



**REGULATORY REFERENCES ~~FOR~~ CONSENT
LANGUAGE FOR FUTURE USE OF
INFORMATION OR BIOSPECIMEN~~ISSUE~~
BANKING ~~CONSENT LANGUAGE~~**

Background

Prior to the implementation of the revised Common Rule (effective date January 21, 2019), the University of Utah policy required specific language to be included in an informed consent document if researchers planned to keep and use biospecimens for future use. The University of Utah now requires language to be included in consent documents if researchers plan to collect and store biospecimens and/or information for future use (i.e., biospecimen banks, data repositories). The University of Utah does not utilize the option for broad consent 45 CFR 46.116(d).

Information that must be included in the consent procedure for the future use of private information or biospecimens is outlined in the Consent Document Checklist on the IRB website. Investigators may also use the model consent language that is also provided on the IRB website. These models have all the required language that should be included and outline options to modify based on different studies.

Acronyms

- HIPAA:** Health Insurance Portability and Accountability Act
- OHRP:** Office of Human Research Protections

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#	Element Description	Commentary and Regulatory References
1	State the purpose(s) for collecting tissues for the tissue bank and the type(s) of future research that may be done on the samples. Is there a description of what is collected, the purpose(s), and the types of future research?	<p>Commentary: Indication of the type of information and/or sample to be collected part of the description of study procedures, as required by the following regulation.</p> <p>OHRP: "In seeking informed consent the following information shall be provided to each subject: (1)...a description of the procedures to be followed..." (45 CFR §46.116(b)(1))</p> <p>Commentary: <u>The purpose for collecting the private information or biospecimens should be explained.</u> The level of specificity for the purpose and types of future research is determined case-by-case. Authority is given to the IRB to determine how specific a consent form should be, based upon the following regulatory requirements and guidelines.</p> <p>OHRP: "In seeking informed consent the following information shall be provided to each subject: (1)...an explanation of the purposes of the research..." (45 CFR §46.116(b)(1))</p> <p>▲ <u>Included among the basic elements of informed consent should be a clear description of...the specific types of research to be conducted. Informed consent</u></p>

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		<p>information describing the nature and purposes of the research should be as specific as possible.” (Issues to Consider in the Research Use of Stored Data or Tissues, November 7, 1997)</p> <p>HIPAA: “A valid authorization under this section must contain at least the following elements: (iv) A description of each purpose of the requested use or disclosure.” (45 CFR §164.508(c)(1)(iv))</p> <p>“In order to satisfy the requirement that an authorization include a description of each purpose of the requested use or disclosure [45 CFR §164.508(c)(1)(iv)], an authorization for uses and disclosures of protected health information for future research purposes must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research.” (Federal Register, Vol. 78, No. 17, pg 5612)</p>	<p>Formatted: Font: (Default) Calibri Light</p> <p>Formatted: Font: (Default) +Headings (Calibri Light)</p> <p>Formatted: Font: (Default) +Headings (Calibri Light)</p>
2	<p>State what type of sample (blood, urine, tissue, etc.) will be collected.</p>	<p>Commentary: Indication of the type of sample to be collected is part of the description of study procedures, as required by the following regulation:</p> <p>OHRP: “In seeking informed consent the following information shall be provided to each subject: (1)...a description of the procedures to be followed...” (45 CFR §46.116(a)(1))</p>	<p>Formatted: Font: (Default) +Body (Calibri)</p> <p>Commented [AS1]: Combined with element 1</p>
23	<p>State who manages the tissue bank and where the tissues will be kept. The tissue bank may be managed by the investigator locally or may be managed by the study sponsor. Is the management of the data repository or the specimen repository described?</p>	<p>Commentary: General background information about the management of the data repository and/or biospecimen tissue bank is required according to the following guidance.</p> <p>OHRP: “Included among the basic elements of informed consent should be a clear description of...the operation of the cell repository...” (Issues to Consider in the Research Use of Stored Data or Tissues. November 7, 1997. Available at: http://www.hhs.gov/ohrp/policy/reposit.html)</p>	<p>Formatted Table</p> <p>Formatted: Font: (Default) +Headings (Calibri Light)</p>
34	<p>Is the option to participate in banking biospecimens or the data repository thoroughly explained?</p> <p>State whether or not it is mandatory to participate in the tissue bank if the participant wants to be in the full study. Some studies require participation in the tissue bank as a condition of participation; this must be stated. Other studies are designed only for the purpose of tissue banking. If tissue banking is the purpose of the study, this must be made clear to the participant.</p> <p>You may not condition participation in a treatment/interventional trial upon mandatory participation in a tissue bank. Participation in the</p>	<p>Commentary: Some studies require participation in a biospecimen bank or data repository as a condition of participation; this must be stated. Other studies are designed only for the purpose of collecting biospecimens or data for future use. If the collection of biospecimens or data for future research is the sole purpose of the study, this must be made clear to the participant. Mandatory biospecimen tissue banking participation as part of a clinical trial, where the clinical trial may potentially provide beneficial treatment to a participant, can be viewed as coercive. Biospecimen tissue banking can be viewed as a component that should be voluntary and separate from the clinical trial such that not participating in the tissue bank does not cause the participant to give up the potential benefit of the clinical trial. Mandatory participation is prohibited in many cases, according to the following regulatory requirements and guidelines.</p> <p>OHRP: “An investigator shall seek such consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.” (45 CFR §46.116(a)(2))</p> <p>“In seeking informed consent the following information shall be provided to each subject: (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and</p>	<p>Formatted: Font: (Default) +Body (Calibri)</p> <p>Formatted: Font: (Default) +Body (Calibri)</p>

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tissue bank must be **optional** for treatment/intervention trials.

the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.” (45 CFR §46.116(b)(8))

HIPAA: *“The final rule adopts the proposal to amend [46 CFR] 164.508(b)(3)(i) and (iii) to allow a covered entity to combine conditioned and unconditional authorizations for research provided that the authorization clearly differentiates between the conditioned and unconditioned research components and clearly allows the individual the option to opt in to the unconditioned research activities. ...[C]ombined authorizations could be obtained for the use of protected health information in a clinical trial and **optional** sub-studies, as well as for biospecimen banking that also permits future secondary use of the data. ...We decline to permit a combined authorization that only allows the individual the option to opt out of the unconditioned research activities (e.g., “check here if you do NOT want your data provided to the biospecimen bank”) because an opt out option does not provide individuals with a clear ability to authorize the **optional** research activity, and may be viewed as coercive by individuals.” [emphasis added] (Federal Register, Vol. 78, No. 17, pg. 5610)*

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54 Is there a description of whether personally identifiable information will be collected with the biospecimens?

State whether or not personally identifiable information will be collected with the sample. Include the type of identifiers (name, date of birth, etc.) that will be collected.

a. If identifiers are collected, state who will have access to the identifiable information (i.e. the investigator, the sponsor, the other future investigators, etc.).

i. In order to allow maximum flexibility for sharing samples and identifiers with future researchers, the IRB encourages you to state that samples and identifiers may be shared within the local institution, as well as the local affiliate institutions. Local affiliate institutions include the University of Utah, VA SLCHCS, and Primary Children's Medical Center. [N/A if the bank is managed exclusively by the sponsor on an external institution.]

b. If identifiers are collected, state whether or not participants can choose to have their samples de-identified (de-identified means no identifiable link back to the participant exists).

Commentary: State whether or not personally identifiable information will be collected. If identifiers are collected, state who will have access to the identifiable information (i.e. the Investigator, the sponsor, the other future investigators, etc.). In order to allow maximum flexibility for sharing samples and identifiers with future researchers, the IRB encourages you to state that samples and identifiers may be shared within the local institution, as well as the local affiliate institutions. Local affiliate institutions include the University of Utah, VA SLCHCS, and Primary Children's Medical Center. [N/A if the bank is managed exclusively by the sponsor on an external institution.]

If identifiers are collected, state whether or not participants can choose to have their samples de-identified (de-identified means no identifiable link back to the participant exists). Tissue samples and associated data must be protected in order to protect the privacy and confidentiality of subjects, according to the following requirements.

OHRP: "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." (45 CFR §46.111(a)(7))

"In seeking informed consent the following information shall be provided to each subject: (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." (45 CFR §46.116(e)(5))

"Included among the basic elements of informed consent should be a clear description of...conditions under which data and specimens will be released to recipient-investigators; and procedures for protecting the privacy of subjects and maintaining the confidentiality of data." (Issues to Consider in the Research Use of Stored Data or Tissues. November 7, 1997. Available at: <http://www.hhs.gov/ohrp/policy/reposit.html>)

HIPAA: "A valid authorization under this section must contain at least the following elements: (i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;...(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure." (45 CFR §164.508(c)(1)(i & iii))

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56 Describe the procedures that participants should follow if they want to withdraw their samples from the tissue bank. Is there a description of the procedures that participants should follow if they want to withdraw samples or information?

Commentary: Participants must be provided with instruction for withdrawing from the study according to the following regulatory requirements.

OHRP: "When appropriate...the following elements of information shall also be provided to each subject: (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject." (45 CFR §46.116(c)(4))

Commentary: If participants are unable to withdraw their samples or information at a later time, it can be viewed as coercive to cause the participant to forfeit their right to voluntary participation in research. In some cases, withdrawal of samples or information is not possible, i.e., if samples or information are de-identified. Authority is given to the IRB to determine case-by-case if withdrawal of samples or information must be provided as an option, based upon the following regulatory requirements.

OHRP: "An investigator shall seek such informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence." (45 CFR §46.116(a)(2))

"In seeking informed consent the following information shall be provided to each subject: (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." (45 CFR §46.116(b)(8))

HIPAA: "In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following: (i) The individual's right to revoke the authorization in writing, and either: (A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization..." (45 CFR §164.508(c)(2)(i)(A))

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67 Is there a statement about whether the future use of the participant's biospecimens may be used for commercial profit?

Include the commercialization language **verbatim**.

Commentary: Language about commercialization intends to inform participants of the expectation for personal compensation resulting from the future use of the samples.

OHRP: "When appropriate...the following elements of information shall also be provided to each subject: (7) A statement that the subject's biospecimens even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit" (45 CFR §46.116(c)(7))

Commentary: Language about commercialization intends to inform participants of the expectation for personal compensation resulting from the research. This statement must not include exculpatory language that would cause participants to waive or appear to waive any legal rights. Requirements regarding exculpatory language are included in the following regulations.

OHRP: "No informed consent, ~~whether oral or written~~, may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." (45 CFR §46.116(a)(6))

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78 Is there a description of whether future results or findings will be given to the participants? State whether or not the future results or findings will be given back to the participant.

If results or findings will be disclosed, describe the process for this interaction.

Commentary: The decision to provide the results of research to the participants stems from the general requirements to provide benefit to the participants, when possible, and to provide participants with significant new findings that may relate to their willingness to participate. Authority is given to the IRB to determine case-by-case if future research results must be provided, based upon the following regulatory requirements and guidance.

The Belmont Report: *“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being... Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”* (Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979.)

OHRP: *“When appropriate...the following elements of information shall also be provided to each subject: (5) A statement that significant new findings developed during the course of the research that which may relate to the subject’s willingness to continue participation will be provided to the subject.”* (45 CFR §46.116(c)(5))

OHRP: *“When appropriate...the following elements of information shall also be provided to each subject: (8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.”* (45 CFR §46.116(c)(8))

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