CCTI Sample Repository Request Form

A. **Title of Study.** One line descriptive title of subject and object of study.

B. **Investigators.**
   - List PI name, address, phone, FAX, and email address
   - List Co-investigators’ names and email addresses

C. **Date Submitted:** ______________

*(Sections D and E combined, should not exceed two single-spaced pages.)*

D. **Study goals:**
   1. **General Aim.**
      This is the abstract for the proposal. Include a concise justification and explanation of the question(s) to be addressed. If applicable, summarize background information and research, and state how they lead to the question(s) of interest. End by stating the aim of the study, and summarizing the method(s) that will be used to address the question(s).
   2. **Specific Aims.**
      Detail each question to be answered by the study.
   3. **Rationale and Background.**
      - Provide background information for the study.
      - Explain why information is lacking with regards to the question(s) of interest, and how the proposed study will address that gap. Include applicable references.
      - Explain how the CCTI sample repository is needed to address the study question(s). Acknowledge any limitations or concerns related to the proposed methods, and explain how they have been or will be dealt with.

E. **Methods.**
   Describe all proposed methods and equipment to be used in the study. In particular:
   1. **Study sample**
      Describe the study participants (sample size, recipients/donors, organ, etc.)
   2. **Specific methods.**
      Include detailed explanations and protocols for each method in the study.
   3. **Statistical considerations.**
      Explain your plans for statistical analyzes of your study data.

F. **Specific answers to the following questions:**
   If a question is already answered elsewhere in the proposal, summarize the answer here and direct the reader to the appropriate section.
1. Does this proposal pose any burden to the CCTI Sample Repository? If so, please provide specifics about the expected burden.

2. What CCTI materials are needed for the study?
   a. What patient population?
   b. How many samples are required?
   c. What type of samples (DNA, RNA, plasma, frozen PBMC, urine, urine pellets)?
   d. Requirement for frozen vs. previously thawed (preferred) samples, and if the latter, are there any limitations on number of freeze-thaw cycles.
   e. Sample quantity, i.e. volume, weight, number of cells (efforts to minimize volumes should be demonstrated whenever possible)
   f. Efforts to integrate sample needs with those of other studies to conserve sample and/or limit freeze-thaw cycles.

3. What collaboration with CCTI investigators is planned? With whom? Have the collaborating investigators approved the proposal?

4. How is the study to be funded? Would any additional un-reimbursed work or personnel time be expected of the CCTI?

5. If applying for a grant, who is the sponsor and what is the application deadline.

6. Provide details about IRB approval of the proposed project.

7. How will the confidentiality and other aspects of protection of human subjects be maintained?

8. Will the findings have clinical implications? If so, describe the plan for reporting results to participants and providing recommendations for follow-up.

9. Where will the data analyses be conducted?

10. Does this study involve industry support or collaboration?  □ yes  □ no