Broad Consent for Use of Human Biospecimens in Future Research

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SingHealth

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Introduction

In both clinical and research settings, biospecimens (also referred to as human biological materials) have been collected and stored. Researchers have been using variable processes and practices to obtain consent for the future research use of biospecimes. These include obtaining consent at the time of biospecimen collection for a specific use, with re-consent for subsequent uses; general consent that covers broad uses; or no consent.

Problem statement

❖ With the enforcement of Human Biomedical Research Act (HBRA) in governing donors' decision to be involved in biobanking, the **legislation mandate the need for donors to be appropriately informed**, including a list of essential information, and that the information are organized in a way that facilitates the prospective participant's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

❖ **Confusion and uncertainty about the format of information** and application of understandable consent process result in decisions to not use certain bisopecimens and consequent loss in public benefit from research.

Methodology

Within SingHealth, the use of consent has been proposed to address these concerns.

What is **Broad Consent**?

More burden, more control

Blanket consent → Broad consent → Specific consent

Less burden, less control

1. Defined on a scale between strictly specified and blanket consent.
2. Permits institutions to seek prospective consent to collect, store and use data and de-identified biospecimens for unspecified range of future research, subject to a few limitation or process restrictions.
3. Participants are given the explicit choice to opt-out during the initial consent process or to withdraw at any time.
4. Specific type of research known to conflict with donar's fundamental values, eg. studies on human cloning or human-animal combination can be precluded by the initial consent.

Results

✓ The proposed broad consent has included all the **mandatory elements** of HRBA for tissue banking activity to be conducted.

✓ Potential subjects must be informed on all the conditions (A and B) based on HBRA section 12(2) for their tissue donation.

✓ In the broad consent, He or she also given the option to consent to the four main condition under (B).

(A)

- Specific research purpose which tissue is intended to be used
- Tissue will be used for any purpose
- Proposed area of research approved IRB
- Reasonable foreseeable risk, compensation and treatment in the event of injury
- Donation of the tissues is voluntary and the renunciation of donor's right and any intellectual property rights
- Donor subject's right to withdraw consent
- Any anticipated expenses
- Identifying donor's information will be kept confidential based on PDPA
- Individually-identifiable information obtain will be used for future biomedical research
- Donor's tissue taken will be destroyed, discarded or stored for future biomedical research

(B)

- Donor authorized to give consent to be contacted in the future
- Donor authorized to give consent would wish to be re-identified in the case of an incidental
- Whether tissue will be used in restricted human biomedical research involving human-animal combinations
- Whether tissue will be exported or removed from Singapore to be place outside Singapore

Pros of Broad Consent

- ➢ No additional consent require for any subsequent storage and secondary research uses of the biospecimens and data.
- ➢ Reduces the costs of research.
- ➢ Reduce burden for researchers/donors of making decision for each new study.
- ➢ Minimize the risk to handle different type of consents.

Cons of Broad Consent

- ➢ Not applicable for biospecimens used for only few type of research.
- ➢ Logistically challenge for tracking the consent status and consent conditions.
- ➢ Ethically challenging to ensure patients are not forced to consent to broad consent.

Conclusion and Future Works

A framework for appropriate broad consent, which includes development of appropriate consent template with mandatory elements, guidance on initial consent, independent oversight and future review will be established, so as the tissue banking activities are compliance with HBRA in Singapore.