

## SUGGESTED HIPAA COMPLIANT LANGUAGE FOR DATA BANKS/REPOSITORIES

When HIPAA regulations took force on 4/14/03 it was necessary to modify the informed consent language for data repositories. This change was needed because HIPAA does not allow subjects to give authorization for *unspecified* future uses of PHI (protected health information). The following language replaces the suggested language currently found in the IRB manual starting on page 57. Those subjects who have signed a consent with the previous language before 4/14/03 do NOT have to be re-consented, unless they are being re-consented for other reasons. The signed pre 4/14/03 consent remains valid for future uses of their PHI as specified.

**NOTE: Not all studies will need to use all of the following language. Select the appropriate options to include in the consent document based on the particulars of the project's protocol (example: some projects make data banking a mandatory part of participating in the research project so question #1 should be deleted if that is the case; some projects require linked data and therefore question #2 would need to be rewritten as a statement that removes the option for anonymous data storage).**

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The researchers would like to ask your permission to keep information collected about you during this study to use it in future research studies. The researchers would also like to know your wishes about how your information might be used in future research studies. You should also know that it is possible that products may someday be developed with the help of your information, and there are no plans to share any profits from such products with you.

**(1)** Will you allow the researchers to store your information to use in future research studies?

Yes \_\_\_\_\_ No \_\_\_\_\_ If no, please stop here. If yes, please continue to the next question.

**(2)** The researchers can keep your information stored in one of two different ways: one way will store your information in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information anonymously (no one will know who this information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your information stored anonymously, you will not be able to change your mind to ask for your information to be destroyed at a future date.

How would you like your information stored? Please initial **ONE** choice:

I would like my information stored with a link to my identity \_\_\_\_\_

I would like my information stored anonymously \_\_\_\_\_

**(3)** Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes \_\_\_\_\_ No \_\_\_\_\_

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**(4)** Do you give the researchers permission to keep the information indefinitely and use it for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes \_\_\_\_\_ No \_\_\_\_\_

**(5)** Do you give the researchers permission to keep the information indefinitely and use it for future studies that are **not related** to the purpose of this study (for example, a different area of research)? Please initial your choice:

Yes \_\_\_\_\_ No \_\_\_\_\_

**(a)** If the future research in a different area can be done without having to know that the information came from you personally, that will be done.

**(b)** If the future research in a different area requires that we know who the specific information came from, then we will do one of the following:

**(i)** If you allowed the researchers to contact you in the future, they will be able to contact you to explain why your information is needed and what will be done with it. Your permission will be asked to use your information 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, we may still use your information. Either all links to your identity will be removed, or an Institutional Review Board will be asked for permission to use the information linked to your identity. The Institutional Review Board (IRB) is a committee of doctors and scientists and non-scientists and people not associated with this hospital or medical school whose job it is to protect people who participate in research. The IRB can give permission for researchers to use and share health information that is linked to people's identities, but only if it determines that doing this will not be more than a minimal risk to people or their privacy.

**(6)** Do you give the researchers permission to have your information **given to other researchers** at Mount Sinai or other institutions for use in research that is either related or not related to the purpose of this study? Please initial your choice:

Yes \_\_\_\_\_ No \_\_\_\_\_