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## GUIDANCE: Consent Language for Banking Samples and/or Data

The research team must ensure that the consent form and protocol reflect whatever data and/or sample-sharing obligations the funder imposes. If requirements for data and/or sample sharing seem inconsistent with PPHS policy on Future Use of Research Data and/or Specimens, please contact the PPHS promptly and directly.

There are THREE possible options you can choose from. The available option(s) depends on whether the research study holds out a prospect of direct benefit to participants, as determined by the IRB.

### INSTRUCTIONS:

**When to use Option 1:** The data and/or samples collected for this study will only be used to complete the study and not banked for future research. You can select this option for any applicable studies regardless of the prospect of benefit to the participant.

**When to use Option 2:** The data and/or samples collected for this study will be used to complete the study and one day the study team may wish to use or share the data and/or samples for future research. This statement can only be used if the study does **NOT** offer the prospect of direct benefit **AND** the researcher does not wish to give participants granular control over future uses of data and/or samples. If there is a prospect of direct benefit then you cannot compel (require) future use and you should use Option 3. Likewise, use Option 3 if you wish to offer choices even if it not mandated by policy. In addition, the consent form should include the suggested description and risks of large public repositories as detailed below if you will be sending data and/or samples to such repositories.

**When to use Option 3:** Use Option 3 if the study offers the prospect of direct benefit and you wish to use or share data and/or samples collected for future research in ways the participant allows. Edit the questions in this option to include only the specific customizations available to the participant. For example, if data and/or samples will always be linked to identity, even with a code, then do not include question 2 and instead state that in a brief description of the data and/or sample banking before asking the questions.



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Using the instructions above, select ONE of the options below, then delete all others:

**OPTION 1:**

The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed.

**OR**

**OPTION 2:**

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. **[Delete any of the following statements that do not apply].** Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

- **[Please review and consider Question 6 under Option 3. If applicable and appropriate, modify Question 6 to make it a statement (rather than a question).**
- **Add relevant additional information here. For example, explicitly saying that future research may involve for-profit, international, non-academic partners; there will be use of a GUID deposition in a large repository]**

**OR**

**OPTION 3:**

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select 'No' each time.



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The following question(s) should be selected and or modified to reflect your protocol. Tailor this section based on whether data and/or samples are collected for the research by removing terms that do not apply. For example, if samples are not collected for the study, delete the word “samples” throughout.

**(1)** Will you allow the researchers to store your data and/or samples to use in future research studies?

**Please initial your choice:** Yes \_\_\_\_\_ No \_\_\_\_\_

If you select No, please stop here and move to the next section, '**Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

It is relatively rare, but occasionally researchers find it useful to offer this option to potential participants. You are not obligated to make this offer and may remove this text.

**(2)** The researchers can store your data and/or samples in one of two ways:

- a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.
- b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously \_\_\_\_\_



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I would like my data and/or samples stored with a link to my identity through the use of a code\_\_\_\_\_

**(3)** Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes\_\_\_\_\_ No\_\_\_\_\_

**(4)** Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes\_\_\_\_\_ No\_\_\_\_\_

**(4.1)** From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes\_\_\_\_\_ No\_\_\_\_\_

- a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
- b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
  - I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
  - II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and



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nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

**(5) Do you give permission to have your data and/or samples given to other researchers, including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?**

Please initial your choice: Yes \_\_\_\_\_ No \_\_\_\_\_

Ask question 6 below if you selected Option 3 and plan to deposit data and/or samples in large public repositories. If Option 2 is being used and it is appropriate, add this language, without making it a question.

**(6) Do you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above?** Please read the paragraphs below which explains repositories, then initial your choice:

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. . Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in the Risks section. [If in the future participants wish to withdraw data and/or samples from the repository, either insert instructions or refer them to the withdrawal section of the consent form.]



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If a GUID will be used, insert language here and expand if necessary. NIMH, for example, has good sample language available on their website.

Researchers will use a Global Unique Identifier, a computer-generated ID, which cannot be linked back to your identity. This is so any data collected from you is linked to one unique ID, so [name the repository] can make sure your data is secure and is not accidentally duplicated if you take part in research at multiple sites.

Please initial your choice: Yes \_\_\_\_\_ No \_\_\_\_\_

Whether or not you have allowed us to share your data and/or samples with [name the repository], the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.