

I. Research Strategy (4-page limit)

Please review the guidelines below to complete the Rationale and Background requirement for your proposed project. Please note that any applicant that fails to adhere to the criteria provided will not be reviewed by the committee. Once you have completed this task, please upload this information as a single PDF document. To attach a document, click the "Choose File" button. Once you have selected the correct file click the "Upload" button.

1. **Rationale:** Briefly describe the studies proposed and the rationale for the proposed analyses.
2. **Background**
Provide the relevant background to justify the request. Be sure to include:
 - a. Importance of the project, including the significance of both the study question and of the specific project.
 - b. Justification for requesting these specific samples, and why other sources of similar samples are not appropriate. This section should explain how the proposed use relates to the design and outcomes of the study that produced the requested samples. The question being posed by the investigator must be appropriate to the source of the biospecimens, how they were collected, prepared, analyzed and stored; their age; and the phenotypic and other accompanying data.
 - c. Relevant preliminary data demonstrating the applicant's experience with the assay or technique that will be used with the requested samples
3. **Sample Information:** If you will be combining the results from the proposed study with those obtained from other samples, be sure to explain how the requested samples will fit in with your overall study design (e.g. from which study and stage of the study the specimens are requested, whether random samples or specific selection of those with subjects with or without specified clinical events and laboratory or imaging findings are sought, etc.). Include a clear justification for the amount of sample being requested. In all cases, applicants should only request the minimum volume needed for the study.
4. **Project Details:**
 - a. *Hypothesis:* There should be at least one important hypothesis that can be tested using the proposed methods and non-renewable samples provided by the repository, or a strong justification for carrying out discovery research.
 - b. *Methodology:* Describe how the requested samples will be used, including a description of the specific procedures by which the samples will be tested and analyzed and the quality control and robustness of the assay. Is this a discovery, optimization or replication study?
 - c. *Power and effect size:* Describe the power of the project and the anticipated size of a detectable effect.
 - d. *Data analysis:* Provide a detailed plan for data analysis. Include a brief summary of the team's expertise and experience and evidence that they can handle the analysis proposed.

- e. *Sample management*: Explicitly address how the samples will be held, managed, and processed. For example, who will have the main responsibility for storing and testing the samples?
- f. *Plans for the next phase*: Describe plans for follow up studies and, if relevant, further biomarker or assay development. If collaborations have been established for follow up, include these letters of collaboration.
- g. *Project Support*: In this section the applicant will be able to provide evidence of project support. Please note that if the applicant proposes to apply for funding subsequent to approval of this application, any approval of access to samples will be conditional on successfully obtaining funding. Conditional approvals will be valid for a period of up to 15 months.
 - NIH funded Project: The applicant will be required to indicate the NIH institute from which they have received funding as well as all applicable grant IDs.
 - Non-NIH project funding: If there is no NIH funding, the applicant must briefly describe the source of funding to support the proposed project.
 - No funding: If the applicant does not have funding he or she must describe his or her plan to apply for funding.

II. Biosamples/tissue/data requested in a table

In a *table*, briefly outline the number, type, and amount of biospecimens/tissue requested, including subject type (e.g. PD, control, any specific clinical parameters), visit number (if applicable), volume of sample required, and the cohort or biorepository through which the biosamples are currently available. In addition, the applicant should determine if the samples required are available through the repository prior to submitting an application. For applicants requesting access to data outside of the PDBP DMR (with funding for analyses), briefly outline what data is required and how the data will be used.