

Standard Operating Procedures for Studies Involving Genetic Sampling: Research Ethics Board Requirements

In reviewing new studies that have a genetic component, the Research Ethics Board (REB) will, as is customary for all studies, consider the matter of risk and benefit to the research subject and the validity of the science of the proposed project. The following are issues which may assist the REB in its deliberations.

Protocol:

- The protocol must include a full explanation of the rationale for taking genetic samples and their planned usage.
- The source of the samples and their subsequent storage or long term banking must be clearly articulated and the length of time of storage specified.
- A full Data Protection Program needs to be included. Issues include, but are not limited to:
 - How samples will be identified. For example will they be identified by code? Will they be totally anonymized?
 - Whether any Personal Health Information will be recorded.
 - Who will have access to samples, codes and data and under what circumstances?
 - If the principal investigator of the study moves or retires, what will happen to the stored samples?
 - How will samples be ultimately destroyed?

Consent and Subject Care issues:

- A separate consent form should be used for the genetics portion of a research study.
- The protocol should specify whether there is provision for feedback of results to those who have donated the sample. For example:
 - If incidental findings are noted in the samples, will the subject be re-contacted?
 - Will there be general feed-back to the subject?
 - Is genetic counseling available?
- Consent can be tiered or layered. For example, at the “closed” end of the spectrum, subjects can be asked whether they agree to the use of their sample in the particular study of disorder “x”, being conducted by Dr. “y” at “z” institution. At the “open” end subjects can be asked to allow their sample to be used in future research. The following are a few

examples of wording for consent for future use, arranged from the “closed” end of the spectrum, to the “open” end of the spectrum:

- “I agree to my sample being used in future studies on depression being conducted at CAMH by Dr. Smith.”
- “I agree to my sample being used in future studies on depression being conducted at CAMH.”
- “I agree to my sample being used in future studies on mood disorders being conducted at CAMH or any University of Toronto teaching hospital.”
- “I agree to my sample being used in future studies on mental illness being conducted in Canada”.
- “I agree to have my sample used in this study and in any future research”.
- The consent form should specify if subjects are to be re-contacted, and how they will be re-contacted.
- Physical and social risks of donating a sample must be included in the consent form. An example of a physical risk would include possible bruising from a blood sample. Social risks could include loss of insurance coverage or difficulty in obtaining employment.
- The form needs to be clear as to what withdrawal from the study would mean. For example:
 - Does this mean that the subject’s sample is destroyed?
 - Does it mean that the sample and associated data would be anonymized?
- Any benefit or commercial gain needs to be discussed. More specifically, who would benefit from the commercialization of, for example, a cell line? The study sponsor? The institution? The investigator? The study subject?

Administrative Issues:

- Consideration needs to be given to whether samples will be shared. Is there a need for a Material Transfer Agreement (MTA)?