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| IRB# | Principal Investigator:  Grant Number:  Grant Title: |
| **Part A – Research Data** | |
| In addressing the following questions, please refer to the NIH Genomic Data Sharing Policy effective January 25, 2015  <http://gds.nih.gov/> | |
| 1. Provide the date range in which consent was obtained for the data collected:       Choose one:   All data to be submitted were collected prior to January 25, 2015  All data to be submitted were collected after January 25, 2015  Data to be submitted includes data collected from both before and after January 25, 2015 | |
| 1. Were all data (to be submitted to dbGaP or another repository) collected initially with an IRB-approved consent document signed by each subject? Yes   **No**   **If no, indicate what data were not collected with consent and describe how those data were collected:** | |
| 3. Describe what data will be included in the dataset submitted to an NIH-designated repository (i.e., type of genomic data, relevant associated data, and information necessary to interpret the data): | |
| 4. Describe how data will be de-identified. Describe the nature of the code as well as the process of assigning that code randomly to each individual’s data prior to submitting the dataset to dbGaP or another repository. Please note: a specific statement that the dataset will NOT include any of the [18 identifiers enumerated in the HIPAA regulations](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#standard) must be included in your de-identification plan. | |
| **Part B – Consent** | |
| 5. Attach copies of **all versions** of the consent documents that were used for the prospective collection of this genetic information. Address each of the following issues in the text boxes below, indicating where (i.e., page/paragraph) in the consent document the information may be found:        a. Cite the consent document language that addressed whether, and to what extent, study data can be shared. Identify any specific statements in the informed consent documents that explicitly limit or entirely preclude sharing these data with individuals or organizations that are not part of your research team:        b. Indicate the appropriate research uses of these data as described in the informed consent documents:        c. Delineate uses of the research data that are **specifically excluded** by the informed consent language:        d. Citing language in the informed consent documents, indicate the extent to which subjects have been informed of the risks (to themselves, to their families, and to groups or populations) that may be associated with the **collection** of genetic data. As appropriate, also indicate how those risks have been mitigated:        e. Citing language in the informed consent documents, indicate the extent to which subjects have been informed of the risks (to themselves, to their families, and to groups or populations) that may be associated with the **submission** of genetic data to NIH-designated data repositories. If this has not been described in the consent document, discuss how those risks will mitigated:        f. Does this project have an [NIH-issued Certificate of Confidentiality](http://grants.nih.gov/grants/policy/coc/index.htm) (CoC)? Yes   **No**  **If No, indicate whether you are planning to obtain a CoC (for the coded information retained in Pittsburgh) prior to submitting your dataset to dbGaP or another repository**: | |
| **Investigator Certification** | |
| **By submitting this form to the IRB, I certify the following:**   * The initial collection of data (including information and specimens) is consistent with all applicable laws, and the regulations under 45 CFR 46), as well as with policies of the University of Pittsburgh for human subject research. * The submission of data to the NIH-designated data repository and subsequent sharing for research purposes are **not inconsistent** with the informed consent of study participants from whom that data were obtained. * The appropriate research uses of the data and the uses that are specifically excluded have been fully described in response to questions 5b and 5c. * The plan for de-identifying datasets is consistent with the standards outlined in the NIH GDS Policy. * The identities of research participants will not be disclosed to the NIH-designate data repository.   \_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Principal Investigator  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Principal Investigator Date | |

**Submission Instructions**

* Complete the form and attach all versions of the consent documents
* Send the request materials to [askirb@pitt.edu](mailto:askirb@pitt.edu)
* If you have any questions, please email us at [askirb@pitt.edu](mailto:askirb@pitt.edu)

If you have any questions, contact