

Instructions for Storage of Biological Materials

Current federal regulation set criteria for use of participant specimens: 1) participant specimens can only be used for research described in the protocol and consent and 2) any new research use of identifiable specimens must be approved by the IRB. The consent form for storage and future use of biological materials from your current study offers several options. The form included in the IRB materials is the recommended template according to University policy. If you are using protocols from organizations outside the University and wish to use their consent form(s) for the storage and future use of biological materials, please note that they must conform in the following manner:

- 1) They must offer the choice for or against storage and future use of biological materials independently of the subjects right to participate in the current study (the subject's participation cannot be contingent on allowing storage and/or future use of the collected materials).
- 2) The consent must offer the subject the right to be contacted before future use of the stored materials OR MAKE IT CLEAR in simple terms to the subject that consent for storage and future use has no such limitations.
- 3) The consent must offer the choice between coded/identifiable storage or unlinked storage OR MAKE IT CLEAR in simple terms to the subject that storage will, if implemented, be of linked or unlinked nature.

Each extramural consent form for storage and future use of biological materials will be compared with the University template for compliance with the general spirit of the conditions listed above. Failure to meet these criteria will result in rejection of the entire protocol OR in elimination of the option for storage and future of biological materials from the current study.

Anonymized biological specimens

Additional consent is not required for the use of biological specimens that have been anonymized. However, consent to obtain biological specimens is required if the specimens are being obtained outside the study protocol or in addition to specimens obtained for study related purposes, even if these specimens are then anonymized.

Consenting Participants

It should be made clear to participants that they may refuse permission for future research use of their biological specimens without affecting their participation in the study or their care by the health provider. It should also be made clear to participants that they may change their mind and refuse to permit their specimens to be used at some time in the future.

Minors

If a parent/guardian gave consent on behalf of a minor, the child as an adult may rescind the permission to use the identifiable biological materials.

Storage of Biological Materials

Stored biological materials (e.g. tissues, blood, body fluids, urine, hair, skin) from research activities are periodically used by investigators to make important new measurements that were not possible at the time that the original research was conducted.

You are being asked to allow storage of your biological materials that remain from the current research. Your consent is needed to store such materials, and certain choices about how your materials may be used, identified, and about how you may be contacted in the future are listed. Future uses may include, but may not be limited to, research, education and commercial development.

Depending upon your choices, information gained from future studies could be linked to you by name or identifying number. Please consider the extent to which you wish your stored materials to be so identified when selecting below.

Choices for Study Participant

Your choice(s) below DO NOT affect your ability to participate in the current study.

Do you wish to allow storage of your remaining biological materials?

✦ Yes ✦ No

The choices below affect only FUTURE research that might be performed on your biological materials if you give your permission for them to be stored. Yes will mean that investigators may store biological materials for future use.

Do you wish to limit the use of your stored biological material?

✦ Yes ✦ No

If you answered Yes to the above question, please check the limits you wish to impose on the use of your stored biological materials:

_____ a. My coded, stored biological materials may be used for any study relating to the condition for which the sample was originally collected, and I may be contacted to seek my permission for other types of studies.

_____ b. My coded, stored biological materials may be used for the specified study only, but I may be contacted to seek my permission to do further studies related to or separate from the specified study.

_____ c. My coded, stored biological materials may be used for the specified study only, and is to be destroyed after that use with no further contact permitted to seek permission for future studies

_____ d. My unidentifiable/unlinked biological materials may be used for future research
Specify any limitations, if desired: _____

If you agreed to allow storage, the samples will be stored by: (name/location)

Security will be provided by: (responsible person/agency)

Research Results/Medical Records

Results from future research using your samples/cultures may be presented in publications and meetings but your name will not be identified.

If future research on your samples provides meaningful information related to your health, you may choose to:

- ✦ Have the investigator contact you. (You must then notify name and phone number of changes in your address or telephone number).
- ✦ NOT be given to you or your doctor and reports NOT to be in your health/medical record.

Confidentiality

In order to prevent misuse of records and to protect your privacy, your identity will not be disclosed, except as described in this consent document.

Right to Withdraw

You have the right to withdraw from the study at any time. If you agree now to future use of your specimens, but decide in the future that you would like to have them removed from research tests, you should contact the study investigator. Any remaining samples you have contributed will be discarded at the point of your withdrawal. However, results obtained prior to your withdrawal from the study will be maintained, and your privacy will be preserved.

Subject's signature

Date

Parent or Guardian Signature

Date

(Must be signed if subject is a minor or cognitively unable to give consent)

Signature of Person Obtaining Consent

Date