

General Consent to Research Use of Biological Samples and Health Information

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Requirement of Informed Consent

Obtaining informed consent from the subject or her/his legal representative is the basic requirement for conducting research using human biological samples and accompanying health information.

Prior to giving consent, potential subjects should be given information concerning the nature, significance, purposes and accompanying risks of the intended research specifically.

Researches Utilizing Left over Samples

For Researches utilizing

Samples left over after preceding research or laboratory test, or

Samples collected from body parts removed for treatment of the patient, or

For Researches using samples donated to and distributed from biobanks,

It is difficult to give specific information regarding researches to sample subjects in the stage of collection or donation.

How to cope with the problem

To cope with the problem, many suggestions have been proposed. Among them, two proposals seem practically significant:

- (1) General/broad consent
- (2) Waiver of consent requirement by research ethics committee (REC) where certain requirements are met.

Which approach is better?

General/Broad Consent

General/broad consent to the research use of the donated or left-over samples has been proposed and being obtained in practice with increasing frequency from participants of researches or admitting patients.

General Consent at National Cancer Center Hospital

Since 2002, at the National Cancer Center Hospital in Tokyo, new patients are requested to give general consent to the research use of their left over samples or body parts originally taken or removed for testing and treatment together with their medical information. Patients are given two months to answer to the request. If they return no answer to the request, they are presumed to have consented. They are free to revoke their consent (or presumed consent) any time.

At the website of National Cancer Center, the list of researches using the samples based on general consent and ethics committee approval is shown.

Opinions supporting the validity of general consent

As long as the donors and patients can understand the significance and accompanying risks of giving general/broad consent and are accorded the right to withdraw consent afterward, they should be free to waive their right to determine whether to allow the research use of their body parts on an individual basis.

Most donors and patients would not object to it as long as no detriment will accrue and approval of ethics committee is required of the research using these samples.

Opinions criticizing the validity of general consent

In order to effectively waive the informed consent requirement, donors and patients should have some degree of specific notion about what they are waiving, whereas they have little knowledge about how their samples will be treated in research (Tomita 2001).

Especially, very few of them can be expected to understand how their samples are immortalized by derivation of cell lines and distributed widely and for a long time.

Waiver of Consent Requirement by REC

In Japan, like the rest of the world, waiver of consent requirement by research ethics committee (REC) is provided for in the ethics guidelines for biomedical research and therapy, on condition that certain requirements are met.

Ethics guidelines for biomedical research and therapy

The departments of Japanese government have promulgated, so far, nine sets of ethics guidelines for biomedical research and clinical application of gene therapy and stem cell transplantation.

- (a) Ethics Guidelines for Human Genomic and Genetic Analysis Research (2001)
- (b) Guidelines for Clinical Study of Gene Therapy (2002)
- (c) Guidelines for Derivation and Distribution of Human Embryonic Stem Cells (2009)
- (d) Guidelines for Utilization of Human Embryonic Stem Cells (2009)
- (e) Guidelines for Handling of Specified Embryos (2001)
- (f) Guidelines for Research Developing Germ Cells from Human iPS or Tissue Stem Cells (2010)
- (g) Ethics Guidelines for Epidemiological Research (2002)
- (h) Ethics Guidelines for Clinical Research (2003)
- (i) Guidelines for Clinical Study Using Human Stem Cells (2006)

Provisions for Waiver of Consent Requirement in Epidemiological and Clinical Research Guidelines

Where researchers intend to use existing/stored samples for research, in principle they should secure informed consent from donors. If securing informed consent is impracticable, researchers may use samples without informed consent, only when the institution head grants permission after the REC confirms that one of the following conditions has been met:

- 1) Samples have been anonymized or coded with link information unavailable to researchers.
- 2) [skipped because fulfillment of the conditions listed herein is difficult]
- 3) All of the following conditions are met:
 - A. Information of the research (including the purposes of use of samples) is made public.
 - B. Arrangement has been made to give the donor the right to opt out from the research.
 - C. There is a strong necessity for conducting the research for the public health advancement and it is difficult to secure consent from the donor.

Epidemiological and Clinical Research Guidelines: Provisions for Waiver of Consent Requirement

In many cases, research use of existing/stored samples will become possible by relying on these waiver provisions. These guidelines are silent about broad/general consent. However, some discussion was made about it in the expert committee considering the revision of the guidelines in 2006 through 2008. Most members of the expert committee were of the opinion that the concept of general/broad consent to research use of samples and health information was not widely accepted in Japan to be included in the guidelines.

Author's Opinion: Preference for General/Broad Consent

Regarding this problem, I am of the opinion that general/broad consent is effective in legitimatizing research if the following conditions are met:

First, donors or former patients are given the right to revoke their consent and opt out from the research;

Secondly, personal information is securely safeguarded and there is no risk of injury occurring to them;

Thirdly, efficient mechanisms are instituted for multi-layered information dissemination about researches using those samples and data, such as on the Internet website, so that participants will be able to obtain information according to their informational needs.

Author's Opinion: Rationale

It seems to me that the general/broad consent scheme is superior to the waiver of consent scheme, in that information sharing tends to become possible at an earlier stage. In the case of research use of removed or left over body parts and accompanying clinical data, patients, when requested to give general/broad consent to their research use at their start of clinical relationship, can obtain some notion (however vague it may be) that if they consent, their parts and data will be used for research, and help medical advancement. If the patient happens to be interested in the research, she/he can turn to the Internet website of the hospital and obtain the information about them according to her/his interest and needs.

Author's Opinion: Rationale

In the case of researches using remaining samples after the preceding research or those stored in biobanks, the participant, in the course of informed consent to her/his enrollment in the first research or biobank, can envision the possibility of other researches using them.

With this availability of information about research using her/his own samples and data, her/his right to opt out will become more meaningful. Furthermore, this will contribute to increase in the transparency of medical research and eventually this increased transparency will translate into better relationship of patients/participants and researchers.

Author's Opinion: Rationale

I will not deny this requirement of multi-layered information dissemination would impose extra burden on researchers. However, information sharing according to the individual's informational needs seems essential for observance of the first norm of biomedical research, i.e. respect for persons.

The image features a silhouette of the Beijing National Aquatics Center (Water Cube) and the Beijing Olympic Tower against a sunset sky. The sun is a bright, glowing orb positioned between the two structures, creating a strong backlight effect. The sky is a deep orange, and the structures are dark, with the lattice-like framework of the Water Cube clearly visible. The text "Thank you." is overlaid in a large, white, sans-serif font on the right side of the image.

Thank you.