**APPLYING FOR LEADS BIOSAMPLES**

CSF, plasma, serum, DNA, RNA, PBMC are being collected at LEADS baseline and follow-up visits. The schedule of visits and sample collection differed between subject groups. See [website](https://www.ncrad.org/resource/leads.html) for the exact schedule of events. All biofluids are curated by the Biomarker Core and stored at -80 C at Indiana University. Details of the collection methodology and processing of CSF and peripheral blood samples are available.

**APPLICATION FORM INSTRUCTIONS**

Applications can be submitted [electronically](https://redcap.uits.iu.edu/surveys/?s=DTJKM9K4EH) and are reviewed by the NCRAD Biospecimen Review Committee (BRC) on a continuing basis. Please provide all information requested in the form, including an estimate of when study data should be available on the LEADS database.

* Research Strategy: The research strategy should be no more than 4 pages and should include a Rationale, Background, Sample Information and Project Details. See [Appendix 1](https://www.ncrad.org/docs/Appendix_1_v2.0.pdf).
* Project Details include: Hypothesis, Methodology, Power and Effect Size, Data Analysis, Sample Management, and Plans for the Next Phase
* A table outlining the number, type and amount of biospecimens requested, including subject type, visit number, biospecimen type, and volume of sample required should be included as well.

**REVIEW PROCESS**

Investigators will receive an email confirming receipt of their electronic application. The BRC reviews applications based on several criteria:

* Is there sufficient evidence supporting the likelihood of this study identifying novel findings, or of otherwise contributing important knowledge regarding disease etiology, pathogenesis, diagnosis or treatment?
* Is the project technically feasible, and if preliminary data is provided, does the assay/platform utilized provide robust and reproducible results?
* Do the investigators sufficiently justify the use of resources?
* Do the investigators have the expertise, personnel and institutional setting to achieve the goals of the proposal?
* Is the number of samples requested reasonable and sufficiently powered to achieve statistical significance for hypothesis testing and to demonstrate conservation of the resource (i.e. are the number of samples requested sufficient but not in excess of what is needed)?

The BRC may recommend changes and ask for revisions in the research plan. The Committee may recommend conditional access: demonstration of feasibility in a subset of samples before granting access to a larger set.

The BRC review applications six times per year on a [fixed schedule](https://ncrad.iu.edu/request_procedure.html). NCRAD BRC will notify the LEADS Data Sharing Committee and the LEADS NIA program officer about its decision on sample access. The LEADS NIA program officer has the final decision on application approval/denials. Within 2-3 weeks of the BRC review, NCRAD prepares a letter notifying the applicant of the review decision. The BRC will provide reviewer comments to the investigator. Resubmissions will not be considered unless invited by the BRC. There is no appeal process.

**Sample and Data Transfer**

Once an application is approved, the Genetics and Biorepository Core will work with approved investigators to finalize details about sample transfer. Samples will not be transferred until the investigators are ready to begin the work and have provided a target date for uploading their results to the LEADS database. When samples are transferred, the application abstract and target date for results will be added on the LEADS webpage. Samples sent to investigators will be identified by code numbers that cannot be linked to LEADS clinical data. Once analyses and QC are completed, investigators will provide their results with any associated data dictionary or method files to LEADS. These data and files will be added to the LEADS database with the correct subject ID codes to permit correlation of results to other LEADS data. Investigators will use the LEADS database to access their now unblinded data.

**Residual Samples and Additional Studies**

The investigator should notify the LEADS Data Sharing Committee if there are residual samples left after completion of the approved study. Investigators should ask for RARC approval if they wish to retain the samples for any additional analyses. Investigators should not dispose of unused LEADS biofluid. Investigators may return residual samples to the Genetics and Biorepository Core, where they will be pooled and used for assay standardization.

There is no charge for BRC review. A cost recovery fee will be charged for sample preparation, processing, and transfer by the Genetics and Biorepository Core. Costs can be found [here](https://ncrad.iu.edu/accessing_data.html).

Questions about LEADS biosamples and the application and review process can be directed to the Data Sharing Committee.