




Section 500:	Reviews Requiring Special Consideration
Title:	HSREB Review of Human Genetic Research
SOP Code:	503.001
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Site Approvals

Signature of Responsible Individual:		
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Approval Authority:		
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1.0 PURPOSE

This SOP describes the special considerations for the HSREB review process with respect to human genetics research.

2.0 SCOPE

This SOP pertains to the HSREB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

All HSREB members and HSREB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

Human genetic research refers to research involving the genetic factors involving human traits and their interactions with each other and their environment. Research may include the human genome, gene function, normal and disease gene characteristics, gene therapy (clinical and laboratory investigations), and genetic and epidemiologic investigation (investigations into the patterns, causes, and effects of health and disease conditions in defined populations) of biological relatives, families, communities and groups.

Human Genetic research may include:

- Molecular gene research: research on single genes or short lengths of DNA to identify variations or mutations,
- Chromosomal genetic research: research to analyze a whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome,
- Biochemical genetic research: investigations in the amount or activity level of proteins,

Implications for genetic research may be applicable to more than just an individual, as it may reveal information about biological relatives.

5.1 HSREB Reviews of Genetic Research

5.1.1 HSREB review of genetic research should follow a proportionate approach, such that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Both the invasiveness of the procedures and/or the information that comes from the research and its potential to harm individuals should be taken into consideration;

5.1.2 Research proposals involving the collection and banking of genetic material, including the secondary use of previously collected material, should outline in the information provided to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings, withdrawal by participants, as well as future contact of participants, families, communities and groups;

5.1.3 Researchers conducting genetic research must:

- Develop and submit a plan to the HSREB for managing information that may be revealed through their research,
- Inform prospective participants or their substitute decision maker in the cases of children/non-competent adults about how any revealing information (i.e. biological relatives, gene-disease associates) will be managed throughout the research project;

- 5.1.4 When Researchers plan to share findings with participants, they must be provided with opportunities to:
- Make informed choices about receiving information about themselves,
 - Express preferences about sharing information with biological relatives or others with whom participants have a family, community or group relationship;
- 5.1.5 When genetic testing results are to be shared with participants, the protocol should describe options for genetic counselling for participants;
- 5.1.6 When family members are to be recruited to participate in genetic research:
- Privacy and confidentiality of family members and other personal interests are respected during the recruitment process,
 - Consent must be obtained from individual family member(s);
- 5.1.7 When participants are recruited based on membership to specific groups/communities, the proposed methods for engaging in discussion must be submitted to the HSREB, including proposed discussions with the group/community members and/or their leaders, in addition to discussions with individual members.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
HSREB Review of Human Genetic Research	v.503.001 2015MAY25	Original: Based on TCPS2 Chapter 13: Human Genetic Research, v. December, 2014

