Ancillary Study Proposal Application Instructions

Please use NIH formatting guidelines: Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins. Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.

Part A: Ancillary Study Face Page

Study Title

- *Provide a brief title and/or name of your proposed study*

PIs (with contact information):

- *For each principal investigator, provide first and last name, affiliation, email, phone, and mailing address. Please include a 4-page NIH-style bio-sketch for each PI enclosed with your application.*

CureGN Sponsor Name (required):

- *Please note that a CureGN sponsor is required for each ancillary study; a list of individuals eligible to serve as sponsors is provided at https://curegn.org/ancillary.asp. If you feel an alternative CureGN sponsor from within the consortium may fit your needs and project better please contact the PCC PI to inquire if this can be arranged.*
- *The sponsor will provide you with assistance assessing the feasibility of your proposal. The sponsor will also advise on how to design your study, so it aligns with the overall objectives of the CureGN project, and how to minimize the burden to individual clinical sites and study participants.*
  Please note that your CureGN sponsor is not required to become a co-investigator on your funding applications, nor a co-author on any publications resulting from this study.

Co-Investigators

- *For each co-investigator, provide first and last name, affiliation, email, phone, and mailing address. Please include a 4-page NIH-style bio-sketch for each co-investigator.*

Funding Source and Dates

- *Describe available funding for this proposal; provide funding source including intramural and extramural funds with relevant grant numbers, if applicable.*
- *If the funding application is being planned, provide grant due date and funding source/mechanism.*

Designation of Core Study or Core Data

- *Indicate if you expect the Ancillary Study to be designated as "Core" or will produce "Core Data." Definitions of Core Study and Core Data can be found in the Ancillary Studies Policy.*

Training Proposal

- *If yes, please include with the application a paragraph from the mentor(s) indicating relevant experience, as well as commitment to the trainee.*

Abstract

- *In a single paragraph, provide a succinct description of your ancillary study proposal. Note that if your study is approved by the ancillary study committee, the abstract will become public and may appear on the CureGN study website.*

Part B: CureGN Study Impact

Requirements

- *Select the required cohort(s) and resource(s) needed.*

Burden to Participants

- *Provide rationale for additional procedures or visits, estimated time of patient participation, the effort and estimated time required of site recruitment coordinators. If the study involves a new questionnaire, provide a*

copy of the proposed questionnaire with this application.

Biosamples

- *For requests of available materials, include specimen type, minimal amount required, sampling time point(s), requirement for frozen vs. previously thawed samples. A checklist of the available bio-specimens can be found at https://curegn.org/ancillary.asp .*
- *If new collection of biological material is requested, describe the procedure for sample acquisition. If applicable, specify which site(s) would be involved and number of subjects per site.*

Data

- *Note what data elements are required, and if any new composite or outcomes variables will need to be created.*
- *Describe the plan for sharing newly acquired data, including new clinical, biochemical, genetic, and/or other data types.*

PCC Burden

- *Describe the effort and estimated time required of the PCCs and/or study sites. Identify which sites will be included. This includes study coordinator training, interface with participants, sample kit creation and delivery or shipping, etc.*

DCC Involvement

- *Describe the effort and estimated time required of the data-coordinating center. This includes project management, subject identification, dataset preparation, study monitoring, CureGN Link modifications, statistical analysis, etc.*

IRB Approval:

- *Describe your plan for obtaining IRB approval for this study.*
- *If IRB-approved, provide IRB name and approval date.*
- *Please note that although IRB review is not required at the time of this application, the letter of approval must be provided before data and specimens can be released.*

Part C: Study Design (3 Pages Maximum Excluding References)

1. **Background and Rationale**
   - *Briefly describe why your study is worth pursuing.*
2. **Hypothesis. Objectives and Specific Aims**
   - *Clearly state your study hypotheses and specific aims.*
3. **Study Design and Procedures**
   - *Describe the plan for data acquisition.*
   - *Describe sample collection and handling.*
   - *Describe specific assays and experiments proposed.*
   - *Describe planned quality control measures.*
4. **Statistical Analysis**
   - *Describe the plan for data analysis.*
5. **Sample Size and Justification**
   - *Is your proposal adequately powered to address the research hypotheses?*
6. **Anticipated Results and Project Timeline**
   - *Describe your anticipated results and provide a clear timeline for the project. Include a projected publication date.*
7. **References (15 Maximum)**
   - *Provide a maximum of 15 key literature references in support of your proposal.*

Please submit completed Ancillary Study Proposal Applications with all supporting documents, including biosketches of all PIs, as a single PDF document to CureGN-ASC@arborresearch.org.