

GUIDANCE NOTES ON MATERIAL INCIDENTAL FINDINGS

INTRODUCTION

As research represents a step into the unknown, unintentional discoveries may arise during the course of the project. When such discoveries have material significance for the participants and/or others not directly involved in the research, caution is needed to ensure such findings are appropriately addressed. This guidance is intended to define material incidental findings and describe the submission requirements to the FHREB when such findings are reasonably foreseeable in the research.

GUIDANCE NOTE #1: DETERMINATION OF MATERIALITY

Material incidental findings are defined by the [TCPS Guidance on How to Address Material Incidental Findings](#) as having the following:

- Analytical Validity: the researchers have verified the accuracy and precision of the finding
- Potential Significance for the Participant: Findings may significantly affect the participant's welfare, health or otherwise. Such findings may be immediate or in the future.
- Actionability: Sharing findings in a timely manner may allow the participant to initiate an action to remove or help manage the risk their welfare.

In order to make such an assessment, expertise relevant to the finding is often needed. The [TCPS Guidance on How to Address Material Incidental Findings](#) advises that researchers should identify the type of expertise needed to determine the significance of the finding and whether it is material. Researchers should also be guided by practices and standards developed by their professional associations or disciplines in making such determinations.

GUIDANCE NOTE #2: SUBMISSION REQUIREMENTS

Incidental findings can arise from a number of different types of studies, including genetic sequencing, medical imaging, and biobanking studies, as well as behavioural studies that may uncover findings such as suicidality or physical abuse.

The submission requirements for material incidental findings are dependent upon whether such findings are reasonably foreseeable or not reasonably foreseeable.

Where material incidental findings are reasonably foreseeable, such as with most human genetic research, the Principal Investigator (PI) must submit the following the REB for review:

1. A material incidental findings plan
2. The disclosure strategy for informing participants of any such findings. This strategy must also be clearly detailed in the consent process for the study.

Where material incidental findings are not reasonably foreseeable but may be possible, a material incidental findings plan is not required. However, researchers are strongly encouraged to develop a process in case such findings occur. In the event of such a finding, the PI must report such findings to the REB, and submit a management plan for the finding. This plan must be approved by the REB prior to implementation. Where actions are required to remove immediate hazards or where time is of the essence to mitigate risks, the PI may implement required actions prior to the reporting the incident to the REB.

2.1 Circumstances that justify an exception to the obligation to disclose material incidental findings

Where the obligation to disclose material incidental findings would be impossible or impracticable, an exception may be granted. The PI should provide the REB with a justification for such an exception.

GUIDANCE NOTE #3: ELEMENTS OF A MANAGEMENT PLAN

Management plans for material incidental findings will differ depending on the context and discipline of the research, and the nature of foreseeable findings. In accordance with the [TCPS Guidance on How to Address Material Incidental Findings](#), basic elements of a management plan include the following:

- 1) The likelihood of discovery of material incidental findings:
 - a) What is the nature of such foreseeable incidental findings?
 - b) When, in the course of the research, are such findings likely to occur? E.g., during screening, study procedures, or follow up evaluations, etc.?
- 2) The management of the findings:
 - a) How does the PI plan to determine the materiality of the findings? This may include seeking additional expertise, obtaining appropriate reasons to cover the costs of confirming materiality, and assessing the analytical validity, potential significance, and actionality of the findings.
 - b) What findings will be disclosed?
 - c) What is the justification for not disclosing some findings?
 - d) Who on the research team will be responsible for communicating the findings to the participants?
- 3) Consent:

- a) Will participants be able to choose the types of material incidental findings they wish to receive or not receive, and at what stages of the research will they be able to do so?
- b) How will the consent process be managed for those who do not have the decision-making capacity to consent on their own behalf at the time of initial consent?

GUIDANCE NOTE #4: COMMUNICATION ABOUT MATERIAL INCIDENTAL FINDINGS

Researchers must consider a number of issues related to communicating material incidental findings, including:

- 1) What information should be shared
- 2) When information should be shared
- 3) With whom information should be shared
- 4) How information should be shared

The communication of such information is made complex by many factors, including the fact participants can only be informed of the exact details of the findings after they are discovered. Researchers should be sensitive to the fact sharing material incidental findings can cause anxiety or distress, and should exercise care in how this information is shared.

In some circumstances, such as genetic studies, the disclosure of incidental findings may have impacts on others, such as family members of the participant. While researchers are not obligated under the [TCPS Guidance on How to Address Material Incidental Findings](#) to share material incidental findings beyond the participant, they may be able to do so if the participant has expressed a preference for such disclosure or when in exceptional circumstances, such as in the case of discovering a life-threatening condition that could be prevented through intervention.