

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER:
SECTION: Banking of Data and Biological Specimens for Future Use
REVIEW RESPONSIBILITY: IRB Leadership Committee and HIC Policy Review
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Yale University School of Medicine HIC Policy Regarding: Banking of Data and Biological Specimens for Future Use

THE PROTOCOL

If a bank or repository is to be created for data or for specimens and the banking is a part of a research study or clinical trial protocol, the protocol must describe its operation and safeguards so that data/specimens can continue to be stored and used for future research purposes. The IRB must approve this aspect of the protocol as well as the current or primary parts of the protocol. If the repository might receive data or specimens from another study or another source, the protocol should be separate and independent. The IRB must approve its creation, operations, and existence.

PLEASE NOTE: Banking for future research, which is usually not yet specified in detail, is often proposed to potential subjects. A general area of future study (e.g., psychiatric diseases, conditions and disorders) must be stated to the prospective subject. Unlimited or unspecified uses of the data or biological specimens are not permitted.

When a developed protocol is ready for the future research, it would be submitted to the IRB that has authority over the repository for approval. Permission to proceed with the research would be necessary prior to releasing the data or specimens. That IRB and/or another IRB could have authority over the new research. If consent and authorization had been obtained when data/specimens went into the bank, approval of the research without further specific consent would often be possible via a waiver of consent if the focus of the research is consistent with the areas of study specified in the original or banking consent. If they had not been obtained, approval would often not be possible.

Generally speaking, OHRP Guidance requires that informed consent should be obtained from each donor-subject in accordance with HHS regulations at 45 CFR 46.116. Included among the basic elements of informed consent, the ICD should have a clear description of

- ◆ the operation of the repository,
- ◆ the specified types of research in general terms to be conducted (e.g., development, cancer, brain biology, mental illness, behavior, heart function, heart disorders),
- ◆ the 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.
- ◆ where human genetic research is anticipated, informed consent information should include information about the consequences of DNA analysis (e.g., disease prediction, if probability is high; possible

discrimination; possible determination of paternity or other family relationships).

Samples of repository protocols have been provided by members of the Yale faculty. You may view these examples at <http://info.med.yale.edu/hic/forms>.

OBTAINING CONSENT

Obtaining informed consent and authorization to bank data or biological specimens for future research purposes can be obtained by using a separate, or stand alone, informed consent document (ICD) and research authorization form (RAF). Alternatively, the investigator may combine the ICD and RAF to create a compound consent and authorization form. The primary ICD and RAF are for the current research protocol. This method allows the consent and authorization documents, or compound consent and authorization form, to outlast the primary study in which the subject is participating. For an example of a compound consent and authorization form see the *Permission to Store and Use Clinical or Research Information for Future Research Purposes* at <http://info.med.yale.edu/hic/forms>.

Consent and authorization can also be obtained by inserting the relevant banking information into the ICD used to obtain consent for participation in a research study or clinical trial. Please note however, that DHHS Guidance requires that a HIPAA Research Authorization Form (RAF) for the storage of collected specimens/data for future research be separate from the RAF used in a clinical study in which research-related treatment is conditioned. This is because HIPAA requires that an authorization be study specific. Thus a single authorization cannot function as a permission document to use protected health information (PHI) in a research-related treatment protocol, including payment, or determining eligibility for benefits and as a permission document to bank the data for future research purposes. Thus, placing a request for banking (for future research) in an ICD triggers the requirement for two (2) RAFs. It also commits the investigator to return to the ICD with the repository or bank to legitimize the future research.

A third method would use a compound consent and authorization form in which the primary study was described and the banking process was also described. The compound form would have to authorize creation, use, and disclosure of protected health information for both the current study and the banking. The form would have to be available for both purposes (for auditors, legal challenges, etc.)

CHECKLIST

Investigators are encouraged to use the “Banking Checklist” to help identify the required consent elements when drafting an ICD that includes the banking of data or biologic samples for future research studies. The checklist can be found at <http://info.med.yale.edu/hic/forms>.

Consent Elements Checklist for Storage of Data or Biologic Samples for Future Use				
1. General Format/Style Issues		Yes	No	N/A
	<p>If the permission to bank biological samples or data is combined with the informed consent document (ICD) used to obtain consent for participation in a research trial proceed to Section 2.</p> <p>If the consent for banking is separate from that consent form approved for the primary study, is the consent form formatted with the proper headers (Study title, name of Principal Investigator, HIC#, Funding Source) and page numbers, using the HIC template?</p>			
	Is the consent form written in lay language that will be readily understood by the intended audience?			
	Is medical jargon avoided, and are any/all technical terms fully explained?			
	Is the consent form legible, written in at least 12-point font, and properly spaced?			
2. Invitation/ Description of Banking and Secondary Uses				
	Does the consent form use the second person (you, your, etc.) throughout?			
	Is the potential subject clearly invited to donate tissue or data to a repository for future research purposes?			
	Does the paragraph briefly (in a few sentences) specify the nature and purposes of the future research in general terms (e.g., development, cancer, brain biology, mental illness behavior, heart function, heart disorders)?			
	Is the potential subject clearly informed why he or she has been invited for participation?			
3. Description of Procedures				
	Does the ICD include a clear description of the operation of the repository?			

	Does the ICD include a clear description of the conditions under which data or specimens will be released for future research purposes to the investigators who are listed on the banking protocol?			
	Does the ICD include a clear description of the conditions under which data or specimens will be released for future research purposes to recipient investigators who are not affiliated with the banking protocol?	Yes	No	N/A
	Does the ICD note that recipient investigators will receive the data or specimens after receiving approval by an IRB ?			
4. Risks and Inconveniences				
	Does the investigator clearly describe potential risks associated with banking (e.g. potential loss of privacy)?			
	When appropriate, does the consent form include a statement that the future research may involve risks that are currently unforeseeable?			
	Where future human genetic research is anticipated, does the ICD include information about the consequences of DNA analysis (e.g., disease prediction, if probability is high; possible discrimination; possible determination of paternity or other family relationships)?			
5. Benefits				
	Does the consent form clearly describe any expected benefits to the subject as a result of the banking activity? (If there is no individual benefit, the consent form should state this).			
	Does the consent form clearly describe any benefits expected to accrue to the population the subject represents or to society in general as a result of future research studies?			
6. Economic Considerations				
	Does the ICD note that subjects will not be compensated for donating their data or biologic samples to the repository?			
	Does the ICD note that subjects will not be compensated for the use of their data or biologic samples in future research studies?			
	Does the ICD note that there are no plans to compensate the donors of data/specimens should the future use of said samples result in a profitable product?			

7. Alternatives to Participation				
	Does the ICD note that the subject need not participate in the banking arm or protocol in order to participate in a primary clinical trial or research study?			
8. Confidentiality		Yes	No	N/A
	Does the consent form provide a thorough outline of the procedures in place to ensure the confidentiality both of subjects' participation, as well as their data?			
	Certificate of Confidentiality is recommended by OHRP for the repository operations. Does the consent form state this, as well as providing a description of the extra protection (and limitations to such protection) that is afforded?			
	Does the consent form list any agencies or persons (such as the study sponsor, members of the HIC, or regulatory agencies) who will have access to study records?			
	Does the study involve diagnostic or genetic testing? If so, are the relevant confidentiality issues (how will samples be stored, withdrawal of samples, plans for return of information to subjects, etc.) addressed?			
9. In Case of Injury				
	For studies posing minimal risk to subjects, this section may be omitted. Do you believe it is appropriate to omit the section? If the section is included and you have informed the subject that compensation for injury is not available, have you also noted that the subject does not give up any legal rights by signing consent?			
10. Voluntary Participation				
	Is the potential donor-subject informed that his or her participation is voluntary, and that he or she may withdraw from the study at any time?			
	Is the potential donor-subject informed that his or her data or specimens will continue to be used in secondary uses for which the data or specimens were released prior to the donor-subject indicating that he/she no longer wished to have identified data shared for future uses?			
	Does the ICD indicate whether the identifiable data or samples will be destroyed or de-identified and whether the subject has a choice between these alternatives if both exist? If de-identified, is the subject-donor informed that data or samples may continue to be used?			
11. Questions				
	Is the potential subject offered the chance to discuss the			

	study with the investigator (or his or her designee), and to ask any questions he or she may have?			
12. Miscellaneous				
	For studies involving non-English speaking subjects, has the ICD been translated into all relevant languages?			
	Does the banking of data include information from any “secondary subjects,” for whom a separate consent form should be developed?			