committee is to provide feedback to a potential ancillary study investigator regarding the suitability for incorporation their protocol into the CRIC Study, feasibility of proposed activities, potential areas of common scientific interest with existing or approved CRIC Study activities, and concerns about the

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proposed science or methods. Feedback about the proposal from the assigned AS Committee reviewers will be returned to the Investigator for responses prior to circulating for formal SC vote. The investigator's response to AS reviewer feedback will then be circulated back to the reviewers and a final recommendation to approve or reject the proposal will be made. A formal decision regarding approval of all ancillary studies is provided by the SC. Approval by the SC requires seven of ten votes in favor of the proposal. Votes from the SC will be based on review of the submitted proposal and de-identified versions of the reviews completed by AS reviewers. Dissenting voters must provide the explicit reason for their dissent. Any issues of concern to dissenting voters will be shared with the applicant and opportunities for clarification provided. SC.

An ancillary study must receive approval before a grant to support it is submitted. Investigators are encouraged to discuss potential proposals with the Chair or Co-chair of the AS Committee, or the CRIC SC Chair prior to submitting a concept proposal.

With over 100 funded CRIC ancillary studies, dozens of new ancillary study proposals approved every year, and the CRIC Opportunity Pool Program, it is becoming increasingly frequent that new ancillary study proposals share areas of common scientific interest with other ongoing and approved work in CRIC. The CRIC SC (CRIC SC) views such commonalities as opportunities to promote research collaborations. Accordingly, the CRIC SC will make potential ancillary investigators aware of other ongoing or approved projects in the topic areas of common interest. While investigators with similar research interests may choose to collaborate, there are no requirements for them to do so. An exception to this is when projects seek to use limited CRIC resource (e.g., biological samples) or engage in data collection from CRIC participants that is duplicative across ancillary studies. In such cases, the project teams will be asked to collaborate to reduce the use of CRIC resources and burden on study participants. To aid potential ancillary study investigators in understanding other work that is ongoing in their area of interest, a list of all funded ancillary studies (PI name and project title) is available on the CRIC website. Potential ancillary investigators may contact the SDCC to inquire about other approved (not yet funded) work in the area of interest.

The ancillary studies policy and processes are contingent upon the work of the membership and chairs of both AS and the SCs. In the event of conflict of interest, the Chair or membership of either committee is expected to recuse him/herself from the approval process. A co-Chair or SDCC delegate can act as a proxy throughout the AS feedback and SC voting processes.

### III b. Requests for Ancillary Studies as Part of Training or Career Awards

The CRIC Study investigators and the NIH anticipate that the CRIC Study will be an important resource for career development and training among members of the academic community.

All training proposals must identify a mentor and potential ancillary trainees are encouraged to include a CRIC investigator on the project. In addition to the typical aspects of ancillary study review, training proposals will also be evaluated for the following:

- Clear identification of mentors who possess the expertise and commitment to train the candidate.

- Availability to the mentor of resources needed for the proposed work beyond those typically available in a training award

### III c. Review Process

The review process will have two steps. The first step is review of the proposal concept and acceptability by the AS Committee. The proposal concept should be summarized using the template in **Appendix A**. All ancillary studies that involve new data collection from CRIC participants, including administration of questionnaires or physiologic measurements, must be reviewed and approved by the CRIC Study’s Observational Study Monitoring Board (OSMB). See section XIII for additional details.

### Conditions for Approval of Ancillary Studies:

- A. High scientific merit
- B. No undue burden on participants (e.g. time, discomfort, privacy).
- C. No interference with the conduct of any part of the CRIC Study protocol.
- D. Does not diminish ability of CRIC Study sites to engage in core CRIC protocol activities.
- E. No more than minimal demand on CRIC Study resources such as biological specimens, personnel, and equipment.
- F. Require the unique characteristics of the CRIC Study cohort to accomplish its goals.
- G. Availability to the investigators of resources needed to complete the project, including:
  - a. Sufficient financial resources and personnel
  - b. Staff who have the requisite expertise to meet the objectives of the project.
- H. Agreement by ancillary study investigators to place all data collected as part of the ancillary study into the CRIC data management system
- I. No potential for jeopardizing the public image of the CRIC Study.
- J. Involvement when possible of the entire cohort rather than isolated subgroups.

### III d. Instructions for Preparation of Requests for Approval of an Ancillary Study

All proposed ancillary studies must be submitted to the CRIC AS Committee in time for circulation and subsequent review by the SC before submission to a funding agency. It is encouraged for proposals to be submitted four months in advance of the anticipated grant submission deadline. Studies submitted for review less than 8 weeks before a funding application deadline may not receive approval.

### III e. Proposal Format

Prior to submitting the proposal for the first review within AS, each Investigator must consider the possible participation of all CRIC centers, if the study involves clinical center participation. There will be times when the study cannot accommodate all interested sites because of budgetary constraints. Under these circumstances, it is expected that ancillary investigators communicate with participating CRIC clinical center PIs so that a plan regarding study implementation can be formulated collaboratively. . The ancillary study investigator must ensure that a sufficient number of CRIC sites agree to participate in the study so that the aims of the study can be achieved.

A written request for approval of an ancillary study should be submitted to the AS Committee using the template in **Appendix A**. All sections of the proposal must be completed in full.

All potential Investigators are strongly encouraged to contact the AS Committee Co-chairs and the Ancillary Management Team (see **Appendix B** for contact information) as early as possible in the grant preparation process (see Section XII). The SDCC participates in budget development and is also helpful in planning study design and analyses.

#### **IV. Changes to A Proposed Study**

Once an ancillary study is approved, if a change occurs in the structure or concept of the study for any reason (for example as a result of the NIH review process), including any change in data elements to be collected or analyzed, or any change to study aims, such changes must be disclosed to the CRIC SC via the AS Committee and the SDCC, for review and approval before the proposal is (re-)submitted to a funding agency. This disclosure should be sent by email to the AS Committee co-chairs and the SDCC (see **Appendix B** for addresses) with a brief summary of the proposed changes and the revised ancillary study proposal with changes tracked. If the changes are considered minor by the co-chairs and SDCC, the proposal will be circulated directly to the SC for a vote. If the changes are substantial, the protocol will need to be routed anew through the AS Committee.

If any changes to approved aims are made prior to the initial submission, the AS Committee and the SDCC need to be notified (via the same process as above) of the changes in advance of grant submission. If it is deemed that there is a change in scope re-approval and possibly changes to the SDCC or clinical center budgets will be necessary before the grant can be submitted. Approved ancillary study proposals are approved only for the aims described in the proposals. Expansions of scope in the body of the grant, beyond what is described in the approved ancillary study proposal are not approved.

#### **V. Proposal Budget**

The investigator applying for an ancillary study must supply all additional funds needed to successfully complete the study. The AS Committee will be concerned with both the overt and the hidden costs to the CRIC Study entailed by an ancillary study. The need for such support must be stressed in research grant applications since provision of this support is mandatory. Such costs include, but are not limited to:

- 1) SDCC Costs
  - a) Data management effort for coordinating the additional data management and analyses
  - b) Statistical staff and investigator effort to conduct additional analyses or verify analyses conducted by the ancillary investigator before publication of results
  - c) Investigator and project management effort to implement the ancillary study
  - d) Expenses involved in altering key identifying data so that subjects' confidentiality will be protected.
  - e) Costs for notification of alert values, if relevant.
  - f) CRIC Central Laboratory costs

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- i) appropriate lab, storage, freezer and office space
  - ii) appropriate lab supplies
  - iii) if assays conducted at SDCC, cost of assays
  - iv) pulling and aliquoting specimens, if necessary
  - v) lab tech effort to receive, track, process, specimens and either complete tests or ship specimens for testing
  - vi) Review of plans for laboratory analyses conducted at labs other than the CRIC Central Lab
- 2) Costs to participating Clinical Centers
- a) Personnel (investigator and staff) effort, equipment and supplies necessary to complete the project including, but not limited to, regulatory submissions, participant recruitment and scheduling, data collection, data entry. Expenses involved in altering key identifying data so that participants' confidentiality will be protected
  - b) If work is to occur on site, rental of appropriate clinic, lab and office space
  - c) Transportation or incentive/reimbursement costs for participants, if relevant
  - d) Costs for notification of alert values, if relevant

Once a study concept is approved, applicants for ancillary studies must work in conjunction with the SDCC to develop a budget that adequately provides for these types of expenses at the SDCC. Ancillary investigators must work with PIs at each of the Clinical Centers (if new data collection or measure are needed) to develop a subcontract budget for work being performed at the Clinical Centers.

### **VI. Human Subjects/Data Confidentiality**

Confidentiality of CRIC participants must be guaranteed. Individually identifiable data may not be released. A signed consent must be obtained from every participant in the ancillary study, if the data collection/request is not covered in the original informed consent process for the main CRIC Study.

- a) Any investigator or personnel having access to CRIC data must abide by the terms indicated in the data use agreement. Key personnel of the ancillary study must be certified in the NIH OHSR or equivalent training course.
- b) A copy of the local IRB approval letter for the ancillary study is to be sent to the SDCC. If a separate consent form is required for the ancillary study, a copy of the signed ancillary study consent form for each study participant must be included in the CRIC Study record.

If requested, a written progress report on ancillary studies must be made periodically to the SC and the Observational Study Monitoring Board (OSMB)

### **VII. Data Management, Analysis, and Publication of Results of Ancillary Studies**

#### Management of Ancillary Study Data

1. All data collected under the auspices of an ancillary study is expected to adhere to the same high standards of quality applied to data collected in the core CRIC study using the same

mechanisms that are in place for the core CRIC study (e.g. oversight by the Quality Assurance Committee and the evaluation of data collection techniques by site visit teams).

2. All data from ancillary studies will be made available to the SDCC either on a real time basis using direct data entry into the CRIC data management system as established by the SDCC or through frequent transfers of ancillary data to the SDCC. The frequency of these transfers will be established prior to the initiation of any ancillary study and ordinarily would be expected to occur no less frequently than on a quarterly basis. This policy regarding data transfer will not only help to assure the highest quality of data from ancillary studies but will enable the SDCC to track recruitment and follow-up of the participation of CRIC subjects in ancillary studies. In addition, the format of data transfer to the SDCC must conform to standards compatible with the CRIC data management system as defined by the SDCC data management group.
3. All cost associated with the collection, transfer, analysis and oversight of data collected by an ancillary study will be borne by the ancillary study. Statistical analyses may take place either at the SDCC under the supervision of its biostatistician-investigators or at another collaborating institution under the direction of a qualified biostatistician/epidemiologist. When data analyses are to be conducted outside of the SDCC an analytical plan and the biostatistician/ epidemiologist who will lead the analyses must be identified in the ancillary study proposal. .

#### Publications

Proposals for manuscripts resulting from all ancillary studies shall be submitted to the CRIC Presentations and Publications Committee and require approval by the SC before establishment of a writing committee or a submission for publication or presentation. It is anticipated that principal investigators of approved ancillary studies will lead at least one scientific paper emerging from the ancillary study analyses as specified in the Publications and Presentations Policy. CRIC Investigators will be invited to join the writing committee for ancillary study manuscripts as described in the Publications and Presentations Policy. The phrase "CRIC Study" should be included in the title in all scientific presentations and manuscripts and listed as a key word whenever possible. Manuscripts will also contain an appendix listing CRIC investigators deemed appropriate.

### **VIII. Feedback of Results of Ancillary Studies to Participants**

Results of ancillary studies shall be reported to participants and/or their physicians if medically useful and allowable under local Institutional Review Board (IRB) regulations. Such reporting should follow standard CRIC protocol for notification of participants.

### **IX. Handling of CRIC Data and Specimens**

It is the strong preference of the SC for all biologic specimen analysis to be performed at the CRIC Central Lab (CCL) whenever possible, in order to assure quality measurements and to minimize sample use and distribution. If after discussions with the SDCC, it is not feasible for testing to be performed at the CCL, specific arrangements should be made, including budgeting

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of adequate funds, with the SDCC to ensure adequate oversight of testing done elsewhere. When laboratory testing will be performed outside of the CCL, the laboratory performing the testing must provide information upon request regarding procedures for sample testing, sample handling, data management and management of specimen identity. A quality control plan for the laboratory testing must also be submitted for review by the CRIC QC Committee. A standard part of quality control plans for laboratory testing will include testing and statistical analysis of blind duplicate samples for 5% of the total samples included in the analysis. The costs of blind duplicate testing will be included in the ancillary study budget.

The CRIC Study Central Lab, AS and the SC reserve the right to request preliminary data validating an investigator's laboratory method against an external standard. In addition, they may also request outside review by independent experts in the area to certify the QA data presented.

Distribution of CRIC specimens and data will occur after appropriate data use and/or material transfer agreements are in place. At the time of distribution of CRIC specimens and/or information, the SDCC will make explicit arrangements with the ancillary study PI for the security of these study materials, and for their final disposition at the conclusion of the ancillary study. The safety and confidentiality of the CRIC data at the collaborating institution is the responsibility of the ancillary study PI, as is the appropriate disposition of these materials after the study has been completed. Leftover DNA and laboratory specimens are destroyed or returned, and files of CRIC data are returned or deleted, as established at the outset of the collaboration via data use and/or material transfer agreements. An archival copy of the newly collected data and/or laboratory results not already held at the SDCC will be sent to the CRIC SDCC when the data are generated and ready for analysis. The SDCC will merge the ancillary study data with other CRIC data to prepare final analytical data sets for manuscript proposals approved by the CRIC Publications Executive Committee. The transfer of ancillary study data to the SDCC is the responsibility of the ancillary study investigator and is required prior to the receipt of the final analytical dataset and/or submission to a journal. Once transferred back to the CRIC Study, these ancillary data will become part of the aggregate CRIC data. Subsequent access to these data will be governed by the CRIC Study Policy on Use of Archived Study Data.

The CRIC Scientific and Data Coordinating Center (SDCC) at the University of Pennsylvania contributes updated CRIC Study data sets, including data generated by ancillary studies, to the NIDDK Data Repository at least annually. Data collected via ancillary studies will not be shared with the NIDDK Data Repository within the first 12 months after the data have been generated. At the end of the 12-month period following generation of the data, the ancillary study data will be included in the next planned transfer of data to the NIDDK Repository.

Data from ancillary studies will also be included in analysis-ready datasets which are shared with the CRIC Study clinical centers for CRIC investigators and colleagues at their institutions to explore the data and submit proposals for formal analyses to the SDCC for approval. Ancillary study data will be shared with the CRIC Study clinical centers no sooner than 12 months after the data have been generated.

## **X. SC Vote**

Once the ancillary proposal has been reviewed by the assigned AS committee reviewers, it will then be circulated among the SC (PIs from the CRIC Centers, the SC Chair and the NIH project officer) to place their vote to approve or reject the proposal. If a PI does not vote in the given time frame of two weeks (or in expedited circumstances, 1 week), their vote will automatically be counted as approved. However, in instances that a reviewer recommends rejection of a proposal, all investigators must vote unless there have already been 3 votes to reject. In that case, three votes to reject a proposal meet the standard for disapproving.

## **XI. Timelines, Investigator Departures and Future Considerations**

Upon initial approval of an ancillary study proposal, the investigator must submit the grant no more than six months later than the submission date indicated in the proposal and no more than one year from the date of approval. If the grant is not submitted within this time frame, the ancillary study will no longer be considered to be approved by the CRIC SC. If the investigator decides to submit the grant for a subsequent funding cycle, the proposal would need to be resubmitted for review and approval by the Ancillary Studies and SCs.

The AS Committee recognizes that most applications will not be funded in their original form. One circumstance is when a career development applicant is no longer active in academics or eligible to receive K funding. In many cases, the previously CRIC-approved K award may be adopted by the mentor and reconfigured into an R application. The AS Committee reserves the right to reconsider such an application since the criteria for approval of a K award are frequently more flexible than those for an R award

If grant is not funded upon initial submission and the investigator plans to resubmit, they must resubmit the grant within one year of receiving the review and funding decision of the initial grant submission. After two submissions or failure to submit a grant within the specified time frame, the ancillary study is no longer considered to be approved by the CRIC SC. If the investigator wishes to resubmit the grant, a revised ancillary study proposal must be submitted for review by the AS Committee.

## **XII. Ancillary Submission Processes and Inquiries**

1. Ancillary studies should be submitted by email to the SDCC (see Appendix) and the AS Committee co-chairs. See **Appendix B** for contact information.
2. Upon request the SDCC can provide information about laboratory testing that has been completed or is planned as well as testing that is supported by the CCL. The ancillary investigator should request information about specific laboratory testing from the SDCC.

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3. Investigators may contact AS Committee Chairs (see **Appendix B** for contact information) to discuss an ancillary study idea, or submit directly to Ancillary Management team (see **Appendix B** for contact information) at SDCC with a cc to AS Committee Chair(s).
4. The proposal is reviewed at the SDCC for completeness and clarity and additional data are requested from the investigator, if needed.
5. The proposal is reviewed by the AS committee (at least two reviewers evaluate the proposal).
6. Reviews will typically take place within two weeks of being distributed to the reviewers. Feedback will be provided to the investigators without identifying the reviewers. The Ancillary Management Team will send AS committee reviewer feedback to the investigator (with additional comments if warranted) with a cc to AS Committee Chairs
7. Investigator will clarify any queries or concerns
8. Investigator will resubmit the proposal to PAM Committee Chair(s) with cc to Ancillary Management Team. AS Committee reviewers assess responsiveness to AS queries and annotate this assessment for the SC.
9. The Ancillary Management Team forwards the reviewer summaries along with the ancillary study proposal to the SC for approval votes.
10. Ancillary Management Team tallies the votes and communicates the decision to approve or disapprove to the ancillary study investigator.
11. For ancillary studies that are approved, the investigator will be notified by email and an approval letter signed by the Chair of the CRIC SC (or designee) will be provided. For ancillary studies that are not approved, an email to this effect will be sent to the investigator.

### **XIII. OSMB REVIEW of ANCILLARY STUDIES INVOLVING DATA COLLECTION FROM CRIC PARTICIPANTS**

All ancillary studies that involve new data collection from CRIC participants, including administration of questionnaires or physiologic measurements, must be reviewed and approved by the CRIC Study's Observational Study Monitoring Board (OSMB). The Ancillary Study Summary for OSMB Review form (see **Appendix B**) must be completed and submitted to the SDCC along with the ancillary study proposal. The SDCC will share the completed form with NIDDK program officers to be reviewed by the OSMB. The ancillary study proposal must be approved by the OSMB prior to submission to a funding agency.

### **Addendum (March 2023). Ancillary studies in CRIC Phase 5**

All ancillary studies that will be conducted during Phase 5 of the CRIC Study (July 2023- June 2028) and beyond must consider the timeline and reduced infrastructure for the CRIC Clinical Centers and SDCC funding to ensure feasibility.

The ancillary study investigator must confirm that the CRIC SDCC is able to support all proposed activities required to implement the study, including any CRIC Central Laboratory activities. Ancillary investigators are required to contact the SDCC to discuss feasibility prior to submitting the ancillary study proposal.

For ancillary studies that include new data collection from CRIC participants, the ancillary study proposal must include an enrollment plan and timeline. The ancillary study investigator must also provide confirmation from the principal investigators of all participating CRIC sites to confirm that their site will be able to support the study activities and that planned financial resources are adequate.

Resubmissions: If the initial submission of the ancillary study is not funded, the ancillary investigator must request approval from the Ancillary Studies Committee to resubmit the grant so that feasibility can be evaluated considering the revised project timeline. The ancillary proposal must include an updated enrollment plan and timeline. The ancillary investigator must also provide updated confirmation from the principal investigators of all participating CRIC sites to confirm that their site will be able to support the study activities and that planned financial resources are adequate, considering the revised timeline.

Data sharing: Ancillary study investigators will be responsible for sharing data generated from the ancillary study with an appropriate data repository, in accordance with NIH data sharing policies. New data generated by ancillary studies conducted during Phase 5 will not need to be transmitted to the SDCC. Ancillary investigators will be responsible for merging new ancillary study data with other CRIC data obtained from the SDCC for statistical analysis.

**Template for Ancillary Study Submission.**

Appendix A

**A. Identifiers: (add or delete lines in tables as needed to answer fully)**

(Sections A&B should be no more than 3 pages all together)

PI name & E-mail Address				
PI Institution				
CRIC Investigator				
Collaborators (name and institution)				
Start date				
End date				
Proposed funding source and mechanism				
Target grant submission date:				
Is this a resubmission? If so, how many times has it been submitted previously?				
FOA #				
Estimated costs	\$			
Is this a training proposal? (Check one.)	Yes		No	
If “Yes”, who is the primary mentor?				

**B. Design and Methods: (add lines in tables as needed to answer fully)**

(Sections A&B should be no more than 3 pages all together)

Title of Study:	
Keywords:	
Background/Rationale:	
Research Questions or hypotheses/specific aims:	
Data collection methodology:	

Within your proposed aims, please list exposures and outcomes in the table below: (add lines in tables as needed to answer fully)

Aim	Exposure(s)	Outcome(s)

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**C. Specifics: (add lines in tables as needed to answer fully)**

1. Burden to participants (fill in tables; use N/A if segment not applicable)

If your ancillary uses questionnaires, please provide a copy of each proposed questionnaire with application, or explain reason for not doing so:

Name of questionnaire	Time required to complete questionnaire? (in minutes)	Who completes questionnaire? (Participant, Study Coordinator, Other (specify))	How often is questionnaire given, and at what study visit(s)?	Which CRIC centers will administer the questionnaire?

If your ancillary uses already stored blood or urine:

What test will be done?	What type of samples will be used? Plasma? Serum? Urine? Other (specify)?	Volume required:	What study time points will samples be requested from (ex. baseline, year 1, etc.)?	How many samples will be tested?

If your ancillary needs additional blood or urine to be collected from participants please describe:

Name(s) of test(s) to be done on the specimens	Type(s) of specimen(s) to be collected (Plasma? Serum? Urine? Other (specify)?)	Volume of each specimen needed.	Years of follow-up when test will be conducted.	When each specimen will be collected. (At regularly scheduled CRIC visit, or additional?)	Special processing specifications, if applicable	Participating Clinical Centers

If your ancillary adds an additional procedure or an additional visit:

Name of procedure/ Reason for added visit	Length of time needed to conduct procedure (in minutes)	Does it require additional visit(s)?	Years of follow-up when procedure/visit will be conducted	Participating Clinical Centers	How many subjects per participating Clinical Center

2. What CRIC Study core data and/or biological samples are needed for the ancillary study? (Please check all that apply.)

√	Items:
	Plasma
	Serum

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	Urine
	DNA/buffy coat
	Existing data in SDCC (provide details below)
	Newly added data to SDCC (examples: questionnaires, X-Rays) – specify item if not shown/detailed in above tables
	Other (describe):

Please list critical elements of existing data that are needed for this ancillary study (ex. assay data, imaging data, etc.). Descriptions of available data resources can be found on the CRIC Study website:

- *Case Report Forms:*
- <http://www.cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/research-data>
- *CRIC DataView:*
- <http://cristudy.org/Chronic-Kidney-Disease/Chronic-Renal-Insufficiency-Cohort-Study/CRIC-DataView>

3. Describe how blood or other biologic sample (either fresh or from the CRIC Study's repository of stored samples) testing will be done? Include the name and location of the laboratory where testing will be done.

If testing will be done outside of the CRIC Central Lab provide the following:

- a. Description of plan for receiving samples, sample tracking and identity management
- b. Description of plan for thawing and aliquotting (if necessary) samples
- c. Description of your QA plan for assays
- d. Description of your QA plan for data management related to the assay data

4. In an effort to ensure that ancillary study measurements and analyses adhere to the highest level of quality expected of a federally-funded study such as CRIC, we ask that ancillary investigators prepare a QA and QC plan for their project. The QA/QC plan should address measures specific to the ancillary rather than core measures from CRIC. This plan must include internally and externally valid metrics of quality assurance, appropriate frequency of measurement, and anticipated corrective actions to address any problems or deficiencies. Commitment should be made to regular reports to the CRIC QA/QC committee for review of the quality data from the ancillary. The details of this plan should be described below:

Quality metric	Specific aim/measurement	Frequency of assessment	Means of assessment	Plan for corrective action (in case of deficiency)

5. Collaboration:

√	Site:	√	P.I.	√	Other Investigator?
	Open to all sites		-----		
	Case Western		Rahman		
	Oakland		Go		
	Maryland		Appel		
	Penn		Cohen		
	Ann Arbor		Rao		
	Chicago		Lash		
	Tulane		Chen		
	SDCC		Dember/Anderson		
	American Indian CRIC		Shah/Unruh		
	NIDDK		Parsa		
	Other: (add name)				

**Considerations for ancillary studies in CRIC Phase 5**

CRIC clinical centers are expected to be funded through June 2026, and the SDCC is expected to be funded through June 2028. Between July 2023 and December 2025, it is expected that active CRIC participants will have one in-person study visit and one telephone visit as part of the core CRIC protocol. All ancillary studies that will be conducted during and beyond Phase 5 must consider the timeline for funding and CRIC Study visit schedule to ensure feasibility.

If the ancillary study includes new data collection from CRIC participants, an enrollment plan and timeline must be provided.

- **Provide enrollment plan and timeline (include below or attach as a separate document)**

The questions below must be answered and additional documentation should be attached as requested.

- **For all studies:** Has the SDCC confirmed that it is able to support study activities as described, including CRIC Central Lab activities?  
Attach documentation of SDCC confirmation.
- **For studies involving new data collection at CRIC Sites:** Have the PIs of all participating sites confirmed that their site will be able to support the study activities and that planned financial resources are adequate?  
Attach documentation of PI confirmation.

**Resubmissions of ancillary studies in CRIC Phase 5:**

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- Provide updated enrollment plan and timeline (for studies including new data collection from CRIC participants)
- Has the SDCC confirmed that it is able to support study activities, based on updated study timeline?  
Attach documentation of SDCC confirmation.
- Have the PIs of all participating sites confirmed that their site will be able to support study activities and that planned financial resources are adequate, based on the updated study timeline and enrollment plan?  
Attach documentation of PI confirmation.

6. What, if any, follow-up is needed? Specify length of time and events to be ascertained.

7. How many participants are required?

√	Numbers required:
	All CRIC subjects
	All CRIC subjects at sites as above in #5
	# of CRIC subjects (enter a number)

7.a. Will the ancillary study use participants enrolled in Phase I (recruited 2003- 2008), Phase III (recruited 2013-2015), or both?

8. When will data be collected? Could the ancillary study be deferred to a later exam cycle?

9. How will the ancillary study be funded?

- i. Would any additional un-reimbursed work or personnel time be expected of the CRIC Study?
- ii. How will the ancillary study budget cover demands on CRIC Study personnel time and Study resources?

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10. Where will the data analyses be conducted? If data analysis is to be conducted outside of the SDCC, a detailed analysis plan must be submitted and approved and the name of the individual who will oversee analyses must be provided.

10.a. How many manuscripts do you expect to produce from this project?

11. Will you be collecting genetic data? Approximately how much storage will you need?

12. List all new data that will be generated by the ancillary study and a description of how data will be collected and managed. For example, what type of data management system (ex. REDCap database) will be used to collect and store data collected by questionnaires or participant measurements? Where will the data be stored?

Description of data	Data management plan	

13. How will the confidentiality and other aspects of protection of human subjects be maintained?

## Appendix B

### Ancillary Co-Chairs

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