



**THE OHIO STATE UNIVERSITY**

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# Data and Specimen Repositories

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## Objectives

- ✓ Review relevant definitions related to data and/or specimen repositories
- ✓ Review regulatory and Ohio State policy requirements for repositories
- ✓ Explore consent and HIPAA authorization requirements for repositories
- ✓ Discuss how current repository requirements affect both new and ongoing studies



## Overview

- Background
- Definitions
- Examples
- Elements of a repository protocol
- Additional consent elements
- FAQs
- Related Ohio State Human Research Protection Program (HRPP) policies and guidance



## Background

- The volume of research involving data and bio-specimens has grown exponentially
- Current practices have evolved nationally to place greater emphasis on the ethical obligation to obtain prospective informed consent for collection and retention of data and/or specimens for future research uses (i.e., banking) and to reconsider research uses of data and specimens (particularly identifiable materials) for which consent was never obtained



## Background (cont.)

- A multidisciplinary working group representing investigators, IRB leaders, and research administrators was convened
- Existing guidance, national and international standards, and peer institutions' policies and practices were considered and recommendations were forwarded to the IRB Policy Committee
- The Research Involving Data and/or Biological Specimens Policy was updated by the IRB Policy Committee to include recommendations from this working group



## Background (cont.)

Most important elements of the revised policy:

- Banking or repository protocols must stand alone (i.e., not included in an existing clinical/research project and not combined with analysis projects)\*
- Consent is required to establish new repositories/banks
- For existing repositories/banks, the IRB may require investigators to develop a consent process/form that conforms to current standards

\*For banks/repositories controlled by Ohio State



# Definitions



## Anonymous

Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information or materials (e.g., data or specimens) that cannot be linked directly or indirectly by anyone to their source(s)







## De-identified

All direct personal identifiers are permanently removed (e.g., from data or specimens), no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s)

**Note:** For purposes of Ohio State HRPP policy, protected health information is de-identified when it is considered de-identified by HIPAA standards



## Coded

Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code

**Note:** A code is sometimes also referred to as a “key,” “link,” or “map”



## Retrospective

Also, **Existing**. Available or “on the shelf” (e.g., data, specimens) at the time the research is proposed and submitted for IRB review or for an exempt determination

If any data or specimens to be used will come into existence after the project is proposed and submitted for review, then the collection is considered prospective (even if all materials would come into existence regardless of the research)



## Informed Consent

Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation

- Informed consent is required for collection of data and/or biological specimens to be stored for future research



## Assent

Agreement to participate in research expressed by an individual (e.g., a child) who cannot provide legally effective informed consent to participate on his/her own behalf

**Note:** Failure to object does not constitute assent





## Protected Health Information (PHI)

Health information that is individually identifiable (contains at least one of the 18 HIPAA identifiers) and created or held by a covered entity

- HIPAA authorization is required when the data to be stored for future research include protected health information





## HIPAA Identifiers

1. Names
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code in certain circumstances
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Phone numbers
5. Fax numbers
6. Electronic mail addresses



## HIPAA Identifiers (cont.)

7. Social Security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code





## **HIPAA Authorization**

A Privacy Rule authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's PHI that is described in the authorization for the purpose(s) and to the recipient(s) stated in the authorization

- Information to be accessed, used, or disclosed
- Identification of those authorized to use/disclose
- Potential for re-disclosure; right to revoke

The requirement for an authorization may be waived (full or partial) or altered as outlined in the regulations



## Repository or Bank

A collection of data and/or specimens obtained and stored for future research uses and/or distribution, including a collection not originally or primarily obtained for research purposes





## Repository or Bank (cont.)

Data and specimen repositories/banks may range from materials held by a single investigator in his/her office or laboratory to large networks with central coordinating centers

- Creating a data and/or specimen bank for future research purposes (i.e., rather than using data/specimens only for pre-defined analyses as described in a specific IRB-approved protocol) is defined as “research involving human subjects,” and IRB review and approval is required



# Examples of Banks and Repositories



## Examples of Data Banks & Repositories

- Collecting education records (grades, assignments, class recordings, etc.) to make them available to investigators for future research
- Recruitment databases: gathering contact information as well as additional information (e.g., conditions, demographics, etc.) to create a resource pool of potential participants for future studies
- Collecting survey data, medical record data, and/or specimens to make available for future research



## Examples of Data Banks & Repositories

- Retaining left-over data or samples from a completed research project (or projects) to make them available for future, unspecified research
- “Virtual” banks/repositories: obtaining permission from participants to access/utilize materials stored for other purposes (e.g., educational records, work records, medical records, etc.) for future, unspecified studies, even if the materials are not actually removed and stored separately from their original sources



## Examples of activities that are not considered banking:

- Ancillary studies or sub-studies as long as they are specified in (and part of) the main project; there is no intent to use the data and/or specimens beyond the described work for future, unspecified research; and the materials will not be distributed to investigators for their own work separate from the main study or ancillary/sub studies



## Examples of activities that are not considered banking:

- Data and/or specimens held for specific testing or analysis that can only occur after all materials are collected
- Asking participants (in a consent form) if they would mind being contacted for a follow-up study
- Retaining data or specimens for a specified time period as required by a journal or standards for your field of study





# Elements of a Repository Protocol



## Purpose & Materials

- Provide the purpose of collecting and storing data/specimens
- Describe the type(s) of data/specimens to be collected and stored, including sample size, inclusion/exclusion criteria, etc.
- Remember, no work can be conducted under the banking protocol, though specific activities can be conducted for the bank to make information available for users of the repository (e.g., specific genetic testing or sequencing)



## Collection Procedures

- Describe the source(s) and circumstances of data/specimen collection (i.e., obtained directly from participants or from a secondary source)
- Describe all processes/interventions involved in the data/specimen collection, including whether collected in the course of non-research activities or if collected specifically for the repository (e.g., extra questionnaires, additional blood draws, etc.)

**Note:** All materials to be used (instruments, questionnaires, interview guides, data collection forms, etc.) must be submitted for IRB review



## Recruitment Process

- Describe the procedures that will be used to identify, recruit, and/or screen participants, as applicable
- If PHI is accessed for recruitment purposes, a partial waiver of HIPAA authorization is needed

**Note:** All recruitment materials to be used (advertisements, postings, scripts, letters, websites, etc.) must be submitted for IRB review



## Consent process

- Describe the process for obtaining informed consent, assent, and/or parental permission
- Include a plan to obtain HIPAA research authorization when the data collected includes PHI
- If children will be enrolled and data/specimens will continue to be used, include a plan to obtain informed consent once these participants become adults

**Note:** All materials to be used (consent forms, assent forms, permission forms, consent scripts, etc.) must be submitted for IRB review



## Storage

- Describe the governance and/or oversight structure, including the roles and responsibilities of individuals involved in the repository's management and operations
- Describe any limits on data/specimens' intended future use (e.g., cancer research only), and ensure that any such limits are reflected in the application and consent materials
- Describe how the data/specimens will be stored: i.e., if they will be identifiable, coded, or de-identified
- Provide the length of time data/specimens will be stored



## Storage (cont.)

- Describe the physical location/equipment and security provisions for data/specimen storage. For more information regarding requirements for handling data, see university policies, Policy on Institutional Data and Research Data Policy
- Describe the procedures to allow participants to withdraw their data/specimens from future research (as applicable). Include the method for tracking participants' decisions regarding data/specimen use
- Include a plan for continuing repository operations in the absence (or departure) of the principal investigator, as applicable



## Releasing data/specimens

- Describe with whom data/specimens may be shared (including non-Ohio State researchers, commercial entities, etc.)
- Describe the process for requesting and releasing data/specimens

**Note:** All materials to be used (e.g., applications to access materials, data use agreements, etc.) must be submitted for IRB review and need to match limits of use (e.g., restrictions on third party transfer)





## Releasing data/specimens (cont.)

- Explain how data/specimens will be released (i.e., identifiable, coded, or de-identified)
- Include the process to ensure/document a requesting investigator's approval to access the materials
- Outline the safeguards to ensure that materials are properly released and confidentiality is not compromised
- Include a process for handling incidental findings, as applicable



# Additional Consent Elements for Repositories



## Consent

Informed consent must be obtained for collection and storage of data and/or biological specimens for future research and should generally be obtained separately from consent to other research participation (separate form or separate addendum)

HIPAA authorization is also required when the data include PHI



## Repository-Specific Consent Requirements

In addition to the regular required elements of informed consent, the consent process should include the following information, as applicable:

- Description of the data/specimens to be collected and how they will be obtained
  - Be sure any additional procedures (questionnaires, additional biopsies, blood draws, etc.) are addressed in the main consent and/or through use of additional addenda/scripts



## Repository-Specific Requirements (cont.)

- Risks associated with obtaining the data/specimens
- Information on how the data/specimens will be used (to the extent known)
- Any limits on data/specimens' intended future use (e.g., cancer research only)
- Information on whether any identifying information will be retained, and if so, how it will be stored



## Repository-Specific Requirements (cont.)

- Certificate of Confidentiality information (when a Certificate is obtained)
- GINA language (when genetic information is stored and/or specimens may be released for future genetic research)
- dbGaP language or related for mandated genetic sharing
- Commercialization language

Template language for these elements can be found at <http://orpp.osu.edu/irb/investigator-guidance/consent/consentlanguage/>



## Repository-Specific Requirements (cont.)

- Description of the repository, including basic information on physical location, security procedures, etc.
- Description of who will have access to the data/specimens and with whom data/specimens may be shared (including non-Ohio State researchers)
- Description of how long the data/specimens will be stored



## Repository-Specific Requirements (cont.)

- How to withdraw data/specimens from future research (and how to revoke HIPAA authorization, as applicable)
- Any limits on the ability to withdraw
- Whether or not participants may be re-contacted in the future (e.g., for consent to future research, to return research results, etc.)
- If data/specimens from children are collected, describe the plan to obtain consent when adults, as applicable





# Frequently Asked Questions



## **Does the new guidance apply to me if my research involves an external bank or repository NOT controlled by Ohio State?**

No. This guidance applies only to current internal banks or repositories controlled by Ohio State researchers. A separate protocol for data and/or specimens collected and sent to external banks (e.g., other institutions, sponsors, NIH, NCI, cooperative groups, etc.) will not be required. However, there may be changes or additional information requested for Ohio State protocols with ongoing data and/or specimen collection



**I have more than one IRB approved protocol that includes banking data and/or specimens as part of the research. Can I combine these collections into one banking/repository protocol?**

Yes. The sources can be combined into a single repository protocol

- ORRP staff can advise investigators on how to amend the current studies and what information needs to be provided for the bank/repository protocol



## **I have an existing Ohio State bank/repository. What will I need to do?**

ORRP has created tables for existing studies to alert investigators of how the changes may affect their projects

See: <http://orrp.osu.edu/irb/investigator-guidance/data-and-or-specimen-banking-and-research-use-of-banked-materials/>



**I do not have a bank/repository, but I am obtaining materials from one for my research – how do these new requirements affect me?**

The working group also made recommendations that have been adopted by the IRB Policy Committee regarding requirements for “secondary research” activities, which use materials obtained from established banks. Depending on the source of your data and/or specimens, there may be changes to the way the bank/repository operates and the types of materials that can be released (e.g., identifiable v. de-identified materials)



# HRPP Policies, Links, and Guidance



## **HRPP Polices**

<http://orpp.osu.edu/irb/osuirbpolicies/hrpppolicies/>

## **HRPP Glossary**

<http://orpp.osu.edu/irb/osuirbpolicies/hrppglossary/>

## **FAQs**

<http://orpp.osu.edu/irb/irb-faqs/>

## **Ohio State Research Involving Data and/or Biological Specimens Policy:**

<http://orpp.osu.edu/irb/osuirbpolicies/hrpppolicies/>



## **Banking Guidance for investigators (with FAQs):**

<http://orrrp.osu.edu/irb/investigator-guidance/data-and-or-specimen-banking-and-research-use-of-banked-materials/>

## **Consent template language (GINA, dbGaP, commercialization, etc.):**

<http://orrrp.osu.edu/irb/investigator-guidance/consent/consentlanguage/>

## **Banking protocol guidance:**

<http://orrrp.osu.edu/files/2011/10/Guidelines-for-Writing-a-Banking-Protocol.pdf>





## **HIPAA Guidance**

<http://orpp.osu.edu/irb/investigator-guidance/hipaa/>

## **Ohio State University Privacy Officers**

[http://orpp.osu.edu/files/2011/10/privacyofficers\\_060115.doc](http://orpp.osu.edu/files/2011/10/privacyofficers_060115.doc)





# Questions?

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## Protecting Human Subjects in Research at Ohio State



### Human Subjects

The Human Research Protection Program is responsible for all Ohio State research involving human subjects. The HRPP's primary responsibility is to protect the rights and welfare of human research subjects, in accordance with Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations.

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