Fraser Health Research Ethics Board
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# GUIDANCE NOTES ON HUMAN GENETIC RESEARCH

## INTRODUCTION

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) states that human genetic research may present a number of ethical complications, in particular because it has implications beyond the individual, as it may reveal information about biological relatives and others with whom the individual shares genetic ancestry. As such, special considerations and precautions are required to ensure the ethical conduct of such human genetic research. This guidance note intends to identify these key considerations and precautions, and the submission requirements for FHREB review for human genetic research.

## GUIDANCE NOTE #1: SUBMISSION REQUIREMENTS

Information revealed by human genetic research may be intentional (i.e., the aim of the study is to discover such information), or may be incidental (i.e., the finding is outside the scope of the research). In either case, researchers conducting studies involving human genetic research must detail their plan for managing information that may be revealed through their genetic research, including whether such information will be shared with study participants or their biological relatives. This plan must be detailed in the protocol or in appendix at the time of study submission.

In cases where findings will be shared with individuals, researchers should provide participants with the opportunity to make informed choices about whether they wish to receive information about themselves and express preferences about whether information will be shared with biological relatives or others whom the participant have a family, community or group relationship. This information must be detailed in the consent process and on the consent form, where applicable.

### 5.1 Genetic Counselling

In accordance with Article 13.4 of the TCPS 2, researchers should make genetic counselling available to participants at the time the results of the genetic research is made available to them. This counselling should explain the clinical significance of the information, whether health care interventions or lifestyle changes are recommended, and any implications of the information for biological relatives. When results will be shared with biological relatives, or other family, community or group members, genetic counselling should also be made available to them as well as participants.

### 5.1 Material Incidental Findings Plan

Where material incidental findings arising from human genetic research are reasonably foreseeable, the PI must submit a material incidental findings plan for review.

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Researchers should consult the TCPS Guidance on How to Address Material Incidental Findings as well as the FHREB Guidance Note on Material Incidental Findings for more information on this requirement.

## GUIDANCE NOTE #2: GENETIC RESEARCH INVOLVING FAMILIES

In cases where family members will be recruited to participate in genetic research, the Principal Investigator (PI) must ensure the recruitment process respects the privacy and other personal interests of family members. Special care should be taken during the recruitment process to respect the privacy of family members identified by existing participants.

The PI must seek consent from all individual family members participating in the research. It is important for researchers to be aware of the potential for conflicting views among family members regarding genetic research. Such conflicting views should be handled with sensitivity and respect.

## GUIDANCE NOTE #3: GENETIC RESEARCH INVOLVING COMMUNITIES AND GROUPS

Research involving human genetics with specific communities or groups raises additional ethical concerns, in particular because the results of such research could identify or cause harm to members of the community or group beyond the individual participants. Article 13.6 of the TCPS 2 indicates that stigmatization, unfair or inequitable treatment, and social disruption are risks of such research, particularly when members of the community or group disagree about participation.

For such research, the PI should engage with that community or group to ascertain the appropriateness of the research and any specific concerns, in addition to consenting individual members. While REB approval is not required to conduct such engagement work, the details of this engagement plan should be submitted to the FHREB for review at the time of protocol submission.