

中文文章名:研究用人體檢體採集與使用注意事項

英文文章名:Guidelines for Collection and Use of Human Specimens for Research

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Guidelines for Collection and Use of Human Specimens for Research

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1. To ensure the proper collection and use of specimens for research purposes, to safeguard the rights and interests of those providing specimens and to promote proper scientific development, these guidelines have been formulated.

The collection of specimens for research purposes, unless otherwise stipulated by laws and regulations, shall be carried out in accordance with these guidelines.

2. Terms used in these guidelines are defined as follows:

(1) *specimen(s)*: cells, tissue, organs, body fluids or derivatives thereof

(containing genetic material) taken from the human body, to include remnant specimens and specimens taken from an embryo, fetus or cadaver.

(2) *specimen donor*: a person from whom a specimen is collected.

(3) *specimen user*: a person or institution who/that directly uses the specimen, directs another person to use the specimen or who/that may use the specimen in accordance with a specific relationship, such as a contract, with the specimen provider.

(4) *specimen custodian*: a person or institution who/that keeps a specimen.

(5) *ID encoding*: a process of using a code composed of numbers or English letters used to take the place of information, like name, national ID card number and case number, that could serve to identify the specimen donor.

(6) *De-linking*: a process where, after the specimen ID encoding is done, the code and corresponding data that serve to identify the specimen donor are completely and permanently destroyed.

(7) *Remnant specimen(s)*: specimen(s) that remain following pathology examinations, medical lab tests or research.

3. Prior to the collection or use of specimens, a research plan shall be presented and approved by the Committee on Human Trials or similar committee dealing with ethical matters (hereinafter, *ethics committee*) before work may proceed.

For research involving remnant specimens, a research plan shall be sent to an ethics committee for approval prior to use.

4. The collection and/or use of specimens may not violate medical ethics, and care should be taken to prevent harm to people, a specific ethnic group or the environment.
5. For the collection of specimens for use in research, the specimen donor shall be informed of the following, and his/her consent obtained, unless otherwise regulated by law:
 - (1) Purpose and possible scope and dates of use.
 - (2) Method, type, amount and area of collection.
 - (3) Possible complications and dangers.
 - (4) The rights and interests of the donor and the obligations of the user and the custodian.
 - (5) The significance of the research.
 - (6) The reasons for selecting the donor.
 - (7) Anticipated research results.
 - (8) Reasonable extent of foreseen risks and negatives.
 - (9) The mechanism for safeguarding the privacy of the specimen donor.
 - (10) The fact that a potential specimen donor may refuse to participate in the research or, after participation, may withdraw from the research at anytime, as well as the procedures for doing so. A refusal to participate in, or a withdrawal from, the research will not affect the medical care the patient is due.
 - (11) The impact of information obtained from the research could have on the specimen donor and the donor's family or ethnic groups.
 - (12) The identity of the specimen custodian and specimen user.
 - (13) Whether or not the specimen will be supplied to, turned over to or authorized for use by a domestic or foreign third party.
 - (14) Handling of remnant specimens.
 - (15) Source of research funding and those institutions participating in the research.
 - (16) Other important information relative to specimen collection, medical case review, follow-up exams and tests or information related to the patient's condition as required by the research plan.

With regard to remnant specimens used for research, except for the items indicated in Sub-paragraphs 2 and 3 of the preceding paragraph, the donor shall be notified of the remaining items and his/her consent obtained.

The notification and consent referred to in the preceding two paragraphs shall be done in writing and accompanied by an oral notification to make certain that the specimen donor has a clear understand of the contents.

6. Collection of a specimen from an embryo or fetus requires the consent of the mother.

If a specimen donor is a minor under seven years of age, consent shall be given by a legal representative of the child; if the donor is a minor seven years or older, consent shall be given by both the legal representative and the donor; if the donor is decisionally impaired, then consent shall be given by the legal representative, but if there is no legal representative, consent shall be given by the closest relative; for a specimen provided from a cadaver, consent may be obtained from the closest relative or be in the form of a written consent agreement signed by the deceased prior to death.

The “closest relative” referred to in the preceding paragraph refers to the following:

- (1) spouse
- (2) an adult inferior lineal relative by blood
- (3) parents
- (4) brothers and sisters
- (5) grandparents
- (6) great-grandparents or third-degree collateral relative by blood
- (7) first-degree direct relation by marriage

A written consent agreement of the closest relative may be done by one person; if there is no unanimity among several closest relatives, a priority list in accordance with the listing of the preceding sub-paragraphs shall be set up. In the case of relatives with the same priority, the degree of relationship shall take precedence; in the case of an identical degree of relationship, the co-habiting relative shall have precedence; if there is no co-habiting relative, age shall take precedence.

7. When the collection and use of a specimen may possibly give rise to rights and interests, such as commercial profits, the specimen user shall notify the donor and complete the necessary written contract.

When the specimen collection referred to in the previous paragraph is done from an embryo or fetus, a cadaver, a minor or a person with decisionally impairment, the specimen user shall notify the designated consent-giver as stipulated in the preceding section and shall complete the necessary written contract.

8. When research results can reasonably be anticipated to have a significant impact on the personal health of an identifiable donor, the specimen user will obtain approval from the ethics committee and, if the donor chooses to be informed, the specimen user shall notify and assist the donor with the relevant and necessary counseling.

The review by the ethics committee as referred to in the preceding paragraph, shall take into consideration the degree to which the health of the donor is endangered as well as the cost efficiency related to prevention and treatment.

9. The specimen user shall use the specimen within the parameters as agreed by the donor or as prescribed by law.

If use of the specimen is to exceed the parameters outlined in the previous paragraph, the notification and review procedures shall be carried out as stipulated in Sections 3, 5 and 7.

10. Unless otherwise provided by law, the potential specimen donor may refuse permission to collect a specimen, may terminate the specimen use agreement or may change the agreed parameters for use. However, cases where personal information has been de-linked from the specimen shall not be subject to this decision.
11. The specimen custodian and/or specimen user shall keep and manage the specimen in an appropriate manner.

When use of the specimen is completed, or when the donor terminates the specimen use agreement, the destruction of the specimen shall be certified; without prior written agreement on the part of the donor, the specimen may not continue to be kept. However, cases of specimens that have undergone de-linking shall not be subject to this decision.

12. The specimen custodian and the specimen user shall respect and safeguard the publicity rights of the specimen donors

All confidential, private or personal information regarding the specimen donor that becomes known as a result of collection, retention or use of the specimen may not be disclosed without cause.

The specimen collection and management procedure shall be carried out using an ID encoding, de-linking or any other method that provides anonymity for the donor.

When a specimen user provides information obtained from a specimen to a third party or makes the information public, the specimen user shall do so in a manner that prevents identification of the donor's personal information.

13. Without an ethics committee review or the safeguarding of the rights, interests and safety of the specimen donor and the public, no specimen shall be turned over or authorized for use in a foreign country.
14. For any one of the following circumstances, the restrictions stipulated in Section 5 and 7 may be waived; however, the stipulations of Section 3 with regard to an ethics committee review and approval shall still be followed before action may be taken:
 - (1) It is difficult to determine the identity of the specimen donor.
 - (2) Because it is impossible to trace or establish contact with the donor, it is difficult to obtain a renewed consent agreement.
 - (3) Specimens that could be publicly obtained prior to the issuance of these revised guidelines.
15. When specimens collected in accordance with these guidelines are used for teaching purposes, the stipulations of Section 12 may be use.