

- Project Summary (300 words or less). This section should describe the project, its scientific significance/impact on healthcare, and the importance of BIG samples/data to project.
- Research Approach and Analysis Methods (200 words or less). This section should include a description and rationale of your proposed sample analysis methodologies. Requests should provide a power estimate based on your sample size (this can include additional samples from other sources) or justification for a low powered cohort.¹

¹UTHSC and CFRI resources available for questions on power calculations and data security include:

- [Biostatistics, Epidemiology and Research Design \(BERD\) Clinic and Online Resources](#)
- [Center for Biomedical Informatics](#).

Status of peer-review of your project:

- NIH: Review complete/under review/planned
- Departmental: Review complete/under review/planned
- Other peer review: Review complete/under review/planned
- If other peer review: Name anticipated agency, institution or journal

Description of ethical concerns or issues that could be raised by the project (150 words or less).

Description of the server facilities to be used for secure data storage and analysis.

What electronic documents should accompany the BIG Distribution Request?

Principal

What Decision Criteria are used by the ROC for Sample distribution?

UTHSC affiliation:

- First priority will be given to PIs whose primary faculty appointment is at UTHSC.
- Second priority will be given to faculty with a primary appointment at St. Jude Children's Research Hospital and a joint appointment at UTHSC.
- Third priority will be given to UTHSC faculty with a primary appointment at another UT campus and a joint appointment at UTHSC.

Complete Application: All requested information is provided.

Scientific Significance: Rate the significance of the proposed project using the NIH 9 point scoring system (1 = highest significance; 9 = lowest significance)

Ethical considerations: If the PI describes potential ethical issues, or a ROC reviewer determines that the proposed project poses potential ethical issues, the application will be routed to the BIG Ethics Committee for evaluation of those issues, to render a determination of whether or not those ethical issues preclude approval, and to suggest possible steps to remedy the issues.

Security of Data and Sample storage

Sample Size and Power Estimate: Power calculations to estimate the appropriate/minimal sample sizes required for a statistically significant result will be afforded 0 g0 G[)]TJE