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CureGN Ancillary Study Proposal Application

*Please submit completed Ancillary Study Application with all supporting documents, including NIH biosketches for PIs, as a single PDF document to* *CureGN-AncillaryReview@arborresearch.org**.*

|  |  |
| --- | --- |
| Study Title |  |
| PI Name  |  |
| Affiliation |  |
| E-mail Address |  |
| Mailing Address |  |
| Co-Investigators’ Names |  |
| Proposed Start date |  |
| Proposed End date |  |
| Funding Source and Application Date: | [ ]  Internal funds from your own institution |
| [ ]  NephCure Kidney International grant program |
| [ ]  Private sector funding (specify source) |
| [ ]  Extramural/Intramural funding |
|  If already funded, specify agency and grant number: |
|  If planned submission, specify agency and application date: |
| CureGN Sponsor (Required) |  |
| Is this a training proposal?(Check one) | [ ]  Yes *Include with the application a paragraph from the mentor(s) indicating relevant experience, as well as commitment to the trainee.*[ ]  No |
| Do you think this study is a “Core Study” and/or will produce “Core Data” | [ ]  Yes[ ]  No |

Abstract (limit to one paragraph):

**Part A. Study Design** (5-page limit excluding references)

1. Background and rationale
2. Hypotheses and specific aims
3. Design and methods
4. Statistical Analysis. *For each study aim, describe the plan(s) for data analysis, stating the specific hypothesis that the statistical method will test or estimate. Make clear whether comparisons are within-subject or between-subject, and if or how controls will be included.*
5. Power analysis and sample size justification
6. Anticipated results and project timeline
7. References *Please include at the end of the application.*
8. Data Sharing Plan

Data (e.g. bioassays, PRO data, etc.) generated from ancillary studies are to be provided, in an agreed upon format, as soon as reasonably feasible and no longer than 6 months after data generation to the CureGN DCC for integration into the CureGN dataset. These data will be made available for use by other CureGN investigators. Data will also be transferred to the NIDDK data repository at the end of the study.

*Please see the CureGN Ancillary Studies Policy for more details.* <https://curegn.org/Ancillary.aspx>

|  |  |
| --- | --- |
| **I agree to the CureGN Data Sharing Policy (Please sign):**  |  |

1. **Public Use Statement** *Please include a one-two (1-2) paragraph Research Use Statement which may be made publicly available on the NIDDK Repository website.*

**Part B. Use of CureGN Data, Biomaterials and Infrastructure**

|  |
| --- |
| **B1. Requirements** |
| B1a.  | Please indicate the study resources you need (Check all that apply)* Use existing clinical data
* Use existing procured samples
* Use existing patient-reported data
* Access to the DPR
* Requires new clinical data collection
* Requires additional sample procurement
* Requires new patient-reported data collection
 |
| B1b. | Please describe your proposed study population. |
| * All CureGN participants

ORSelect Population (Check all that apply)* FSGS Cohort
* MCD Cohort
* MN Cohort
* IGA Cohort
 |
| * Adult
* Pediatrics
 |
| * + Incident (first kidney biopsy within 6 months of enrollment)
	+ Incident (first kidney biopsy at a CureGN site after 1/1/2015)
	+ Prevalent
 |
| **B1c.** | Provide the total number of adult and pediatric CureGN patients who meet your study requirements. *We encourage you to use tranSMART or work with a DCC member to assess case counts for your study design. If you need access to tranSMART, please contact* *CureGN-AncillaryReview@arborresearch.org*.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | FSGS | MCD | MN | IGA | Total |
| Adult |  |  |  |  |  |
| Pediatric |  |  |  |  |  |

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| --- |
| **B2. Data Request** |
| B2a. | **Indicate what existing CureGN data you will need for your proposed study:** (Check all that apply) |
| * Demographics
* Comorbidities
* Family History
* Birth History
* Pregnancy History
* Prior Disease Course
* Medications
 | * Laboratory values/Clinical Information
* Hospitalizations and ER Visits
* Limited Physical Exam
* Patient-reported data (quality of life, adherence)
* Access to DPR Imaging
* Other (specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)
 |
| B2b. | **Provide schedule for Standard Analysis File (SAF) delivery and updates. (e.g., 2020 with 2 annual updates)** |
| B2**c.** | **Will your proposed study require additional derived variables?** ***If yes, list variables requested*.** | * Yes
* No
 |
| B2d. | **If this ancillary study will result in new data, how will data be transferred to CureGN following the completion of your study? *Note: genomic data will also need to be submitted to dbGAP.*** |
| **B3. Biospecimen Request** |
| **B3a.** | **Will your proposed study require** use of existing CureGN biospecimens? *If no, go to B4.* | * Yes
* No
 |
| **B3b.** | **If yes,** In the table below, provide the **minimum amount of sample**, at each visit, you are requesting for your proposed study. Due to the limited nature of all biorepository specimens. Individual requests exceeding 10% of original stored volume may not be approved.*See* [*https://curegn.org/publicdocuments/Biospecimens%20List.pdf*](https://curegn.org/publicdocuments/Biospecimens%20List.pdf) *for more information.*

|  |  |  |
| --- | --- | --- |
| **Type of Specimen** | **Volume Requested** | **Visit(s)** |
| Whole blood for genomic DNA - EDTA tube DNA |   |   |
| Extracted genomic DNA |   |   |
| Whole blood for genomic RNA - PAXGene tube RNA |   |   |
| Extracted genomic RNA |  |  |
| EBV immortalized cell lines (PEDS ONLY) |  |  |
| Plasma - EDTA tube |  |  |
| Plasma - Sodium Citrate Tube |  |  |
| Plasma - Sodium Heparin (light protected) |  |  |
| Serum - Serum separator tube |  |  |
| Spot urine cleared supernatant - with Sodium Azide (NaN3) |  |  |
| Spot urine cleared supernatant - with protease inhibitor (PI) |  |  |
| Spot urine cell pellet - Harvested in RNAlater stablizing Nucleic acids at RT |  |  |
| 24-hour urine - 24-hr urine collection container |  |  |

  |
| **B3c.** | Justification for the request of limited and irreplaceable biomaterials:1. Discuss how the proposed project will take advantage of the depth of larger CureGN clinical data set and make the case clearly that the proposed study will have significant scientific impact.
2. Provide preliminary data to support the proposal’s hypothesis and technical feasibility. The ancillary studies committee may consider the use of CureGN biosamples to develop preliminary data in an iterative fashion in some cases. In this case, explain why alternative samples cannot be obtained from other sources.
3. Describe assay details and methodology including: amounts and type of samples (applicants should request the minimum volume required for their assays), anticipated assay variability, quality control (assay "robustness") assessment.
 |
| **B4. Additional Study Visits, Additional Procedures or Specimen Acquisition** |
| **B4a.** | Does your proposed study involve additional study visits, additional procedures or specimen acquisition beyond the core NEPTUNE protocol? *If no, go to B5.* | * Yes
* No
 |
| **B4b.** | If yes, describe the rationale for additional procedures, specimens or visits. |
| **B4c.** | **Does this ancillary study add new questionnaires/questions?** *If yes, provide a copy of each proposed questionnaire/question with application.* | * Yes
* No
 |
| **B4d.** | **If yes, check all that apply:*** **Patient surveys**
* **Clinical data (may be collected by patient interview)**
* **Clinical data (chart review only)**
* **Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
 |
| **B4e.** | Use the table below to specify the proposed visit schedule and procedures (questionnaires, intervention, laboratory sampling and tests). Provide a subject level time estimate of additional study procedures (e.g. self-administered questionnaire x 10 minutes).

|  |  |  |  |
| --- | --- | --- | --- |
| Procedure | Visit (Time) | Visit (Time) | Visit (Time) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*Add rows as necessary*  |
| **B4f.**  | Use the table below to specify the proposed additional blood or urine collection beyond that collected in the CureGN protocol**. *If no additional biosamples are proposed, go to B5.***

|  |  |  |
| --- | --- | --- |
| **Specimen** **(Plasma, Serum, Urine, Other - specify)** | **Sampling Times\*** | **Volume Requested** |
| Specimen 1 <SPECIFY> |  |  |
| Specimen 2 <SPECIFY> |  |  |
| Specimen 3 <SPECIFY> |  |  |

\* Specify CureGN Visit # or additional visit time*Add rows as necessary* |
| **B4g.** | Describe assay details and methodology including: amounts and type of samples (applicants should request the minimum volume required for their assays), anticipated assay variability, quality control (assay "robustness") assessment. |
| **B4h.** | **Will there be remaining biomaterials available for future use?** **If yes, where will they be stored and what is the expected remaining volume?** | * Yes
* No
 |
| **B5. Other Ancillary Study Considerations** |
| **B5a.** | **Will the ancillary study require the DCC to perform study monitoring activities? (e.g., study coordinator training, IRB and/or other regulatory assistance, label creation and delivery, etc.)** | * Yes
* No
 |
| **B5b.** | **Will any additional effort or personnel time be expected of the CureGN DCC?** (Check all that apply)* CureGNLink questionnaire changes
* CureGN Link functionality changes
* Custom SAF
* Other (describe)

If yes, describe in detail with timeline for proposed activities. *Please consult the CureGN DCC early in the phase of development.* |
| **B5c.** | **Where will the data analyses be conducted?*** The DCC will conduct all analyses, OR
* The ancillary study investigator (ASI) team will design and conduct the analysis with quality review from the DCC, OR
* The DCC will conduct some analyses, and the ancillary study investigator (ASI) team will conduct others. Please explain.
 |
| **B5d.** | **For analyses conducted by DCC, will the resulting manuscript(s) be submitted by the DCC or other institution?*** + **DCC**
* **Other, specify:**
 |
| **B5e.** | **Estimated Number & Timing of Publications** (e.g. # per project year) |
| **B5f.** | **Describe any additional burden to PCCs or study sites (e.g., study coordinator training, interface with participants, sample kit creation and delivery or shipping, etc.)** |
| **B5g.** | **Describe your plan for obtaining IRB approval for this study *(Required prior to sample shipment/data transfer or initiation of ancillary work.*** |
| **B5h.** | **Do you anticipate need for an amendment to the approved CureGN IRB package at sites where subjects are participating? *(This would apply to new surveys, new biospecimens, etc.)*** | * Yes
* No
 |
| **B5j.** | **Indicate if the study has an active Investigational New Drug (IND) or Investigational Device Exemption (IDE) number:**

|  |  |  |
| --- | --- | --- |
|  | **Number** | **Responsible Investigator(s) or Sponsor(s)** |
| **IND** |   |   |
| **IDE** |   |   |

 |
| **B5k.** | **Does this research have the potential to be used when applying for an IND or IDE to the FDA?** | * Yes
* No
 |