

**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 also covers 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 Human Research (2007)* prior to submitting an application to conduct any form of research. For researchers using Module 3, it is especially important that chapters 3.2, 3.4 and 3.5 of the *National Statement* be consulted prior to submitting the application. The sections of the *National Statement* that have particular relevance to questions in the Module Three application form are cited at each question. It is strongly recommended that researchers consult the *National Statement* when completing their 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, urine, breath condensate). 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 Type and Volume/Size of Samples

- (a) Note that the data in the chart is included to provide examples only. If there are multiple tissue types being used, then multiple entries (rows of information) are required.
- (b) Indicate whether the samples are being collected for routine diagnostic purposes with the intention to later use these for research purposes or whether their collection is purely for research purposes.

### 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 NOT to be required for the use of fresh tissue. The type of consent being sought (i.e. specific, extended, unspecified) must be clearly stated in the *Participant Information and Consent Form* that participants are provided with during the consent process.

### 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).

- (b) Indicate whether you intend to obtain additional consent from individuals for use of their stored human tissue. Where the response is negative, provide reasons for not obtaining consent.
- (c) If imported tissue is intended for use, it is important for the researcher to identify ethical or professional policies governing the collection and use of human tissue in research in the country from which the tissue is to be imported.

The Human Research Ethics Committee may waive the requirement for consent to use the tissue if the provisions in 2.3.6 of the National Statement apply. Consent may also be waived for use of imported tissue if the collection existed overseas or was imported prior to the release of the National Statement in 2007. In this case, the HREC may consider waiving the requirement for consent without referring to sub-sections (a) and (b) of 2.3.6 in the National Statement.

### **3.7 Consent to Use Cadaveric Tissue**

Wishes which have been expressed by an individual for the use of their post-mortem tissue must be respected. If no wishes were expressed regarding the use of post-mortem tissue, consent for the use of such tissue should be sought from the available senior next of kin [see *National Statement* 3.4.8].

The manner with which the cadaveric tissue will be disposed of on completion of the research should be negotiated with the next of kin during the consent process and their wishes should be taken into account [see *National Statement* 3.4.9] provided that these do not conflict with standard approved methods of safe disposal.

### **3.8 Storage of Sample/s and Data**

Institutions should have a policy regarding the storage of samples and data. Researchers are required to conform to such policies and are required to demonstrate that they will maintain confidentiality, secure the privacy of the samples and information and have measures in place for appropriate access to the samples or data [see *National Statement* 3.4.1-3.4.3].

### **3.9 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.

As with databanks, researchers should describe in detail how samples will be collected, stored, used and accessed by others and how the processes proposed conform to the *National Statement* (2007) [see *National Statement* 3.2.1].

Conditions of release, in particular those pertaining to identifiability, as specified by the custodian of the bank, must be adhered to by researchers. Custodians have the responsibility to ensure that the tissue/data are used

responsibly and respectfully and that participants' privacy is safeguarded [see *National Statement* 3.2.5]

There may be cases where there is a need to convey information arising from the research to participants in research which uses re-identifiable data. In such cases the custodian is required to re-identify the data to the extent that this is possible [see *National Statement* 3.2.6].

### 3.10 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*.

### 3.11 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.

### 3.12 Protection of Privacy

(a) **Identifiable** 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.

**Non-identifiable** samples and/or data refers to samples/data that have had all identifiers removed and from which the identity of the individual cannot be ascertained by the researchers conducting the project.

*\* Note: The National Statement specifies that "human tissue samples should always be regarded as, in principle, re-identifiable". [NS p.29]. Also note that identifiers should not be removed without participant consent if removal would make it difficult to communicate personal results. [NS 3.5.5(a) and 3.4.6]*

### 3.13 Genetics

(a) Refer to the definitions of *genetic analysis* and *genetic testing* in Question 3.1 above.

(b) Before consenting to participating in research where genetic material will be collected, participants should be provided with sufficient information which enables them to gain an adequate understanding of the aims, methods, potential risks and benefits of the research [see *National Statement* 2.2]. In addition to this information, genetic research requires that potential participants be informed of and understand all the additional information listed in the National Statement under sections 3.5.8.

If researchers are contemplating approaching relatives, there are specific issues that need to be considered [see *National Statement* 3.5.9 and 3.5.10].

- (d) The offer of counselling to participants and/or family members is strongly recommended in any of the situations for which the answer is 'Yes' to this question.

### **3.14 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 Institutional Policy**

Researchers are advised to consult their institutional policies developed in relation to the collection, use, storage and disposal of human tissue. In the application to the HREC, researchers are required to demonstrate that they comply with such policies [see *National Statement* 3.4.1-3.4.3].

### **3.16 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 3.13(d).