**Template for CRIC Ancillary Study Submission.**

1. **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? |  | | | |

1. **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) |
|  |  |  |

**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)? | WhichCRIC 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 requireadditional visit(s)? | Years of follow-up when procedure/visit will be conducted | Participating Clinical Centers | How many subjects per participating Clinical Center |
|  |  |  |  |  |  |

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

|  |  |
| --- | --- |
| √ | Items: |
|  | Plasma |
|  | Serum |
|  | 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:**

* 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?

* + 1. Would any additional un-reimbursed work or personnel time be expected of the CRIC Study?
    2. How will the ancillary study budget cover demands on CRIC Study personnel time and Study resources?

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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