IRB RESEARCH REPOSITORIES
SBER & OTHER DATA ISSUES

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Why a Policy Now?

- The regulations have always included oversight for research repositories, with guidance dating back to 1997 and new guidance in 2004 & 2010
- Recent cases and the increased interest in maximizing the utility of limited resources have created a focus on how to do this correctly.
  - When done improperly, can lead to limitations on future uses, destruction of valuable resources, court cases, and distrust.
  - Consideration of what is legal vs. what is ethically acceptable

Recent Cases

- Havasupai – secondary research uses on stored samples and data. Under a waiver of consent. Findings adversely affected the rights and welfare of the subjects. $700,000 settlement.
- Texas stored bloodspot samples – After newborn heel stick, bloodspots were accessed by researchers at UT. Done under a waiver of consent. Agreement to destroy 4 million stored samples.

Goals of Compliance Program

- Compliance with regulatory requirements
- Maximize utility of resources
  - Facilitating sharing of data/samples
  - Decreasing limits on use
- Standardize the process institution-wide
- Decrease ongoing compliance requirements for continuing reviews.

Compliance Program: One Year Goal

- Launching June 1, 2010
- The IRB will develop many tools and host training sessions to help you develop the appropriate structure for your repository.
- Compliance initiative runs for one year
- After May 31, 2011 – any OHSU human subjects research repositories discovered to be operating without IRB approval will be reportable to the Office for Human Research Protections – constitutes conducting unapproved research.

Applicability of the Policy

- This policy applies to human subject research repositories established by OHSU investigators for the purpose of storing data and/or specimens for future research purposes.
- This policy does not apply to data/specimens that are collected and stored as part of routine clinical care or hospital procedures, for example, blood banks, pathology, surveillance, or quality assurance. However it does apply to data/specimens from these sources that are then stored for future research.

Repository - Defined

- Registries, data banks, and tissue banks are all considered "repositories" for regulatory purposes. Any reference in this policy to repositories applies equally to data banks, tissue banks, and registries.
- Generally, a repository collects, stores and distributes human tissue, specimens and/or data for use in future research projects. Any collection of human biological materials (including data) is considered to be a repository when there is no explicit plan to destroy the materials when the specific research project that generates the materials ends.

More on Repository Definition…

- The collection and storage of specimens/data becomes a research repository when there is a specific intention for the data/specimens to be used repeatedly for research purposes, or stored for future research and/or shared with other investigators.
- The prospective collection and storage of data/specimens only for a defined research purposes (including holding samples to "batch" them for assays), as part of a single IRB-approved protocol is <u>not considered a repository.</u>

More on Repository Definition…

- If there is no explicit plan to destroy the data/specimens when the specific original research project ends, the investigator may maintain the data/specimens under continued IRB approval for uses as approved in the original protocol.
- Once a use is desired beyond the primary research goals of the original protocol, the PI must establish an IRB-approved research repository protocol for any future research uses or submit data/specimens into an existing IRB-approved repository.

Approval Requirements

- A human specimen/data repository may be categorized in one of three ways:
  - Non-human subjects repositories (NHS)
  - Exempt Repositories
  - Non-Exempt Repositories
- All research repositories, except those qualifying as non-human subjects research, require review and approval by the IRB.

Definitions on Identifiability

- **Coded -** A system exists to re-identify samples or data that are not identifiable on their own.
- **De-Identified –** A HIPAA term that can be done by either remove all 18 HIPAA identifiers or having a statistician certify.
- **Anonymized –** identifying information is removed by the research team and no links are retained.
- **Anonymous –** the data and/or specimens have no identifying information and cannot be re-linked.

Definitions on Identifiability

- **Identifying information** is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.
- **Identifying characteristics** include things such as: name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.
- **Private information** includes information about behavior which an individual can reasonably expect to be private.

Difficult to Anonymize

- Videos and Audio - May be special considerations with video and audio data. If the tapes must be maintained, they will likely be identifiable. A transcript can be anonymized.
- Signed Consent forms – Are identifiable. If you must maintain records for research purposes, you may not anonymize them until the record retention requirements have passed.

Non-Human Subjects Research Repository

- Non-Human Subjects Research – this is an activity that doesn't meet the definition of human subject or research.
  - Research projects that are originally deemed non-human subjects (NHS) research and converted to a repository are considered NHS repositories.
  - Data/specimens that are de-identified as part of the original research protocol will likely be deemed NHS repositories.
  - A request for determination should be sought to have the IRB confirm the NHS status.

Exempt Repositories

- Exempt Repositories – these meet the regulatory definition of being exempt from the full requirement of IRB oversight.
- For repositories that are exempt, continuing oversight by the IRB is limited to annual renewals.
- Repositories will NOT be found to be exempt if the data/specimens retain any identifier or link that would permit anyone to identify, directly or indirectly, the person whose data/specimens are stored.

Non-Exempt Repositories

- The operation of any non-exempt research repository requires standard continued oversight by the IRB.
- Creating a repository specific protocol will be required for the review.
- The IRB will review and approve the repository protocol specifying the conditions under which data and specimens may be accepted into the repositories, how they will be securely stored, and the procedures under which they will be shared in order to ensure that adequate measures are employed to protect the privacy of subjects, maintain the confidentiality of the data and the integrity of specimens.

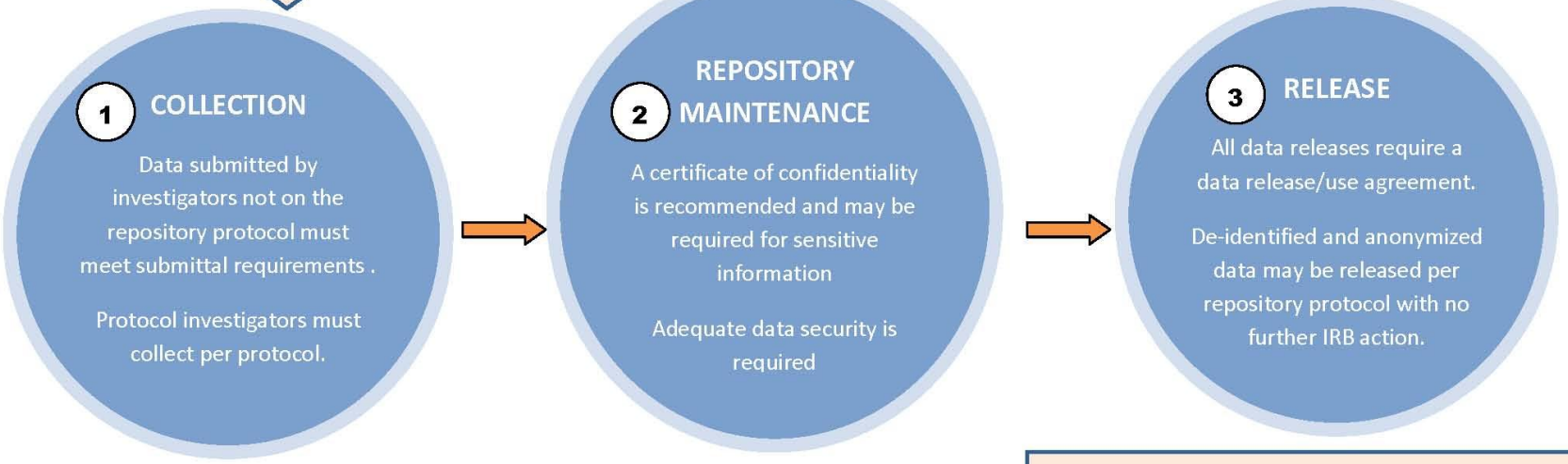
The Basics of a Repository

- Repository activities involve three components:
  - 1) the collection of materials,
  - 2) the repository storage and data management

    and
  - 3) the use by recipient investigators.

Research Repositories with Identifiers/links – No or non-specific Consent.

A. Research data collected under a waiver of consent.
B. Research data collected with consent, but no specific provision for future research.
C. Research data collected with consent, but with limits on future uses.
D. Medical records data.



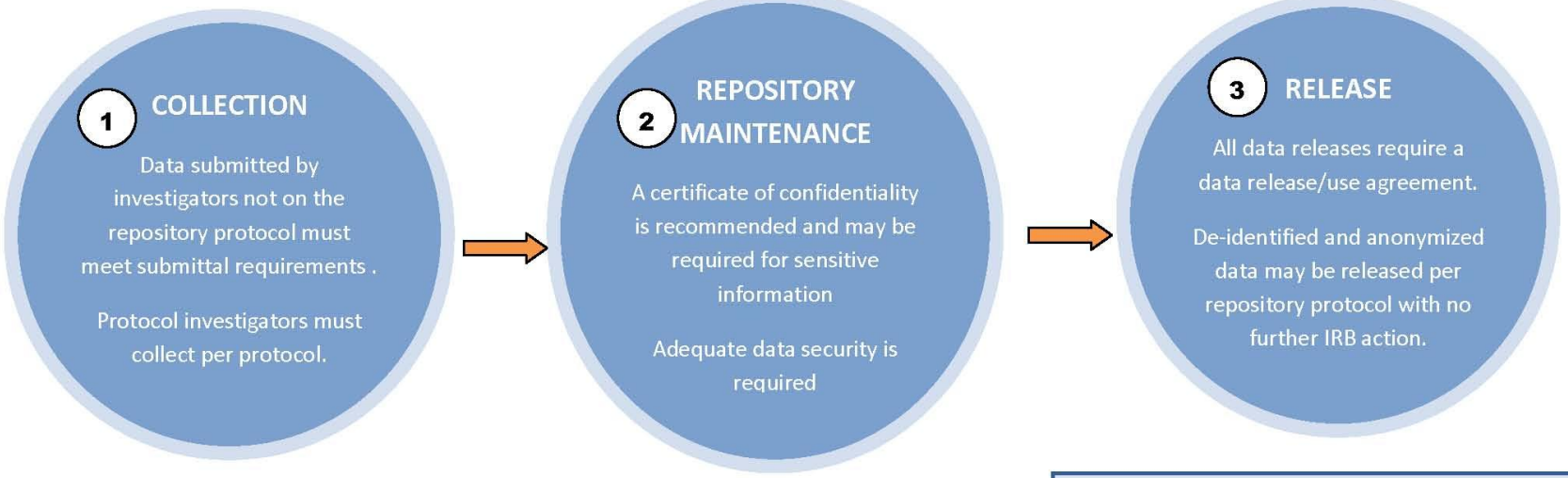
Identifiable data may be released or used by the Protocol Investigators under a waiver of consent and authorization with approval from the recipient's IRB (which may be OHSU) and from the OHSU IRB.

Some limits may be applicable due to legal requirements or prior consent specifications.

Research Repositories with Identifiers – Future Research Consent Obtained.

Data collected via research interactions or clinical care with specific consent obtained for storage for future research.

Research data collected with consent, but with limits on future uses.



Identifiable data may be released per repository protocol with a waiver of consent and authorization and approval from the recipient's IRB.

Some limits may be applicable due to legal requirements or prior consent specifications.

Submitting for IRB Approval

- The electronic IRB (eIRB) will contain a specific application for the creation of new research repositories.
- Any existing study that is completed but has collected data and/or specimens for future research purposes may choose to convert the study to a repository via a modification or continuing review application.
- It is recommended that a request for determination be sought from the OHSU IRB whenever there is a question of IRB oversight requirements.

Study Specific Repositories

- When collecting data/specimens in the course of a study and depositing them into a database/repository that will be used ONLY for the research goals of that specific study:
  - A separate repository protocol/consent form is recommended, but not required.
  - Any proposed use beyond the original study will require creation of a repository protocol.
  - Some modifications to that study may be required to become compliant with this policy.

Study Specific Repositories [2]

- If a separate repository protocol is not created, the study protocol/consent form must contain the following information about the database/repository:
  - Method of data/specimen storage and use;
  - Data points and specimens to be stored. Include all identifiers.
  - Designated repository guardian and list of who will have access to the repository; and
  - Methods to protect confidentiality
  - A statement that the samples/information may be used for future research. This statement may be specific or broad; however it will dictate the limits on future uses.

Conversion of a Study Protocol to a Repository

- For currently approved IRB protocols, including those not only with a specific research study, but also a research database/repository to store data/specimens for future studies:
  - Once the research study and subsequent data analysis are complete, the repository protocol can be separated into a repository specific IRB submission and the original research study submission can then be terminated.
  - This can be done at continuing review or via a modification

Modifications & Continuing Reviews

- Modifications must be submitted only for changes to the protocol, not for every data/material exchange. If you are accepting data/material that is beyond what is described in the scope of the study or wishing to release beyond the scope, the modification must be submitted for review.
- Releases requiring a waiver of consent & authorization require review by an IRB.
- Continuing reviews must include a summary of data exchanges for the past year.

Terminating a Repository

- When there is no intent to continue to operate a repository for future research or if the data/specimens are being transferred to another repository, the repository should be terminated via a modification in the eIRB.
- The termination request must include the disposition of the data and samples, including details on transfer, donation or destruction of specimens or data in a secure way.
- When applicable, a description of any communications with research participants regarding disposition of data and samples should be submitted for approval.

Termination Definition

- **Termination –** Taking action to end a study with the guarantee that:
  - no further contact with human subjects or their individually identifiable information is planned;
  - no subjects are or will be treated or followed; all data are gathered and analyzed; and
  - any final reports or publications are complete.
- A study may be terminated when it no longer constitutes human subject research, such as de-identifying the data.

Data & Records Retention

- In summary SIX YEARS after termination of research.
- HIPAA requires PHI and all HIPAA forms to be maintained for six years from the date of its creation or the date when it last was in effect, whichever is later.
- Common Rule - 3 years after completion of the research.

Should I convert to a Repository?

- Refer to document entitled

  Decision Tree for Transitioning a Study to a Repository

- Decision centers on how immediate the future uses may be and your level of comfort with maintaining a study via the CRs or transitioning to a repository.

Protocol Deviations

- A protocol deviation occurs when there is an inconsistency in a research study between the protocol that has been reviewed and approved by the Institutional Review Board (IRB) and the actual activities being done.
- All protocol deviations should be tracked, but minor protocol deviations do not require reporting to the IRB unless they are so multiple that they may raise to the level of a moderate deviation.

What is considered a minor PD?

Direct Harm/Risk of Harm

- The deviation resulted in no substantive direct harm or risk of harm to research participants; or
- The deviation did not result in or require any substantive action to be taken or result in a substantive change to the subject's condition or status.

Administrative

- The deviation had no substantive effect on the value of the data collected (i.e., the deviation does not confound the scientific analysis of the results); or
- The deviation did not result from willful or knowing misconduct on the part of the investigator(s); or
- The deviation is easily corrected (e.g., consenting a subject with an old version of an ICF, recording data on an expired/incorrect form, forgetting

Will Repositories have PDs?

- Maybe!
- When data or specimens are shared beyond what is approved in the protocol/SOPs, then this is a protocol deviation that would be considered above minor.
- May be moderate or major, depending on the data and scope of release.

Outside Collaborations

- **Database/Repository is Maintained Outside of OHSU**
  -When an investigator is contributing data/specimens to a repository not held by OHSU, the OHSU IRB must approve at a minimum
  - the collection protocol,
  - the consent process and
  - the submittal agreement.
- This can be done as a new application or an amendment to an existing study. However, not all submittals meet the requirements for engagement in human subjects research and a request for determination may be sought.

Outside Collaborations

- **Requesting Data/Specimens from a Repository**
- When an investigator is requesting coded or identifiable data from an established repository, a study submission is required either as a new study or as a modification to an existing study.
- The OHSU IRB must approve at a minimum the protocol, data request/collection tools, the usage agreement, consent process (most likely a waiver), and IRB approval of repository from which the request is being made.
- For anonymous and some coded data, a request for determination should be submitted.

Outside Collaborations

- Although this is a current national issue, not all institutions have repository standards. Our IRB can help you to work with partners to reach agreement on process.
- When a community sight is contributing to a repository, they may be considered engaged in research and need Co-I approvals and other FWA approvals.

Upcoming Educational Sessions

- ~~May 04 - PI Town Hall~~
- ~~May 11 - Targeted Training – Basic Scientists~~
- ~~May 27 - Repositories & Consent~~
- June 3 - Targeted Training – SON/SBER
- June 08 - Writing a Repository Protocol
- June 22 - Submitting & Releasing Data from Repositories
- TBD eIRB Changes
- TBD Repositories FAQs

Questions?

Effective Date 6/1/2010

Year-long compliance initiative ends 5/31/2011

- Repository Information Page http://www.ohsu.edu/xd/research/about/integrity/irb/repository-policy.cfm
- More details & Updates are in development – Keep checking back.