

- 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 data analysis methodologies. Requests should provide a power estimate based on your sample size (this can include additional data 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 Investigator's NIH Biosketch or Curriculum vitae.

Questions about the BIG Review Process

How will my BIG Distribution Request be reviewed?

Submitted applications are electronically distributed to five rotating members of the BIG Research Oversight Committee (ROC) for initial review and disposition.

Email notification of unanimously approved requests will be passed on to the IGB and the Principal Investigator.

Applications given any negative decisions (denials) from ROC reviewing members will go to an ROC meeting for group discussion and a vote. Simple majority rules.

An invitation to attend the ROC meeting will be issued to the Principal Investigator of any application under group review. The PI will be given the opportunity to give a brief 5 to 10 minute presentation to the ROC to support the request as well as to address questions from the ROC.

Official ROC approval or denial letters will be sent to the Principal Investigator after the ROC meeting. ROC Approval Letters should be included with IRB applications and can be used as supporting documents for grant applications.

What Decision Criteria are used by the ROC?

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)

Security of Data storage

Sample Size and Power Estimate: Power calculations to estimate the appropriate/minimal sample sizes required for a statistically significant result will be afforded wide latitude by the ROC. BIG data may be combined with data from other sources to reach significance and may also be used as a separate validation cohort.

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.

Questions about BIG Data Receipt

After the ROC approves my request, what other steps are needed to receive data?

Submit ROC approval letter with your study protocol application to the IRB.

Receive IRB approval for your study protocol.

Provide a copy of the IRB approval letter with protocol number and approval date to BIG (biglist@uthsc.edu). BIG will email