IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM:

INFORMATION FOR BASIC SCIENTISTS

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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

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.

What Constitutes Human Subject Research?

- First, does the activity involve research?
  - Sometimes studies that involve the collection or banking of specimens or other data for future unspecified research will raise the question or whether such activities will constitute research under the regulatory definition.
  - It is OHRP's view that such activities will often meet the regulatory definition of research since they will constitute systematic investigations that are designed to develop or contribute to generalizable knowledge.

Second, Are Human Subjects involved?

- There are two ways in which an individual becomes a human subject under the regulations.
  - If an investigator is intervening or interacting with a living individual for a research purpose to obtain a specimen or other information.
  - If an investigator is obtaining individually identifiable private information or specimens.

Why do the regulations apply to the research use of human biological specimens?

- OHRP interprets human biological specimens to be private information.

Remember:

Human subject means a living individual about whom an investigator conducting research obtains:

1. Data (including specimens) through intervention or interaction with the individual, or
2. Identifiable private information.

IRB Oversight for Specimens

- If an investigator obtains a specimen from a living individual through a research intervention or interaction, then the research would involve human subjects under the regulations.
  - You must know the origin of your specimens.
  - If they are being collected or were being collected for research purposes via a research intervention or interaction with a living individual, the IRB has oversight for the use of those specimens.

IRB Oversight for Specimens

- Always - If an investigator obtains individually identifiable specimens about living individuals, then the research will involve human subjects.

What is meant by individually identifiable?

Common Rule:

- Individually identifiable information means that the identity of the individual to whom the specimen or the data pertain can be readily ascertained or readily associated with the information by the investigator.

HIPAA Identifiers:

- 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.
- Names, Geographic subdivisions smaller than a state, some elements of Zip Code, Telephone numbers, FAX numbers, E-mail addresses, Social security numbers, Medical record numbers, Health plan beneficiary numbers, Account numbers, Certificate/license numbers., Vehicle identifiers and serial numbers, including license plate numbers, Device identifiers and serial numbers, (URLs), Internet protocol (IP) address numbers, Biometric identifiers, Full-face photographic images and any comparable images.
- Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

When can specimens or other private information be used for research without involving human subjects?

- If two things are both true, then the research would not involve human subjects.
  - The first is if the research does not involve an investigator either intervening or interacting with a living individual in order to obtain data or a specimen.
  - The second thing would be if the investigator does not obtain individually identifiable private information or a specimen about living individuals.

Example of NHS research: (NHS = Non Human Subjects)

- A research study that would not involve human subjects would be a study that involves the investigator obtaining data that was solely collected for clinical purposes and before the investigator OBTAINS this information, all of the identifiers would be removed from the clinical data before being provided to the investigator. There was no research intervention or interaction to obtain the data, since it was collected solely for clinical purposes and the investigators do not receive information that would allow the researchers to identify the individuals to whom the data pertain.

What if specimens or data are coded?

- Generally, coded information is considered individually identifiable.
- To meet the definition of individually identifiable, the information by which the identity of the individual to whom the information pertains must be either readily ascertainable or associated with the information by the investigator.
- mechanisms may be put into place to prevent a recipient investigator from being able to readily ascertain the identity of the individuals to whom the data or specimens pertain and human subjects would not be involved.

What if specimens or data are coded?

- Q: If there is a firewall that prevents the investigator from obtaining or accessing individually identifiable information, then human subjects would not be involved and the regulations would not apply?
- A: Yes, provided that there is no research intervention or interaction with a living individual in order to obtain the specimens or data.

Exempt vs. NHS?

- Some studies are considered exempt from IRB oversight. This is different than NHS and does require IRB review.
- The is a distinction between the use of existing specimens and other private information which does not involved human subjects versus when their use is exempt.

Exemption 4 is most often applicable to research involving human biological specimens or data.

- Exemption 4 pertains to research that involves existing data, documents or specimens, provided that at least one of two conditions is met:
  - that the information or the specimens be publicly available (most cases specimens are not), or
  - that the information be recorded by the investigators in such a manner that subjects could not be identified either directly or indirectly through links that are retained with the data.

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.

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.

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.

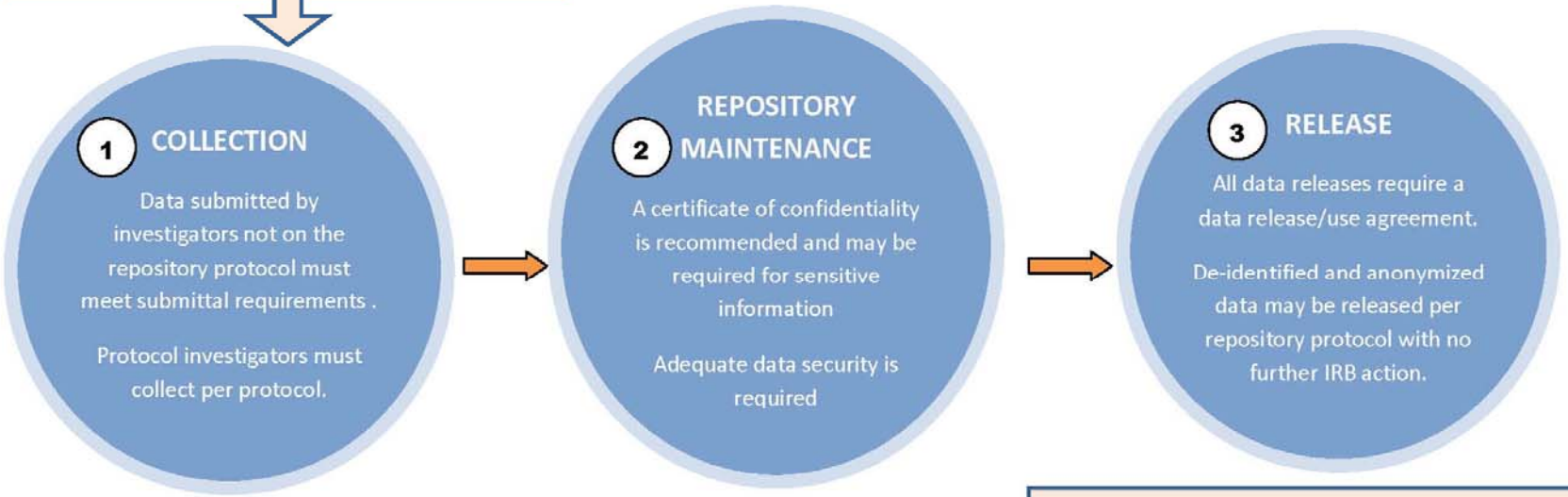
The Basics of a Repository

- 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.



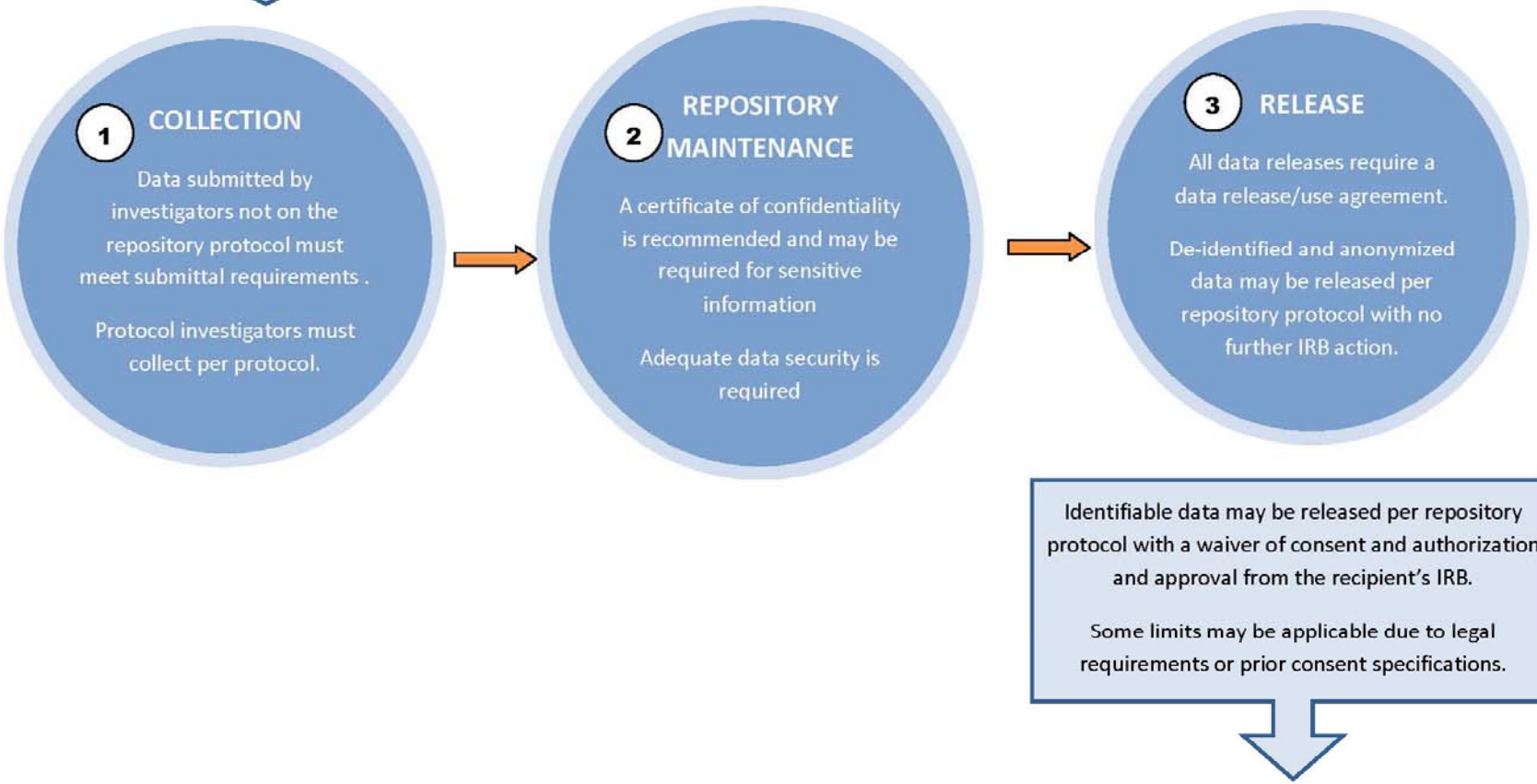
Identifiable data may be released or used by the Protocol Investigators under a waiver of consent and authorization with approval from the recipient's IRB (which may be OHSU) and from the OHSU IRB.

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.

Collection

- Data & Specimens to be Included
  - Description
  - Sources
  - Acquisition process
  - Consent & Authorization (or waiver)
  - Conditions for Acceptance – Submittal Agreement
  - Confirmation of local IRB approval

Maintenance

- **Security and confidentiality.**
  - Description how and where data/specimens will be stored, and
  - Description of how the privacy of subjects and the confidentiality of data will be protected, including if a Certificate of Confidentiality will be obtained.
- **Access to the data/specimens.**
  - Description of who will have access to the data/specimens,
  - Description of what the requirements are for access.
  - Indication of who is designated as the Guardian.

Release

- Description of Mechanisms release of data/specimens.
- A statement that separate IRB approval/determination will be required for each specific human subject research activity that uses identifiable data/specimens from the repository.
- Methods for securing Usage Agreements from recipient investigators.

Release [2]

- Usage requirements - A complete description of the process for requesting and releasing data must be included.
- Methods for certification that the release are not contrary to any previously imposed limits, via law, previous consent, genetic opt out, or other applicable limits.
- Ensuring that material transfer agreements are used when necessary for the transfer of biological materials

Some definitions

- **Submittal Agreement:** An agreement that attests that specimens collected were obtained with written informed consent of the donor-subjects utilizing an informed consent document approved by the local IRB or under an IRB Approved waiver of informed consent.

- **Usage Agreement:** An agreement that details the conditions for receipt and future use of data and/or specimens from a repository.

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.

Submitting for IRB Approval

- **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.

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.