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EQUIP CRITERIA	<p>Standard 15.10 – Corporate Systems and Safety.</p> <p>Criterion 15.10 – Fostering and encouraging clinical and health services research.</p> <p>Criterion 15.11 – Ensuring research integrity through governing body oversight.</p>
SUMMARY	<p>The Guidelines for the Use of Human Tissue Samples in Research have been developed to clearly set out the responsibilities of Melbourne Health (MH) staff and others using MH resources in conducting research involving the use of human tissue samples in research. They outline when and how human tissue may be used for research.</p> <p>These guidelines have been written in accordance with the <i>National Statement on Ethical Conduct in Human Research (2007)</i> and the <i>Australian Code for the Responsible Conduct of Research (2007)</i>.</p> <p>These guidelines provide for the registration of all Human Tissue Banks in use at MH.</p>

1. ASSOCIATED POLICY

MH Research Policy

2. PURPOSE AND SCOPE

These guidelines for the use of human tissue samples in research have been developed to clearly set out the responsibilities of MH staff and others using MH resources in conducting research involving the use of human tissue samples in research. They also outline when and how human tissue may be used for research.

These guidelines govern the:

- collection, labelling, storage, use and disposal of human tissue for use in research;
- set up and management of Human Tissue Banks at/or for MH;
- use of tissue that has been previously collected and stored for research or other purposes and which a researcher may wish to access for new research; and
- use of samples in quality assurance projects, for example, the collection and use of blood samples for establishment of “normal levels”, instrument calibration, etc.

For the purposes of this document, it is understood that the term, “research purposes” incorporates quality assurance activities.

3. DEFINITIONS

Human Tissue sample	A human tissue sample is any blood, body fluid or product or body part (piece of, whole part or derivative).
Tissue Bank	A tissue bank is a repository of samples that is kept for a period of time and that it could be foreseen at some point in time may be used for research purposes. It does not include collections of samples that are stored for a defined period prior to being shipped to a laboratory for testing.
HREC – Research Ethics Committee	This term is used throughout this document to indicate the MH Human Research Ethics Committees.

Identification of samples and accompanying data:

Identifiable:	Where the identity of an individual can reasonably be ascertained. Examples of identifiers include individuals’ names, UR numbers, and address.
Re-identifiable:	Tissue from which identifiers have been removed and replaced by a code. It remains possible to re-identify a specific individual by, for example, using the code.
Non-identifiable:	Tissue samples that have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can ever be identified.

4. RESPONSIBILITIES

The Office for Research will keep a register of all Human Tissue Banks at MH.

Researchers must be aware of and abide by these guidelines.

5. GUIDELINES

5.1 INTRODUCTION

These guidelines have been developed in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) and the *Australian Code for the Responsible Conduct of Research* (2007).

All research that proposes to collect and /or use human tissue samples must be submitted to the Office for Research for ethical and governance review and approval. This includes for MH patient tissue samples by researchers at other institutions who wish to access these tissues via an agreement that describes the materials and conditions of transfer.

Researchers who wish to conduct research that involves the use of human tissue must ensure that their research meets the following requirements. Failure to comply with these guidelines may constitute research misconduct. (Refer to: MH Guidelines for Research Practice –Chapter 12 Research Misconduct).

5.2 CONSENT

In most cases where human tissue samples are collected for purposes including research, consent for their use in research **is required**.

Informed consent must be:

- voluntary;
- specific to the purpose for which the tissue is to be used and provide full written information about the project, including information as to whether, after completion of the research for which consent is given, the tissue samples are to be stored for possible future research and if this consent covers that research, or if consent will be sought at that time in the future (refer to: Appendix B);
- in writing.

1. Consent for collection, use and/or storage for future use of new human tissue samples

In projects where collection, use and storage for future use of new human tissue samples are required, the above requirements for consent must be met.

Researchers are advised that it is wise to consider any possible use of tissue that maybe useful, in research terms, when formulating their research protocol and Participant Information and Consent Form (PICF). Whenever possible, to facilitate future use of samples, researchers should include consent for the future use of the samples in the original PICF.

Access to stored samples

In projects where it is proposed that previously collected and stored samples be used in a research project, the researcher must provide the HREC with the original written informed consent that was obtained when the samples were collected.

If the initial written informed consent meets the requirements for consent as stated above, the HREC may waive the requirement for further consent in the present research proposal.

If the initial written informed consent does not meet the requirements for consent as stated above, the HREC will require:

- a) consent to be obtained; or
- b) the researcher to demonstrate why it is not possible or practicable to obtain consent, or that attempting to obtain consent may have deleterious effects on the tissue donor or their family; and that there is benefit to the community in conducting the research.

If the requirements set out in b) are satisfactorily addressed, the HREC may waive the requirement for consent.

If the requirements set out in b) cannot be met, the HREC may not be able to approve the project.

2. **Access to samples that were stored as part of diagnostic requirements**

Hospitals have collections of stored archival samples as required by law, for diagnostic and forensic requirements. Use of these samples in research that may advance medical knowledge and/or treatment of a disease may be of benefit to the community and is therefore encouraged.

The HREC may waive the requirement to obtain consent in a research project with scientific merit and a potential benefit to the community, that involves access to samples that were stored as part of diagnostic purposes, if the research:

- a) does not have any clinically significant health implications for the tissue donor; and
- b) does not have a potentially adverse effect on the wellbeing of the donor (eg. Loss of privacy, injustice or commercial exploitation).

5.3 DOCUMENTATION

Consent, when required as above, must always be written informed consent. A full copy of the written informed consent for the research project must be stored in the tissue donor's hospital medical records. The original PICF must be stored in the investigator file. In the case of Tissue Banks, copies of all of the Participant Information and Consent Forms must also be stored within the access of the person who manages the tissue bank. i.e. the Tissue Bank Trustee and Tissue Bank Coordinator.

An entry should be made in the donor's hospital medical record that includes: the name of the study, who conducted the consent process and what samples the donor has consented to being taken. A further entry should be made when the samples are taken.

Tissue Banks

It is the responsibility of the Tissue Bank Trustee to ensure that all required documentation is kept in relation to tissue stored in tissue banks. This includes:

- the PICF of the original project that allow the creation of the tissue bank;**
- the scope for which the tissue may be used;
- any restrictions on the use of the tissue;
- records of all access to and use of samples within the tissue bank, including HREC approvals for such projects;
- names and designation of all persons who have accessed the tissue bank;
- a register of samples, including records relating to when they are due for destruction, approval for destruction and actual destruction.
- documentation relating to the effective storage of the samples, eg. temperature control checking procedures and checks performed: and
- the key to the code, in the case of samples that are labelled in the re-identifiable fashion.

Documentation must be stored securely in the vicinity of the tissue bank, in lockable filing cabinets and password protected computer systems, in an access controlled area.

** In the case where MH is a partner in a large Australian tissue bank, this may involve copies of the consent forms being transferred outside of MH. By their nature consent forms are identifiable. Therefore,

the HREC will only allow this when the participants have been made aware that their identifying information will be disclosed in such a manner and it can be demonstrated that that the external tissue bank operates under similar policy, and complies with the National Statement on Ethical Conduct in Human Research (2007), The Australian Code for the Responsible Conduct of Research (2007) and similar privacy laws.

5.4 COLLECTION OF SAMPLES

Samples must be collected in accordance with the declared process as stated in the PICF, including the stated amount, frequency and type of collection that has been approved by the HREC.

The PICF must contain full disclosure relating to how the samples will be collected, who will collect the samples and any risks involved in the collection of the samples.

5.5 CONFIDENTIALITY, PRIVACY and LABELLING

Confidentiality must be maintained in all aspects of research. Researchers are responsible for ensuring that confidential information is maintained as such whilst samples are in their care.

In most cases, samples can be used satisfactorily in research in a re-identifiable or non-identifiable state. This is the preferred method of labelling and should be used in all research whenever possible. Researchers should endeavor to develop coding that does not use part of, or the initials of, donor's name.

It is understood that in circumstances where the sample may be taken for both diagnostic as well as research purposes it may be labelled in an identifiable fashion. Researchers must justify the use of samples in an identified fashion in their submission to the HREC.

Written information that accompanies samples, includes but is not limited to pathology request forms, shipping documents, etc. must comply with these labelling requirements.

5.6 ACCESS TO AND USE OF SAMPLES AND INFORMATION

Samples may only be used in accordance with the statement of use as specified in the PICF and as declared in the submission to the HREC for approval of the project. All types of testing must be clearly declared in the PICF in plain English.

Samples can only be sent interstate and/or overseas if the researcher is aware that the jurisdiction to which the samples are being sent is covered by similar laws and codes of conduct as apply in Victoria in relation to the use of human tissue in research. Tissue donors must be made aware of where their sample will be sent, via the PICF.

In accordance with privacy laws, identifiable tissue samples should not be sent outside of MH, interstate or overseas in research. If it is necessary to be able to identify the sample donor, the sample and accompanying documentation must be made re-identifiable prior to being shipped. The key to the code must remain within MH and cannot be given to a third party.

Melbourne Health Shared Pathology Service (MHSPS)

The Pathology department is a repository for human tissue collected for diagnostic purposes as part of a patient's clinical care. As such, requests for archived tissue, including tumour tissue, blood, bacterial isolates and other tissues are made frequently by researchers. In view of this, requirements for the release of human tissue, with particular reference to tumour excision or biopsy material from Pathology are outlined below.

Pathologists have obligations as custodians of biopsy tissue material this includes ensuring that it is available for future review or further testing. Pathologists also must ensure that the material remains available for medico-legal purposes.

Further, patients expect pathologists will keep the biopsy material safe for future reference, including in relation to any future treatment they may need. While patients may consent to the release of their biopsy material, MHSPS must also take into account other obligations and rights. Those may include ensuring that diagnostic material is not totally released or lost, damaged or all used as that can have a significant

effect on the patient's and the pathologist's rights and obligations.

Consequently, Melbourne Health Shared Pathology Service (MHSPS) will provide researchers with sections of formalin fixed and paraffin embedded tissue (FFPE) tissue when archived biopsy material is requested as part of a clinical trial protocol or research project. MHPS understand, however, that this is not a suitable option for the construction of tissue microarrays or tissue banking for future biomarker studies. In these circumstances, MHSPS will consider requests on a case by case basis.

All requests for tissue for research purposes must be approved by the MH Human Research and Ethics committee (HREC) or other approved HREC. In addition, requests for human tissue for research **held by MHSPS** must be reviewed and approved by the Pathology Clinical Trials Coordinator. The Clinical Trials Coordinator is responsible for completing required documentation; ensuring resources are available to provide services and managing tissue requests made as part of a clinical trial or research project. Required documentation may include:

- i. Completing a *Statement of Approval (SOA)* form for Research Governance Approval for projects submitted to the MH HREC
- ii. Executing an appropriate agreement between MH and external party e.g. *Laboratory Services /Research Collaboration Materials Transfer Agreement* or other approved agreement as applicable.

The SOA and Agreements ensure the appropriate ethics approvals are in place and the rights and obligations of both MH and the Researcher are addressed. This documentation ensures that human tissue is released by Pathology in accordance with legislation and costs for services (e.g. preparation of tissue sections) are recovered by MH.

All research-related requests for human tissue or pathology services should be directed to the Pathology Clinical Trials Coordinator.

5.7 TISSUE BANKS

Notification of intention to set up a Tissue Bank must be made to the Office for Research and the relevant HREC. This must be done by submission of the MH Tissue Bank Registration Form (Appendix A) and a submission to the relevant HREC. Any Tissue Banks that already exist within the organisation must also be registered with the Office for Research.

It is understood that Tissue Banks set up prior to the introduction of these guidelines may not be able to fully comply with these guidelines; however, every effort must be made to comply where the Tissue Bank is able to, and any future addition of samples to the Tissue Bank and use of such samples must comply with these guidelines.

A tissue bank must be set up according to the following:

1. A charter for the purpose of, the scope of use, the protocol for access of the tissue being stored must be instated.
2. A Tissue Bank Trustee must be appointed. This person is the person ultimately responsible for the Tissue Bank. The Tissue Bank Trustee must ensure that the tissue bank is kept in accordance with this policy and any laws, codes of practice or contractual arrangements. In some instances this person will also be the Tissue Bank coordinator.
3. A Tissue Bank Coordinator, who controls the daily management of the tissue bank, must be appointed and his/her responsibilities defined. In some instances this person will also be the Tissue Bank Trustee.
4. A protocol stating how and where samples will be stored, labelled, accessed, used and disposed. This protocol should also state where the PICFs are to be stored.
5. Establishment of a committee to review applications for use of stored samples.
6. Development of a record keeping system.

5.8 DISPOSAL

Samples should be disposed of according to the time frame stated in the PICF or according to law in regard to samples kept for hospital diagnostic and forensic purposes. Samples must be disposed of in a manner that does not risk the confidentiality of the donor and according to standard laboratory practices.

Documentation relating to the disposal must be kept.

5.9 IMPORTED TISSUE

Where tissue is imported from another country for use in Australia, researchers should try to establish whether there are ethical and professional policies in that country, or relevant institution, governing the collection of tissue for use in research. This information must be communicated to the HREC with the project submission for approval and include any certificate or comments from a local HREC from the institution where the project was/is conducted.

Where such a policy exists and reasonable inquiry reveals no reason to believe that the collection of the tissue contravened it, the HREC may consider waiving consent for the use of the tissue in accordance with waiving consent as stated in this policy.

Where it cannot be established that a policy exists, or where it exists but inquiry reveals that it exists but the tissue was not taken in accordance with it, the tissue should not be used in research at MH.

For research with tissues that were in collections either imported or existing overseas before the release of the National Statement on Ethical Conduct in Human Research (May 2007), the HREC may consider waiving consent if the involvement in the research carries low risk to participants and the benefits from the research justify any risks of harm associated with not seeking consent.

5.10 CADAVERIC TISSUE

Any wish expressed by a person about the use of his/her post-mortem tissue for research should be respected. If no such wish is discovered, consent for the use of the tissue should be sought from the senior available next of kin.

At the time of seeking this consent it should be agreed with the next of kin how the tissue is to be disposed of when the research has been completed. Researchers should try to accommodate any reasonable wishes of the next of kin about this.

All research-related requests for human tissue should be directed to the Pathology Clinical Trials Coordinator.

5.11 AGREEMENTS

An agreement (Materials transfer, collaboration, services agreement etc.) must be in place before samples are sent to or received from external organisations for the purpose of research. Researchers should contact the Office for Research for assistance to determine which agreement is appropriate for their research. Approval of agreements by the Melbourne Health Business Development Unit and/or Legal Services is required where non-Melbourne Health agreements/approved template agreements are submitted for research projects.

5.12 COMMERCIALISATION

MH prohibits trade in human tissue.

5.13 OWNERSHIP AND RIGHTS

Human tissue collected and held at Melbourne Health, and all Confidential Information, including any copyright that subsists in any part of the Confidential Information remain the absolute property of Melbourne Health.

6. ASSOCIATED PROCEDURES

Registration of Tissue Banks

Notification of intention to set up a Tissue Bank must be made to the Office for Research and the relevant HREC. This must be done by submission of the MH Tissue Bank Registration Form (Appendix A) and a submission to the relevant HREC. Any Tissue Banks that already exist within the organisation must also be registered with the Office for Research.

7. REFERENCES

- National Statement on Ethical Conduct in Human Research 2007
- Australian Code for Responsible Conduct of Research – 2007
- Melbourne Health Guidelines for Research Practice 2015
- Melbourne Health Policy: Privacy and Confidentiality of Patient Information MH03.08
- Human Tissue Act (Vic) 1982
- Health Records Act (Vic) 2001
- Health Records Act 2001(Vic) – Health Privacy Principles
- The Privacy Act 1988 with amendments up to Act No.159 2001. (Cmwlth)
- International Conference on Harmonisation – Guideline for Good Clinical Practice 2016 (ICH-GCP)
- Therapeutic Goods Administration Note for Guidance on Good Clinical Practice 2000

8. DOCUMENTATION

Appendix A: Melbourne Health Tissue Bank Registration Form

9. FURTHER INFORMATION

Contact the Office of the Office for Research on (03) 9342 8530.

10. REVISION AND APPROVAL HISTORY

Date	Rev No	Author and approval
1/10/2007	First Draft	Angela Gray, Assistant Manager Office for Research
13/11/2007	0	Angela Watt, Manager Office for Research
25/07/2011	1	Angela Gray, Manager and Executive Office Human Research Ethics Committee
23/6/2015	2	Sarah Rickard, Manager Research Governance
29/10/18	2	Jessica Turner and Sarah Rickard, update of error to reinstate appendix B – document not reviewed in full, version date unchanged

MELBOURNE HEALTH TISSUE BANK REGISTRATION FORM

RD Ref. No: TB

Appendix A: Guidelines for the Use of Human Tissue Samples in Research

MELBOURNE HEALTH TISSUE BANK REGISTRATION FORM

1. Relevant HREC/MHREC/QA project no: (Specify which)	
2. Name of Tissue Bank:	
3. <u>Trustee</u> of Tissue Bank and contact details:	Name: Phone: Email:
4. <u>Coordinator</u> of the Tissue Bank and Contact Details ('as above' if the same person)	Name: Phone: Email:
5. Department:	

6. Location of the Tissue Bank (describe exactly where it is / will be kept)

7. Please describe the security system to protect the Tissue Bank. Include the security of the identity of individual samples and any information that is/will be kept with the samples (labelling) as well as the overall security of the facility.

8. When was/will the Tissue Bank be setup?

9. What is/was the original purpose of the Tissue Bank? (This may include for archiving for diagnostic and forensic purposes, research, etc.)

10. Where, or from whom was / will the tissue be sourced?

11. Was/will consent to add tissue to the Tissue Bank be sought from the tissue donors? (Include if tissue has been imported from overseas, if an HREC has approved the collection, use and disclosure of the tissue sample) Yes No

Give details:

12. Are/will copies of the Participant Information and Consent Forms for the collection, use and storage of the tissue, be stored with the tissue samples?

Yes No

Give details:

13. What tissue is/will be stored in the Tissue Bank?

14. Is new tissue still being added to the Tissue Bank? Yes

No

If No: Please provide the date reception into the Tissue Bank closed: _____

15. For what research purposes is/will the Tissue Bank used? (List any projects for which the Tissue Bank is and/or will be used either to store samples or to access samples. Provide the corresponding HREC numbers)

HREC / MHREC / QA Number (Specify which)	Name of the Principal Investigator for the project	Name of the project

– add more rows if needed

16. Is there a written policy and procedure (Charter) that governs access to samples in the tissue bank? If “yes” please attach a copy.

Yes No

Give details:

17. Is there a committee which reviews requests of researchers for use of tissue in the Tissue Bank for research? If “yes” please provide details of the membership below or attach a copy of the membership and the terms of reference of the committee

Name	Position

– add more rows if needed

18. Is it the intent to keep this Tissue Bank indefinitely? Yes No
If No, when and how and when will samples be disposed?

Signature of Trustee	
Date	

Appendix B. Guidance for Wording for Participant Information and Consent Forms (PICF) involving the use of human tissue samples in research.

This document provides guidance on how to provide information to participants about their samples. It covers:

- collection of the sample/s
- use of the sample/s
- labelling of the sample/s
- storage of and Access to the sample/s
- disposal of the sample's
- risks associated with collection of the sample/s
- results of the testing.

All of these topics must be included in the PICF.

A. Collection of the sample/s

Include:

1. What will be collected.

Include an explanation of what tissue will be collected. For example: blood, plasma, tumour tissue, organ tissue (eg. skin, liver, kidney) urine, stool, saliva, etc.

2. Who will collect the sample.

For example: study staff, doctor, nurse, phlebotomist (person trained in collecting blood samples).

3. How the sample will be collected.

For example:

- Blood Samples: "Blood is taken by a needle inserted into a vein in your arm".
- Biopsy Samples: Include an explanation of how the sample will be collected. This should include: hospitalisation required (outpatient or inpatient), time commitment, anaesthetic and analgesia and a description of the procedure.

4. When and how often the sample will be collected.

For example:

- Blood samples: "A blood sample will be taken at each study visit (once per month) for two years, commencing at the screening visit."
- Biopsy samples: "The biopsy sample will be taken during your operation that is part of your treatment for your condition."

5. The volume of the sample.

For example:

- Blood samples: "10mls (2 teaspoons) or 45mls (about 2 tablespoons)". Please note that in Australia a tablespoon is equal to 20mls.
- Biopsy samples: Endeavour to provide measurements. Eg. "A sample measuring about, 1cm by 1cm will be taken."

6. Where the sample will be collected.

For example:

- “Blood samples will be taken at outpatients pathology”
 - “Blood samples will be taken at outpatients clinic”
 - “Blood samples will be taken at the study site”
 - “Blood samples will be taken at an external pathology clinic (note: name clinic)”.
- If a sample is to be collected at an external site, include arrangements that will be made for this to occur.

6. An example paragraph for collection of samples:

“The study nurse will take a blood sample of 20mls (about 1 tablespoon) via a needle inserted into a vein in your arm. A blood sample will be collected in the hospital clinic at each study visit (once per month) for two years commencing at the screening visit.”

B. Use of the Sample/s

Include all uses that the sample will be used for. This includes: diagnostic, research, safety, pharmacokinetic, biomarkers, pharmacogenetic and genetic testing.

1. Diagnostic and/or Research:

For example:

- “ The blood sample will be tested to see if you have (the illness being studied).”
- “Biochemistry tests (tests that check substances in the blood) will be done to see if you are responding to the treatment”

2. Safety:

For example:

- “Haematology and biochemistry tests (checks of blood, kidney, and liver function and general health indicators) will be performed.”

3. Pharmacokinetic:

For example:

- “A 10ml blood sample will be taken one hour before the study drug is administered, then hourly, whilst the infusion is running and then at 1, 6, and 12 hours after the infusion has finished. These samples will be used to test the amounts of study drug in your system at the above stated time points. This gives us information about how the study drug is processed by the body.”

4. Pharmacogenetic/genomic:

For example:

- “The cells in our bodies all contain genes. Genes are inherited from our parents. Genes provide the instructions for the structure and function of the cells that make up our bodies. Sometimes we can identify a gene or part of a gene that may influence on how the study drug works. These are called genetic markers. The tumour sample (or blood sample) will be tested to try to identify genetic markers or genes that may determine how a person responds to treatment. We may then be able to use this information in the future to develop new medications that target the identified genetic markers or genes.”

5. Biomarkers:

For example:

- “Healthy cells and cancer cells in our bodies produce substances. Sometimes we can measure these substances to diagnose a disease, to find out how a disease is progressing or how it is responding to treatment. We call these substances biomarkers. Your blood sample will be tested to see if we can identify any biomarkers that may help to develop new tests for the disease.”

6. Genetic:

For example:

- “The cells in our bodies all contain genes. Genes are inherited from our parents. Genes provide the instructions for the structure and function of the cells that make up our bodies. Genes contain the information that determines our physical features such as our hair and eye colour. Differences in our genes help explain why we are all different. Sometime our genes can be altered. This is called a genetic mutation. The alterations to these genes can sometimes cause specific diseases or make a person more likely to develop a specific disease. Your blood sample will be tested to identify any genetic changes, (genetic mutations). These changes may indicate that you or your family are more likely to develop a specific disease.”

7. Tissue Banking:

For example:

- “The samples will be added to the (name and location of the tissue bank). The samples may be accessed in the future by researchers conducting research into this (“study medication” or “disease”). Access to the samples will only be given to researchers whose projects have been approved by a Research and Ethics Committee.”

C. Labelling

Include an explanation of how the data/sample will be labelled to protect the individual’s identity.

For example:

- “All samples and accompanying documents will be labelled with a unique study code. This code is made up of a site code and a participant number. Eg 0101. Your name, hospital number will not be used to identify your sample. The key to this code will be kept by the investigator and will not be released to the sponsor.”

D. Storage and Access

Include an explanation of how and where the samples will be stored and who will have access to the samples.

For example:

- “The samples will be stored in the Pathology Department at Royal Melbourne Hospital for two years and will only be used for this study as described in this document. Only the study staff and laboratory staff will have access to the samples.”
- “The samples will be sent to (name and location of the outside laboratory) where they will be tested as described in this document and stored until the end of the study. Only staff from (name of laboratory or sponsor) will have access to the samples.”

Tissue Banking

For example:

- “The samples will be stored (name and location of the Tissue Bank) for up to 15 years. They will be accessed for research as described in this document. Access to the samples will only be given to researchers whose projects have been approved by a Research Ethics Committee. Researchers will not be given information that could identify you. Samples will only be identified by a code number.”

E. Disposal of Samples

Include an explanation of how and when the samples will be disposed.

For example:

- “Samples will be disposed of using standard laboratory disposal methods, immediately after the testing has been done. This will be about two weeks after they have been collected.”
- “Samples will be stored for 5 years then destroyed using standard laboratory disposal methods.”
- “Samples will be destroyed using standard laboratory disposal methods at the end of the study.”

F. Risks

Include all risks associated with collection of the sample including any risk associated with the knowledge of the results of the testing.

For example:

- “Taking a blood sample can cause pain, bruising and infection at the site of insertion of the needle. Some people feel unwell and faint when having blood taken.”
- Biopsy Samples -
The statement should include any risk of death, bleeding, pain, infection and scarring. Rates of occurrence and severity should be given when available. Short term incapacity, after the biopsy procedure, if relevant, should also be declared.
- Psychological Risk -
“You should be aware that knowing that you (“have (include the name of the disease)”) or (“that you are at risk of developing (include the name of the disease)”) may cause you distress. The study doctor will provide you with information to help you understand the meaning and outcome of the results. Also you may be required to declare this knowledge when applying for health/life insurance”

G. Results of the testing

Participants should be informed of all result of tests that have or could have an effect on their health or treatment now or in the future. Participants should be informed of the results of all diagnostic and safety tests and any genetic tests that may indicate a predisposition to the development of a disease or a potential to pass on a disease to their offspring. Further, participants should also be informed of results that may be relevant to the health of family members.

Results of testing that do not have a bearing on an individual's health or treatment, such as pharmacokinetic and pharmacogenetic testing, do not need to be reported to participants,

although participants should be advised in advance that they will not be given the results of these tests and why.

The PICF should include a statement informing participants that they will or will not be given the results of the tests as per the guidelines above.

For example:

- “You will be informed of any information obtained from the tests that could have an impact on your health or treatment”.

“As the results of the testing will not affect your health or treatment you will not be informed of the results of the tests