

Did you know...

Article 3.4 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2-2018)* states, “Within the limits of consent provided by the participant, researchers shall disclose to the participant any material incidental findings discovered in the course of research.”

The Panel on Research Ethics (PRE) has released a guidance document entitled “How to Address Material Incidental Findings: Guidance in Applying TCPS2-2018 – Article 3.4”.

As outlined within the guidance document,

An “incidental finding” is a discovery about research participants or prospective participants that is made in the course of research, but is outside the objectives of the research study. The introduction of Article 3.4 describes incidental findings to be “material” if they are reasonably determined to have significant welfare implications for the participant or prospective participant. Material incidental findings may appear at any stage, and in any type of research (TCPS 2, introduction to Article 3.4). Material incidental findings can also occur in retrospective research studies such as chart reviews.

The Determination of Materiality:

Incidental findings would be considered material if they have all three of the following key determinants: Analytical Validity, Potential Significance, and Actionability

The TCPS2 principle of Justice places an obligation on researchers to treat people fairly and equitably. A consistent approach in the disclosure of material incidental findings should be followed – and therefore, researchers may need to develop a management plan, or at least a process to follow, in the event that they discover material incidental findings. Such a plan or process should recognize individual differences, and any developments or changes to context or circumstances.

For ethics applications where material incidental findings are reasonably foreseeable, the researcher should develop a plan from the outset: (i) for review by the REB, and (ii) to inform participants about their disclosure strategy as part of the consent process.

For ethics applications where material incidental findings are not reasonably foreseeable, the researcher is encouraged to think about a process to follow in case material incidental findings occur, but does not necessarily require a detailed plan at the outset of the research. In the event of an unexpected discovery of incidental findings that are likely to be material, the researcher shall report the finding to the BUREC, and should develop a management plan for the BUREC’s approval before implementing it.

Material Incidental Findings

A new question on material incidental findings as been added to the BUREC Application Form. Please be sure to download the most current form from the BUREC webpage when preparing an application. The above guidance document and BUREC applications forms are available on the BUREC webpage at: www.brandonu.ca/burec.

If you have any questions or concerns, please contact BUREC at burec@brandonu.ca.