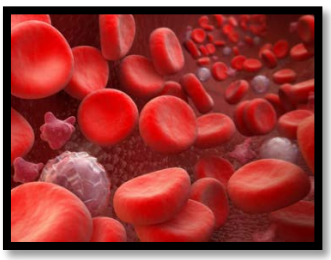
Collection, storage and use of biological materials and related data



When biological materials (may include: tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, or other bodily fluids) and related data, such as health or employment records, are collected and stored, institutions must have a governance system to obtain authorization for future use of these materials in research. Researchers must not adversely affect the rights and welfare of individuals from whom the materials were collected.

The materials will mostly come from patients following diagnostic or therapeutic procedures, autopsy specimens, and donations of organs or tissue from living or dead humans, or bodily wastes or abandoned tissue.

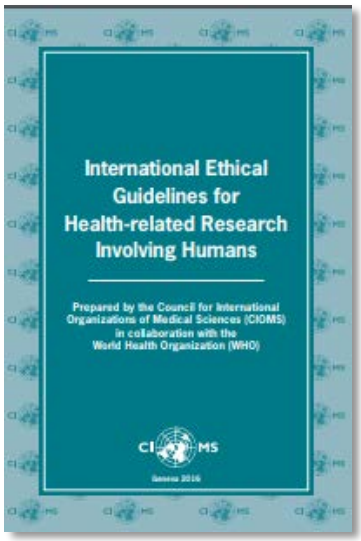
They may be collected expressly

- ✓ for a specific research purpose;
- ✓ from medical or diagnostic procedures with no initial intent to be used in research;
- ✓ for research or medical or diagnostic purposes with the expectation that they may, or will, also be used in future research, although the precise research project(s) may not be known at the time.

When specimens are collected for research purposes, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained from the person from whom the material originally is obtained. The ethical acceptability of broad informed consent relies on proper governance.

Governance. Institutions in which biological material and related data are archived after collection for research purposes or as “left-overs” from clinical diagnosis or treatment must have a governance structure in place in which at least the following items are regulated:

- ✓ to which legal entity the material is entrusted;
- ✓ how authorization from the donor is obtained;
- ✓ how the donor can retract this authorization;
- ✓ in which circumstances donors need to be re-contacted;



Compiled by: Prof. Punkae Mahaisavariya, Former Director of MUCERif

References: CIOMS Guidelines 2016

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- ✓ a procedure for determining whether unsolicited findings should be disclosed, and if so, how they should be managed;
- ✓ how the quality of the material is controlled;
- ✓ how confidentiality of the link between biological specimens and personal identifiers of the donors is maintained;
- ✓ who may have access to the materials for future research, and under what circumstances;
- ✓ which body may review research proposals for future use of the material;
- ✓ appropriate mechanisms for keeping donors informed of research outcomes;
- ✓ how participatory engagement with patient groups or the wider community is organized;
- ✓ to which other sources of personal information the results of analyses on biological materials may be linked;
- ✓ in broad terms, which types of research will be pursued;
- ✓ which types of research will be excluded or included only after re-contacting the donor for consent;
- ✓ to whom any benefits from the research are expected to accrue;

When human biological materials are left over after clinical diagnosis or treatment (so-called “residual tissue”) and are stored for future research, **a specific or broad informed consent may be used or may be substituted by an informed opt-out procedure**. This means that the material is stored and used for research unless the person from whom it originates explicitly objects.

The informed opt-out procedure must fulfil the following conditions:

1) patients need to be aware of its existence;

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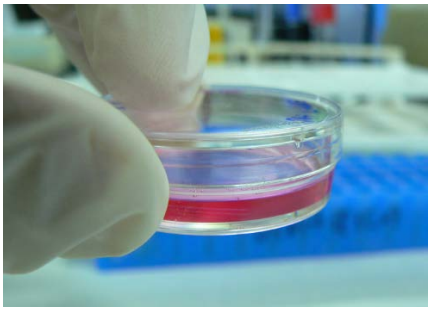
2) sufficient information needs to be provided;

3) patients need to be told that they can withdraw their data; and

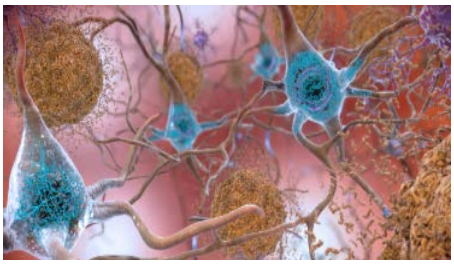
4) a genuine possibility to object has to be offered.

Broad informed consent. Broad informed consent encompasses the range of future uses in research for which consent is given. Broad informed consent is not blanket consent that would allow future use of bodily material without any restriction. On the contrary, broad informed consent places certain limitations on the future use of bodily materials.



Broad informed consent forms should specify:

- ✓ the purpose of the biobank;
- ✓ the conditions and duration of storage;
- ✓ the rules of access to the biobank;
- ✓ the ways in which the donor can contact the biobank custodian and remain informed about future use;



- ✓ the foreseeable uses of the materials, whether limited to an already fully defined study or extending to a number of wholly or partially undefined studies;
- ✓ the intended goal of such use, whether only for basic or applied research , or also for commercial purposes;
- ✓ the possibility of unsolicited findings and how they will be dealt with.

The research ethics committee must ensure that the proposed collections, the storage protocol, and the consent procedure meet these specifications.

Research ethics committees and biobanks. The protocol for every study using stored human biological materials and related data must be submitted to a research ethics committee, which must ensure that the proposed use of the materials falls within the scope specifically agreed to by the donor, if the donor has given broad informed consent for future research.

If the proposed use falls outside the authorized scope of research, re-consent is necessary.

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When researchers seek to use stored materials collected for past research, clinical or other purposes **without having obtained informed consent for their future use** for research, ***the research ethics committee*** may waive the requirement of individual informed consent if:

1) the research would not be feasible or practicable to carry out without the waiver;

2) the research has important social value; and

3) the research poses no more than minimal risks to participants or to the group to which the participant belongs.

Custodians of biological materials must arrange to protect the confidentiality of the information linked to the material, by sharing only *anonymized or coded data with researchers*, and *limiting access to the material of third parties*. The key to the code must remain with the custodian of the biological material.

The transfer of biological materials must be covered by a Material Transfer Agreement (MTA).

Biological materials and related data should only be collected and stored in collaboration with local health authorities. The governance structure of such collection should have representation of the original setting. If the specimen and data are stored outside the original setting, there should be provisions to return all materials to that setting and share possible results and benefits (see Guideline 3 – Equitable distribution of benefits and burdens in the selection of individuals and groups of participants in research, Guideline 7 – Community engagement, and Guideline 8 – Collaborative partnership and capacity building for research and review).

References: CIOMS Guidelines 2016