



MINISTRY OF HEALTH
MALAYSIA

MALAYSIAN GUIDELINES ON THE USE OF HUMAN BIOLOGICAL SAMPLES FOR RESEARCH

NATIONAL COMMITTEE FOR CLINICAL RESEARCH,
MINISTRY OF HEALTH MALAYSIA

Prepared by:
Secretariat for National Committee for Clinical Research,
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FOREWORD

Thank you for giving me this opportunity to say a few words in this important document. I would like to acknowledge the efforts made by the members of the committee to come up with our own “Malaysian Guidelines on the Use of Human Biological Samples for Research”. These guidelines are indeed timely, in keeping with the progress of both clinical and non-clinical research in Malaysia over the last decade, in which biological samples are generally part of the research and development.

The Ministry of Health Malaysia through the National Committee for Clinical Research realised how important it is to be clear on the implementation of research involving biological samples. Concerns on patient consent, ethical issues and ownership must be addressed accordingly following approved guidelines.

These guidelines should be used by all parties involved in conducting and approving research involving human biological samples. These include the clinical researchers, ethics committees, sponsors and research laboratories. It is our duty to instill public trust and conduct clinical research in an ethical fashion.

It is my hope that with the launch of these guidelines all stakeholders are clear on how we handle human biological samples, with the foremost aim of benefiting mankind. With these guidelines in place, my wish is that the standard of research which utilize human biological tissues will move forward in the right direction.

A handwritten signature in black ink, appearing to read 'Hisham'.

Datuk Dr Noor Hisham bin Abdullah
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1. GLOSSARY

Anonymised tissues/samples

Anonymised samples or data have had all identifying information removed, such that it is not possible for the researcher using them to identify the individual to whom they relate. The term is used in these guidelines to refer to both linked and unlinked anonymised data and samples.

- Linked anonymised samples or data are fully anonymous to the people who receive or use them (e.g. the research team) but contain information or codes that would allow others (e.g. the clinical team who collected them or an independent body entrusted with safekeeping of the code) to link them back to identifiable individuals.
- Unlinked anonymised samples or data contain no information that could reasonably be used by anyone to identify the individuals who donated them or to whom they relate.

Biobank

A biorepository where activities of receiving, processing, preservation, storage or distribution of human biological samples and cells are undertaken. It may also be responsible for procurement or testing of human biological samples and cells.

Custodianship

Responsibility for safe keeping of samples and control of their use and eventual disposal in accordance with the terms of the consent given by the donor and any legal and good practice requirements.

Custodianship implies some rights to decide how the samples are used and by whom, and also responsibility for safeguarding the interests of the donors.

Human biological sample

The terms human biological material, human biological samples, human material, material and samples are used interchangeably and refer to all biological material of human origin, including organs, tissues, bodily fluids, teeth, hair and nails; but not established cell lines. Many of the principles and approaches in this guidance could equally apply to extracted material such as DNA and RNA.

Personal information

All identifiable information about individuals, living or dead. This includes written and electronic records and information obtained from samples.

2. PREAMBLE

Human biological tissues or organs, removed in the course of medical procedures / treatment or excess samples left over after diagnostic investigations, are rich resources for immediate or future research.

Generally, patients undergoing surgery do not have their consent obtained nor are informed regarding the further use or handling of their biological materials. To protect the rights and fundamental freedom of these patients and in view of the increasing flow of biological materials across countries and borders, there is a need to standardise practices amongst the various Institutional Review Board / Independent Ethics Committee (IRB/IEC) and institutions in the country in the collection, storage and use of such materials for research.

Clear guidelines must be established particularly on the principle of requesting consent, be it at the time of collection of the materials or after, and the introduction of a layered consent. This is extremely important as more researchers and institutions are leveraging on the vast research potential of human tissues made available through routine medical procedures and investigations.

These guidelines aim to draw attention to important ethical issues that should be considered when:

- Conducting research on stored/archived human biological samples which had been collected during routine investigation/treatment;
- Conducting research on biological samples prospectively collected from patients undergoing routine investigation or treatment.
- Conducting research involving planned prospective collection of human biological samples including those for the purpose of bio-banking.

These guidelines are not intended to cover the use of such biological tissues for medical diagnostic purposes, disease surveillance, teaching or stem cell research.

It serves to advise the IRB/IEC on the general principles and approaches to address issues on using human biological samples for research. While the IRB/IEC is expected to comply with these general guidelines, there may be a need for adaptations to suit the individual institutions' environment and/or the requirements of a particular study.

The following ethical principles form the basis for the formulation of these guidelines:

- beneficence (doing good)
- non-maleficence (preventing or mitigating harm)
- justice
- fidelity and trust within the investigator/participant relationship
- personal dignity of study participants or subjects
- autonomy pertaining to both informed, voluntary, competent decision-making (informed consent)
- privacy of personal information

3. TYPES OF RESEARCH INVOLVING HUMAN BIOLOGICAL SAMPLES

3.1 Conducting Research on Stored/Archived Human Biological Samples Which Have Been Collected During Routine Investigation/Treatment

Tissue or organs removed in the course of surgical treatment or excess human biological samples left over after diagnostic testing can be of considerable value for research and teaching and are widely used for such purposes. However, there is currently little public awareness of this practice, nor indeed of what normally happens to such material if it is not used for research.

Some people are of the opinion that it is better that the material should serve some useful purpose rather than simply be disposed. However, it would be wrong to assume that such a view is universal, and it is recommended that wherever practicable individual consent should be obtained for the use for research of human material surplus to clinical requirements.

3.1.1 Confidentiality

Where surplus material is to be used in a way that allows research results to be linked to the individual patient, individual informed consent should be obtained (refer to Section 3.3).

3.1.2 IRB/IEC Approval

Prior IRB/IEC approval should be obtained before conducting the research.

3.1.3 Informed consent

An individual informed consent should be obtained. However, if it is not practical, a waiver of the informed consent should be obtained from the IEC/IRB. The permission to use the material should be obtained from the custodian of the biological samples.

3.2. Conducting Research on Biological Samples Prospectively Collected From Patients Undergoing Routine Investigation or Treatment

3.2.1 IRB / IEC Approval

Prior IRB/IEC approval should be obtained before collecting the biological samples for research.

3.2.2 Informed Consent

There must be an explicit separate consent to the routine consent for surgery, or other forms of treatment / procedure to collect the biological samples for research.

Informed consent for collection of human biological tissues for research should be taken before or after the surgery/procedure. However, it is important that such consent should not take precedence over consent for treatment. It should be made clear to patients or subjects that the consent is voluntary and can be withdrawn at any time and this will not affect their treatment in any way.

For children and individuals incapable of giving consents, the consent should be obtained from the legal guardian or next-of-kin.

3.3. Conducting Research Involving Planned Prospective Collection of Human Biological Samples Including Those For The Purpose of Bio-Banking

3.3.1 IRB/IEC Approval

In research which has been planned to include collection of human biological tissues, approval from the IRB/IEC and informed consent from the participating subjects must be obtained prior to conducting the study.

3.3.2 Informed Consent

If the researcher plans to store and use the tissues for future research, a multi-layered consent with several options should be obtained. The request for consent may include:

- Consent to the specific planned research
- Consent for storage and future use
- Consent for access to medical records and information for data relevant to the bio-banking
- Consent for re-contacting the subject for more data

3.3.3 Feedback of Research Information

Researchers should decide at the beginning on the type of information that will be made available to the patients and/or the community and this should be indicated in the submission to the IRB/IEC and included in subject information sheet

4. INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE (IRB/IEC) APPROVAL

IRB / IEC approval must be obtained to collect samples of human material for research, and for all research projects using samples of human material.

Although consent from patient/subjects has been obtained for the use of the tissues in future research, approval from IRB/IEC must first be obtained for each subsequent study.

Despite IRB/IEC approval for use of human biological tissues for future research, the researchers must obtain new approval for specified projects utilizing these tissues.

The process of anonymisation should be reviewed and approved by the IRB/IEC.

When vulnerable groups, such as (including but not limited to) children, prisoners, pregnant mothers, mentally disabled, and the economically and educationally disadvantaged are the participants selected for the research, particular cognizance should be taken of their rights and the safe-guarding of their rights. Special attention is given to situations where the consent from the next of kin, guardian or legal representatives, are sought. Both ethical and legal consideration should be taken into account in decision making.

5. PATIENT INFORMATION SHEET

In the information sheet for the primary/main study for which approval of IRB/IEC is requested, researchers must provide potential study subjects the following information:

- Purpose of the research
- Possible future research including type of studies, type of diseases that could be investigated, possible impact of research and benefits
- Type and amount of tissue to be taken (as well as location)
- The manner in which tissue will be taken, the safety & invasiveness of acquisition, and the duration of storage
- The potential uses for the tissue including any commercial uses
- The safeguards to protect the individual's privacy and confidentiality
- Identifying information attached to specific tissue, and its traceability
- How the use of the tissue could affect privacy
- The right to withdraw and arrangement for disposal of tissues and data

6. CONFIDENTIALITY AND ANONYMISATION

6.1 Confidentiality

Confidentiality is important as personal data and information may prejudice participants against health insurance and employment. Hence, personal identifiers should be removed as far and as early as possible (anonymisations) so that it is not possible to link the results of the tests to identifiable individuals.

The key principles on personal information are:

- Personal information must be treated as confidential
- All medical research using identifiable personal information must be approved by an IRB/IEC
- All personal information must be coded or anonymised as far and as early as possible in the data processing
- Principal investigators are responsible for ensuring that procedures and security arrangements are sufficient to prevent breaches of confidentiality
- Researchers must decide which information or results will be made available to the people involved

6.2 Anonymisation

It is acceptable to use archived or surplus human materials collected during routine surgical treatment or medical diagnosis for research without the need for individual written consent provided the samples are anonymised and not possible to be linked to identifiable individuals/data.

The level and process of anonymisation should be approved by the IRB/IEC. There must be a clear and stringent privacy framework so that data are protected.

7. CUSTODIANSHIP

The custodianship of research samples lies with the institution.

7.1 Responsibility

Once a sample has been obtained from a patient or subject, the appropriate custodian of the sample is the institution that collects the samples. The custodian therefore retains the responsibility to protect and regulate the use, storage, access, transfer and disposal of the tissues.

7.2 Intellectual property (IP) and Commercialization

Policy regarding intellectual property arising from the research should follow applicable rules and regulations.

Biological samples should not be used for financial gain or sold to a third party, without prior permission from the donor or the legal representative. Patients should be duly informed that their donated tissues or products derived from it may be used for potential commercial utility arising from the research.

7.3 Accessibility

Any request for access to the human biological tissues should be approved by the institution or custodian following a set of agreed criteria.

Custodians should ensure that any use of the tissue samples for research must have prior IRB/IEC approval.

8. STANDARDS

Human biological tissues collected for research should be kept and handled according to specified bio-banking standards and standard tests should be conducted in current laboratory best practice. It is unethical to collect and process specimens without regards to proper standards because it may impact on the reliability and validity of the tests performed and consequently the research findings.

Issues of varied bio-banking standards and varied quality of specimens remain relevant and important concerns in research employing new technologies. A set of Standard Operating Procedures (SOP) such as samples acquisition, transport, processing, archiving, disposal, safety should be made available.

REFERENCES

1. Human tissue and biological samples for use in research: Operational and ethical guidelines Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council, 2001.
2. MRC Operational and Ethical Guidelines. Clarification following passage of the Human Tissue Act 2004, 2005.
3. Nuffield Council on Bioethics Report: "Human Tissue: Ethical and Legal issues", 1995.
4. Trouet C (2004) New European guidelines for the use of stored human biological materials in biomedical research. J Med Ethics, 30, 99-103.
5. Garrath W (2005) Bioethics and large-scale biobanking: Individualistic ethics and collective projects. Genomics, Society and Policy, 1, 50-66.
6. Malaysian Guidelines for Good Clinical Practice, 3rd edition, 2011.
7. Guidelines for Stem Cell Research and Therapy, July 2009
8. National Standards for Stem Cell Transplantation: Collection, Processing, Storage and Infusion of Haemopoietic Stem Cells and Therapeutic Cells, July 2009
9. National Standards for Cord Blood Banking and Transplantation, January 2008
10. Guideline of The Malaysian Medical Council: Clinical Trials and Biomedical Research, November 2006
11. Garispanduan Pengimportan Dan Pengeksportan Tisu Manusia Atau Mana-Mana Bahagiannya, Edisi Pertama, Ogos 2006. (Guidelines on Importation and Exportation of Human Tissues and/or any Body Part, August 2006)
12. Medical Act 1971
13. Infectious Diseases Act 2007
14. Prevention and Control of Infectious Diseases (Importation and Exportation of Human Remains, Human Tissues and Pathogenic Organisms or Substances) Regulations 2007

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