

## **Study Proposal/Letter of Intent**

Letters of Intent should briefly outline the hypothesis being proposed, its significance, the reason for proposing use of HBS biomarker specimens and required covariate data. Proposals are approximately one- to two- pages in length, and can be submitted at any time throughout the year. Within approximately 14 days, the applicant will be notified whether more information is required, or whether the project has been approved.

The format of the proposal should include specific aims, background and significance, preliminary studies, and methods. A copy of a pertinent NIH or Foundation grant applications can be submitted in place of the study proposal, if the following points are clarified. If biospecimens are requested, the following information must be included within the proposal:

### *Sample and Data Specifications:*

- Type(s) and volume of the biospecimens
- Results of power analysis describing the sample size required, and the predicted effect size.
- A complete list of all required clinical data.
- A description of all covariates.
- Definitions for case and control participants, as well as the number of enrollment visit and follow-up visit data requested (i.e. will the project require biospecimen and/or clinical data from a single time-point, or across multiple study visits).

For details regarding assay specifications, please see the Collaborator Agreement.