**CACTI Study**

**Ancillary Study Application Package**

This document includes the necessary CACTI Study ancillary study application materials that will be reviewed for approval by the CACTI Executive Committee.

An ancillary study is defined as one that derives support from other than CACTI grant funds and makes new or additional measurements on CACTI participants or uses banked specimens collected by the CACTI Study. The CACTI investigators recognize the value of and welcome the addition of those ancillary studies judged to be of general interest and high scientific merit; that do not duplicate or interfere with existing CACTI activities; that do not constitute an unacceptable burden on CACTI participants, staff, or specimen banks; and that are in line with CACTI objectives. Proposals that heavily overlap with existing CACTI projects will receive a relatively lower priority as will those that are deemed not to be consistent with CACTI Study objectives or to otherwise not enhance the overall study. CACTI investigators are encouraged to consider ancillary studies and to involve other investigators, within and outside of the study, to participate in this process.

Please note that allancillary study principal investigators (PIs) will be given the first and exclusive opportunity to analyze, present and publish data collected under the auspices of their ancillary study. **Twelve months after data collection has been completed, ancillary data are to be provided to the** CACTI **data manager for integration into the main** CACTI **database** and, potentially, for use in the publications and presentations of other CACTI investigators. In the spirit of promoting overall CACTI Study productivity as well as collaboration across ancillary studies, ancillary study PIs are encouraged to submit the data from their ancillary study to the CACTI coordinating center **prior to the end of the 12-month period of exclusivity**. For ancillary studies to a contract supported examination, CACTI recommends ancillary data be transmitted to the data manager simultaneously with all other examination data. All requests for use of ancillary study data during the exclusivity period will require approval of the ancillary study PI. Failure to submit ancillary study data to the CACTI data manager at the end of the 12-month exclusivity period may result in the refusal of publication of the data.

**CACTI Ancillary Study**

**Table of Projected Burden**

**In the “Activity/Burden” column include a brief description of the activities and an estimate of the amount of time that will be devoted to participation of the proposed study.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Category** | **Activity/Burden** | **Costs** | **Comments** |
| **CACTI Investigators burden and support** |  |  |  |
| **Participant burden**  **(Include interviews, specimen collection, examinations, etc.)** |  |  |  |
| **Field Center staff burden** |  |  |  |
| **Analysis**  **staff burden** |  |  |  |
| **Laboratory staff burden** |  |  |  |

**Request for Use of CACTI Study Stored Materials**

1. Study Full Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Material requested:
   1. Serum
   2. Plasma

xxxx

* 1. DNA
  2. Urine

1. Year of sample collection (baseline, year 3, year 6, year 12): \_\_\_\_\_\_\_\_\_\_\_
2. Amount of sample requested: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Number of participants for whom sample is requested: \_\_\_\_\_\_\_\_
4. Participant selection criteria (e.g. gender, age, risk factors, etc.; include number of

control samples, if indicated): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Re-frozen samples acceptable? Yes No
2. If approved, when will samples be requested for retrieval? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Requested by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Upon completion, please e-mail this form to [cactistudy@ucdenver.edu](mailto:cactistudy@ucdenver.edu)