CARRA

Process for Obtaining Samples and Data Collected as Part of a CARRA study

In order to facilitate open, transparent and fair future access by investigators to the samples and data collected during the course of CARRA studies, the following is the process for project submission and evaluation. It is expected that each study will have a Study Oversight Committee to handle the requests for sub-studies to the main study. The Study Oversight Committee will at a minimum include the main study Principal Investigator(s), large and small site representation and a representative of the tissue repository lab for the study. Such a committee could be the Steering Committee or a Data and Specimen Committee for the study.

1. Investigators who are interested in submitting a proposal should contact the CARRA study PI via e-mail. Sample inventories and database metrics may be provided at the discretion of the study PI to facilitate development of a proposal. A letter of intent that includes a brief description of the project aims, significance, and an estimate of the nature and amount (number and if appropriate, quantity) of samples/data needed should be provided to the study PI by email. This brief description should not exceed one page in length.
2. The letter of intent will be reviewed by the main study PI to ensure that:
    a. There is no overlap with an existing project.
    b. The project does not directly compete with the use of samples and/or data needed for an already-approved project
    c. The project appears feasible in consideration of the number and nature of the samples and data collected or to be collected
3. If the project is rejected by the PI of the main study, the applicant will be advised of this decision and the reasons for rejection explained. Feedback from the main study PI should occur in a timely manner after receipt of the application by the prospective investigator.

If the letter of intent meets the conditions stated above in item # 2, then the investigator will be asked to submit a *Project Proposal* (5 pages or less) to the Study Oversight Committee for review.

At any time the PI and Study Oversight committee may decide to issue an RFA for use of data and samples resulting from a CARRA study. This mechanism may be used to encourage use of the study resource, to solicit protocols addressing an important or timely topic, or to obtain the "best" applications for a project. The RFA mechanism will utilize the same 5-page *Project Proposal* described below.

The *Project Proposal* must include the following sections:

1. Study Aims
2. Collaborators. If the investigator is a fellow, then the faculty mentor for this project must be identified.

3. Background and significance
4. Preliminary data (if exploratory and preliminary data do not exist, adequate scientific rationale should be provided to justify the approach and questions to be answered)
5. Justification of need for samples/data, including a detailed description of the type and amount of samples needed. If clinical data is needed, the proposal must list the data elements/fields required
6. Methods – including how the data/samples will be used, statistical analysis and sample size calculation
7. NIH formatted Biosketch of investigator
8. Anticipated funding sources and the start and end dates of the investigation

The Project Proposal should be sent via e-mail to the main study PI, who will then distribute the document to other members of the Study Oversight Committee.

The Study Oversight Committee will formally review each application using the checklist appended to this document. In cases of competing projects of equal quality, a CARRA member application will be given priority. The reviews will be done in chronological order based upon date of receipt of the *Project Proposal*. The Study Oversight Committee may ask for outside expert consultation in this evaluation process, which may be particularly relevant for proposals resulting from the RFA mechansim. A reply to the applicant will be made within 2 weeks of receipt of the *Project Proposal.* If the Study Oversight Committee is no longer active, final approval/decision on the *Project Proposal* will be provided by the PI of the study and the appropriate PES.

If the project is approved, by the Study Oversight Committee, the application will be sent to the appropriate CARRA Protocol Evaluation Subcommittee for review.

4. Investigators whose projects are approved will have access to the data and/or samples requested in a timely manner, based upon availability and final approval by the PI. The repository for the main study will be responsible for ensuring that distribution of samples and/or data is done such that the success of the proposed project is maximized. Investigators should anticipate that there may be costs associated with obtaining/distributing samples and/or data. Data and Samples may not be available until the study is complete.

PRIOR to sample/data release, investigators will demonstrate sufficient resources to complete the proposed project.

Investigators of approved projects will be responsible for the submission of yearly progress reports (typically about 3 pages, double spaced) to the Study Oversight Committee to include:

1. Synopsis of progress made toward the accomplishment of the project's aims
2. Significant problems encountered, including scientific, ethical, or logistical issues
3. Rationale for major changes in specific aims or process objectives
4. List of any publications/abstracts resulting from the project
5. Plans for the coming year