### Ancillary Study Proposal Form

**Cameron County Hispanic Cohort (CCHC) Study**

**I. Basic Study Information and Projected Impact on CCHC**

1. Title of study:

2. Principal investigator(s) (name, address, phone and fax numbers, e-mail address):

3. Collaborators (must include at least one CCHC investigator):

1. Summary of CCHC data management team or Clinical Research Unit (CRU)\* tasks involved – Leave cell blank if Not Applicable

|  |  |  |
| --- | --- | --- |
|  | Needed (Yes / No) | Proposed participants (N) |
| Enroll or examine participants |  |  |
| Assay biospecimens |  |  |
| Provide biospecimens |  |  |
| Analyze data |  |  |

\* Clinical Research Unit (CRU) at UTHealth School of Public Health (SPH) Brownsville campus

5. CCHC participant and staff involvement:

A. Participants:

Describe number of subjects needed; special characteristics of study population; age and sex distribution. Will participants be contacted, interviewed, examined, or asked to provide specimens? Will the study involve radiation or administration of a drug or contrast? If so, describe participant involvement. Estimate time required of each participant.

Note that contacts with participants must be done in cooperation with CRU and all contacts must be recorded in the CRU's data system for tracking phone calls and contacts. The latter requires data management updates by the CCHC, to be reimbursed by the ancillary study.

B. Stored CCHC specimens:

Describe materials to be used (e.g., stored plasma, urine, DNA). If blood samples are requested, please submit the completed form to the CCHC Research Committee (email to: CCHCresearch@uth.tmc.edu) **PRIOR** to obtaining data or specimens in consideration of your description in the following:

* + 1. Study participants and material requested:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of Specimen | N | Volume Requested | Time point  (e.g. visit\*) | Specify proposed lab and analytes to be assayed at catch lab (be specific) |
| Serum |  | ul |  |  |
| EDTA plasma |  | ul |  |  |
| hard spin plasma |  | ul |  |  |
| DNA |  | ug/ng |  |  |
| Urine |  | ul |  |  |
| Other (specify) |  |  |  |  |

\* Please contact the CCHC CRU in advance and indicate here which collection time point (Visit 1, Visit 2 (i.e., 5 YR visit), or Visit 3 (i.e., 10 YR visit)) and sample type you are requesting

* 1. Is the proposed work consistent with the stipulations in the CCHC informed consent form?  Yes  No (The informed consent forms can be obtained from the collaborating CCHC investigator).
  2. Are thawed/re-frozen acceptable?  Yes  No

If No, specify reasons for specific assays:

* 1. Describe efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.
  2. If approved, when will samples be requested for retrieval?

C. CCHC CRU:

Describe effort (and estimated time) required of CRU staff. Include consent, collection of samples, etc.

D. CCHC Data Management:

Describe effort (and estimated time) required of CCHC data management staff. Specifically:

\* *Unless you provide strong justification, the CCHC data management staff must be included and its costs budgeted.*

1. Will the CCHC data management staff be involved in data collection, tracking, or preparation of forms or software? or Will these tasks be completed locally by the Ancillary Study, and a data file sent to the CCHC data management team (email to: CCHCresearch@uth.tmc.edu)?
2. If a Reading Center or laboratory is involved, will data be sent directly from the Reading Center or laboratory to the CCHC data management team for processing, or will processing be done locally (either by the Ancillary Study or at the Reading Center/Laboratory)?

1. Will analyses be done locally by the Ancillary Study or by analysts at the SPH Brownsville campus laboratory or CRU?

6. Genomic information (defined as any data from a participant’s DNA):

A. Does your proposal include any genomic materials? (please check one)

No (go to question 7)  Yes (see question 6B)

B. Name the gene(s), genotypes, SNPs to be investigated:

C. Is genetic information used to address a primary aim or secondary aim of Ancillary study? (please check one or both)

Primary aim (heart/vascular disease)

Secondary aim (other health conditions)

List the conditions addressed:

D. Should DNA-based results be reported to patients’ physicians? Base your response on your knowledge of existing literature and current practice regarding increased risk and availability of treatment for adverse outcomes associated with the gene mutations to be studied.

7. Proposed starting and ending dates:

8. Estimated cost by year; number of years:

9. Source of funding; date of submission:

10. Does this study involve the support or collaboration of a for-profit corporation, or do you intend to use the data to patent any process, aspect or outcome of the analysis?

11. What is the advantage, both to CCHC and yourself, of conducting the study within the CCHC cohort versus another population?

12. Impact on ongoing CCHC studies (main study or other Ancillary Studies):

13. Provide the following assurances (answer each):

1. Who (name and position) will report annual progress of the study? (Ancillary Study PI or designate preferred)

(2) How will confidentiality of CCHC participants be maintained?

1. Data collected by the Ancillary Study must be provided to the CCHC Research Committee for integration into the main database, and will be subject to CCHC Data Sharing Policy. This will include documentation of newly collected data with labels, and/or laboratory results including any omics analysis results as well as documentation on methods, visits and units used with specific instructions for using the data in analyses such as exclusions that were applied. After that has been done the Ancillary Study investigators will receive the integrated file containing data from the main study.

The Ancillary Study PI will be given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of the Ancillary Study. After a reasonable time (in general, 12 months after data cleaning is complete or 12 months after acceptance of primary manuscripts, whichever is earlier), Ancillary Study data will be made available for additional uses by other CCHC investigators. On request, new data generated in Ancillary Study will be made available to other investigators with the approval of CCHC Research Committee once the Ancillary Study is completed.

It is the responsibility of the Ancillary Study PI to state in writing to the CCHC Research Committee any special circumstances that would warrant an exception to these guidelines for data sharing. In the spirit of encouraging collaboration, reasonable and justified requests for limiting other investigators’ access to the data will be honored, or a compromise will be worked out.

1. How many papers do you estimate will be written from the Ancillary Study?
2. Variables/measurements from the CCHC main study database to be analyzed:

14. If the study will have clinical implications, explain and describe the plan for reporting results to participants and providing recommendations for follow up:

# II. Abbreviated Ancillary Study Proposal

Please provide a brief (2 to 4 page) description of the proposed study. Include the following:

**Purpose/Aims:**

**Background:**

**Hypotheses:**

# Experimental Design (include sample size justification):

**Methods, including:**

**Participant involvement (if any):**

**Data to be collected by the ancillary study (attach questionnaires and forms):**

**Analysis Methods:**

**Literature References**

**Please send an electronic copy of the completed proposal to CCHC Research Committee –** [CCHCresearch@uth.tmc.edu](mailto:CCHCresearch@uth.tmc.edu)

For CCHC Research Committee Use Only

**Approved?  Yes No**

**Date:**

**If approved, ancillary study #**