

**MODULE 3:
PROJECTS INVOLVING USE OF HUMAN TISSUE
SAMPLES – GUIDELINES**



GUIDELINES

These guidelines provide information and instructions to assist researchers in answering the questions in the **Module 3: Projects Involving Use of Human Tissue Samples**. Refer to these guidelines when answering many of the questions in the form. Please note that this form replaces the previous version of Module Three as well as Module Four (Human Genetic Research).

The application forms and guidelines are modified and updated from time to time. Please go back to the website each time you make a new application, to ensure that you have the latest version of this Module.

Researchers are expected to have reviewed the *National Statement on Ethical Conduct in Research Involving Humans* prior to submitting an application to conduct any form of research. For researchers using Module 3, it is especially important that chapters 15 and 16 of the *National Statement* be consulted prior to submitting the application.

As you answer each question, you should consider what information, if any, needs to be included in the Participant Information and Consent Form that you will be using for your research project.

Definition of 'Tissue': For the purposes of this Module, **tissue** includes the substance, structure, and texture of which the human body or any part or organ of it is composed. Tissue includes tumour samples, blood, blood components and waste products (eg sweat and urine). It also includes tissue derivatives such as DNA, RNA and proteins obtained from human beings. (Note: Tissue does not include cell lines unless the primary purpose of deriving/developing the cell line and the purpose of the project is to undertake genetic testing for germ line predisposition to disease).

3.1 Purposes For Which the Samples Will Be Used

Pharmacogenetic and **pharmacogenomic** tests are intended to discover genetic markers and/or to identify candidate genes whose expression may have an impact upon drug action or disease pathogenesis. The terms *pharmacogenetic* and *pharmacogenomic* are used interchangeably (or variably) among scientists.

Genetic analysis pertains to the evaluation of the somatic genetics/epigenetics of cells in which the primary purpose is not to identify germline disease-predisposing mutations. **Genetic testing** involves the

analysis of genetic material in which the primary purpose is to identify high or low penetrance germline disease-predisposing mutations.

Tissue Bank (although potentially any collection of tissue samples) refers here to a larger repository established for the collection of tissue samples from multiple sources for the purpose of use in future unspecified research and/or specific research projects. The term *Tissue Bank* includes a collection of genetic material sometimes known as a *Gene Bank*.

3.2 Source of Human Tissue Samples

If answering 'Other' to Question 3.2, specify the source, for example 'tissue collected at autopsy,' or 'tissue collected as part of another research project.'

3.3 Nature and Volume

Note that the data in the chart is included to provide examples only. If there are multiple purposes or tissue types being used, then multiple entries (rows of information) are required.

3.4 Collection and Processing of Fresh Tissue

Fresh tissue is defined as tissue provided directly to the researcher (ie not obtained via a tissue bank or other tissue archive).

- (a) If there are multiple tissue types, modes of collection or modes of processing being used, then multiple entries (rows of information) are required. If you are not collecting fresh tissue, then proceed to Question 3.6.
- (b) An example of where you would answer 'No' is if blood were collected using standard processes. An example of where you would answer 'Yes' would be if the sample were collected via an additional bone marrow biopsy.

3.5 Consent to Use Fresh Tissue

It would be unusual for consent to NOT be required for the use of fresh tissue.

3.6 Consent to Use Stored Tissue (Banks/Archives)

- (a) Although it may sometimes not be possible to obtain information regarding for which purpose/s consent was obtained, it is the researcher's responsibility to obtain whatever information is available.

Donor specified research refers to the possibility that a tissue donor, at the time of consent, may have specified that the donated tissue be used for a specific type of research (eg breast cancer research or multiple sclerosis research).

3.8 Tissue Banking

See the definition of *Tissue Bank* in guidelines for Question 3.1 above. Check your institution's policy on tissue banking before applying to the HREC. HREC approval may be necessary to obtain access to and/or establish a tissue bank.

3.9 Genetic Register

If you intend to establish a genetic register, you are advised to consult all relevant guidelines, including guidelines published by the NH&MRC that are additional to the *National Statement*.

3.10 Cell Lines

Note the reference to cell lines in the *Definition of Tissue* above. The purpose of the development of the cell line should be included in your answer.

3.11 Protection of Privacy

- (a) **Identified** data refers to the retention of information/data that makes it possible for a specific individual to be identified. Identifiability is determined by context; what may make an individual identifiable in one context may not in another. Note that it is the identifiability of the sample/data *when provided to the research team* by the collector and/or processor that is relevant in this question.

Coded data refers to information/data that has had identifiers removed and replaced by a code, but where the code can be used to re-identify the individual.

De-identified data refers to information/data that has had all identifiers removed and which cannot be linked to any individual.

3.12 Genetics

- (a) Refer to the definitions of *genetic analysis* and *genetic testing* in Question 3.1 above.
- (d) The offer of counselling to participants and/or family members is considered mandatory in any of the situations for which the answer is 'Yes' to this question.

3.13 Cultural or Religious Sensitivities

The use and disposal of tissue samples may be particularly sensitive to members of certain cultural groups or religious communities. You are advised to consult relevant literature on these matters. One source of information with

which you should be familiar is the NH&MRC document *Values and Ethics: Guidelines on Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)*.

3.15 Post-Study

Although these questions are also asked in Module One, it is necessary to ask them again in this Module, as the answers may differ for this component of the research project.

- (a)** Note that you do not need to repeat here any information that you have already provided in your answer to question 3.12(d).