Instructions for Requesting BIG Data

Who is eligible to apply for BIG data?

- Principal Investigators with a faculty appointment at UTHSC are eligible to apply to BIG.
- Principal Investigators who do not have a primary or joint faculty appointment at UTHSC must establish a collaboration with a faculty member with a primary appointment at UTHSC in order to receive data and/or samples.
- *Please note* Principal Investigators with primary appointments at an institution other than UTHSC must receive Institutional Review Board (IRB) approval from their primary institutions along with UTHSC IRB approval in order to receive samples and/or data.

Where do I find out if DNA data are available for my study?

- BIG genomic data are linked to BIG participant health and demographic data in the research enterprise data warehouse (rEDW) maintained by the UTHSC Center for Biomedical Informatics (CBMI). The rEDW contains a variety of de-identified clinical and demographic information for patients in the Methodist Le Bonheur Healthcare system, including Le Bonheur Children's Hospital patients, dating back to January 1, 2014. More information on the rEDW can be found here: Research Enterprise Data Warehouse. When UTHSC investigators would like to identify available BIG data that are appropriate for their proposed study in the rEDW, contact CBMI directly (Lokesh Chinthala at lchintha@uthsc.edu or Melanie Hayes at mhayes74@uthsc.edu) for assistance.

How do I formally request DNA data from BIG?

After receiving the BIG List of data that are relevant to your proposed study cohort, go to our on-line portal and fill out and submit a BIG Distribution Request. Please contact CBMI for assistance in completing the application.

What information is required for the BIG Distribution Request?

- Information on the Applicant, Principal Investigator, and any project collaborators:
  - Applicant/PI name
  - Applicant/PI department/affiliation
  - Applicant/PI campus/institution location
  - Applicant/PI contact info
  - Names and affiliations of project collaborators.
- Descriptive sections about the project and its scientific merits:
  - Project Narrative (1-3 sentences). This section should be suitable for the general public and may be included in BIG Newsletters to its participant community and other public relations media.

- Project Summary (300 words or less). This section should describe the project, it's 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]

[1] *UTHSC 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 the Research Materials Use Agreement to you.
- Sign and return the BIG Research Materials Use Agreement to BIG (biglist@uthsc.edu).
- BIG will contact you (the Principal Investigator) when the data are ready for distribution.