



July 10, 2014

Reply to Attn of : SA-14-053

TO: Distribution

FROM: SA/Director, Human Health and Performance

SUBJECT: NASA Flight Institutional Review Board (Flight IRB) Review of Proposals
Involving Genetic Analysis

I. Purpose and Scope

NASA subjects have recently been sought for whole genome sequencing research. These studies pose the potential for significant advances in our understanding of human interactions with the space environment. The studies also present the potential for significant invasions of the subjects' privacy and the privacy of their family members as well. As a result, JSC has developed a policy to guide review of and participation in studies involving genetic analysis.

For purposes of this policy, the term "genetic analysis" includes research involving human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. It excludes the analysis and collection of bio-specimens that will not be submitted to genetic analysis.

This directive is applicable to the Flight Crew Operations Directorate and Human Health and Performance Directorate at JSC.

II. Flight IRB Guidelines

Flight IRB Approval of Studies Involving Bio-Specimens or Genetic Analysis

All research studies that involve genetic information from current or former astronauts shall be approved by the Flight IRB.

The Flight IRB shall categorize all studies involving bio-specimens or genetic analysis as "greater than minimal risk."

In addition to meeting all the requirements of the Common Rule and the Genetic Information Nondiscrimination Act (GINA), all studies submitted to the Flight IRB shall comply with the following requirements:

The protocol shall clearly state whether genetic data will be recorded or analyzed as part of the study.

The protocol shall clearly state whether or not genetic data will be extracted from bio-specimens.

When genetic data is to be collected or extracted, the proposal shall disclose the purposes for which the genetic data will be used.

All studies involving bio-specimens or genetic analysis shall provide a scientific merit review acceptable to the Flight IRB.

In the case of pilot research or preliminary analysis of existing data that is being used to prepare a full research proposal, the merit review may be waived by the Flight IRB.

All personnel who will have access to the genetic analysis data shall be documented in the protocol.

No bio-specimens will be provided to researchers except under an approved protocol.

Investigators that wish to use genetic data from human subjects shall sign a statement certifying that they understand and agree to abide by this policy.

Use and Security of Bio-Specimens and Genetic Data

Use and Disposal of Bio-Specimens

Bio-specimens shall not have genetic analysis of any kind performed unless the analysis is documented in a protocol approved by the Flight IRB.

The bio-specimens and data shall not be used for other purposes beyond those documented in the proposal and approved by the Flight IRB.

Investigators shall archive and preserve any bio-specimens remaining after the approved studies are completed. Remaining specimens shall not be destroyed and may not be used for other studies without prior approval by the Flight IRB.

All remaining bio-specimens or products of the original bio-specimens shall be returned or given to NASA if requested at any time.

Use of Genetic Data

Data shall not be disseminated beyond the immediate control of the individual investigators documented in the protocol approved by the Flight IRB.

Genetic data shall not be data-mined or cross-referenced with other databases of any kind unless approved in advance by the Flight IRB.

Investigators shall not attempt to identify individual participants within de-identified data sets or pooled specimens, or to otherwise "reverse engineer" or "disassemble" data sets for bio-specimens involving NASA research subjects.

Security and Storage of Data

Genetic data shall be encrypted and stored on secure servers. All IT systems used to store, process, or analyze genetic data shall comply with NASA's IT security standards for systems containing Privacy Act-protected information. In addition, no genetic data may be stored on mobile devices such as tablets, smart phones, or on removable media.

Genetic data stored on laptops shall be limited to the minimum amount required at any one time for current research purposes.

Once a study is completed, attributable data shall be archived in a secure manner by the investigator. Investigators may be required to archive original study data at NASA or elsewhere at NASA's direction and to destroy all copies of the original study data after the study is complete.

Release of Data

No whole genomic sequence data will be posted online or otherwise published or made public.

No genomic sequence data will be publicly released without the prior approval of the Flight IRB. Genomic sequence data approved for public release shall be limited to the minimum data necessary to support the research conclusions. The informed consent of the affected research subjects shall be obtained prior to such release.

Genetic analysis data shall not be publicly released without the prior approval of the Flight IRB.

The privacy of genetic information shall be protected to the full extent of the law, including after the death of the subject to avoid the unwarranted invasion of personal privacy of surviving family members.

Additional Informed Consent Requirements

Any study involving genetic data shall provide test subjects with genetic counseling as appropriate to the study objectives and when requested by the Flight IRB.

Genetic counseling shall be provided by an independent qualified counselor who is not a principal investigator or co-investigator on the study and who is otherwise without a conflict of interest.

Investigators proposing to use bio-specimens and genetic information shall provide a post-analysis briefing to each participant with genetic counselor available or present as necessary.

At the time of data collection, the investigator shall provide an estimated schedule of analysis and participant briefing.

At the end of all participant briefings, the investigator shall report completion to the Flight IRB.

Subjects have the right to review presentation slides prior to public presentation and to review manuscript drafts and final publications before public release. Research subjects have the right to have their identifiable information removed from the presentation or publication.

III. Other Matters

1. The IRB shall not accept third party IRB approvals.
2. Nothing in this JSC Interim Policy Document limits the authority of a physician to provide medical care to the extent that the physician is permitted to do so under applicable Federal, State, or local law.
3. This JSC Interim Policy Document may be superseded in the future by a NASA Agency Policy Document under the direction of the Office of the Chief Health and Medical Officer at NASA Headquarters.

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