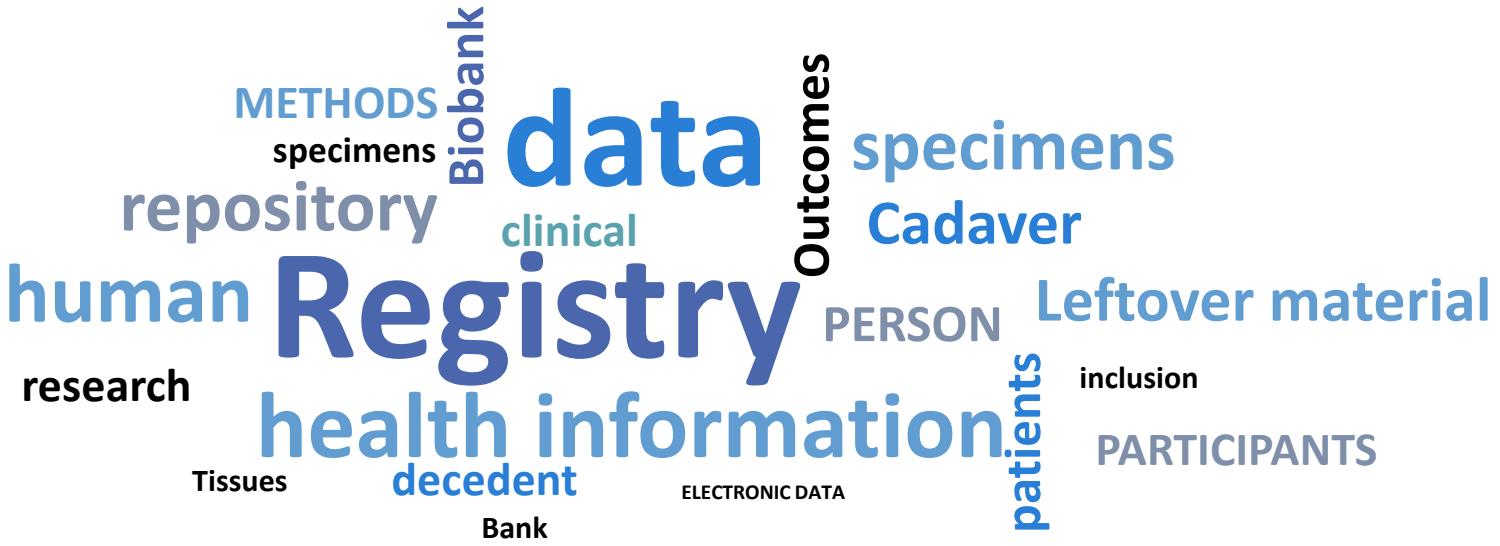
UT Southwestern
Medical Center
Human Research Protection Program

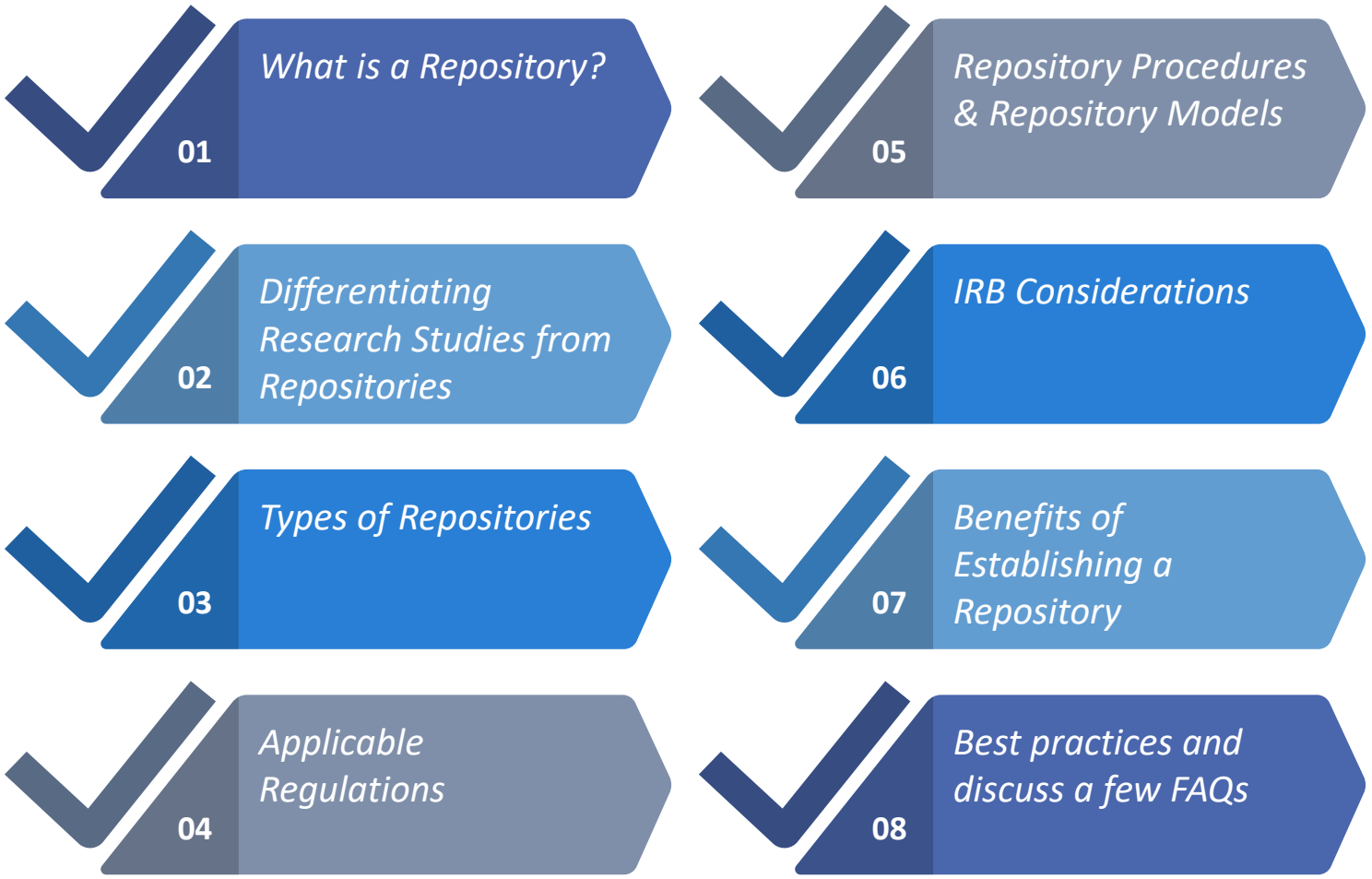
Research Matters

March 19, 2024

Navigating Institutional Review Board (IRB) Approval: Research Repositories


METHODS
specimens
Biobank
data
Outcomes
specimens
repository
clinical
Cadaver
human
Registry
PERSON
Leftover material
research
health information
patients
inclusion
PARTICIPANTS
Tissues
decedent
ELECTRONIC DATA
Bank

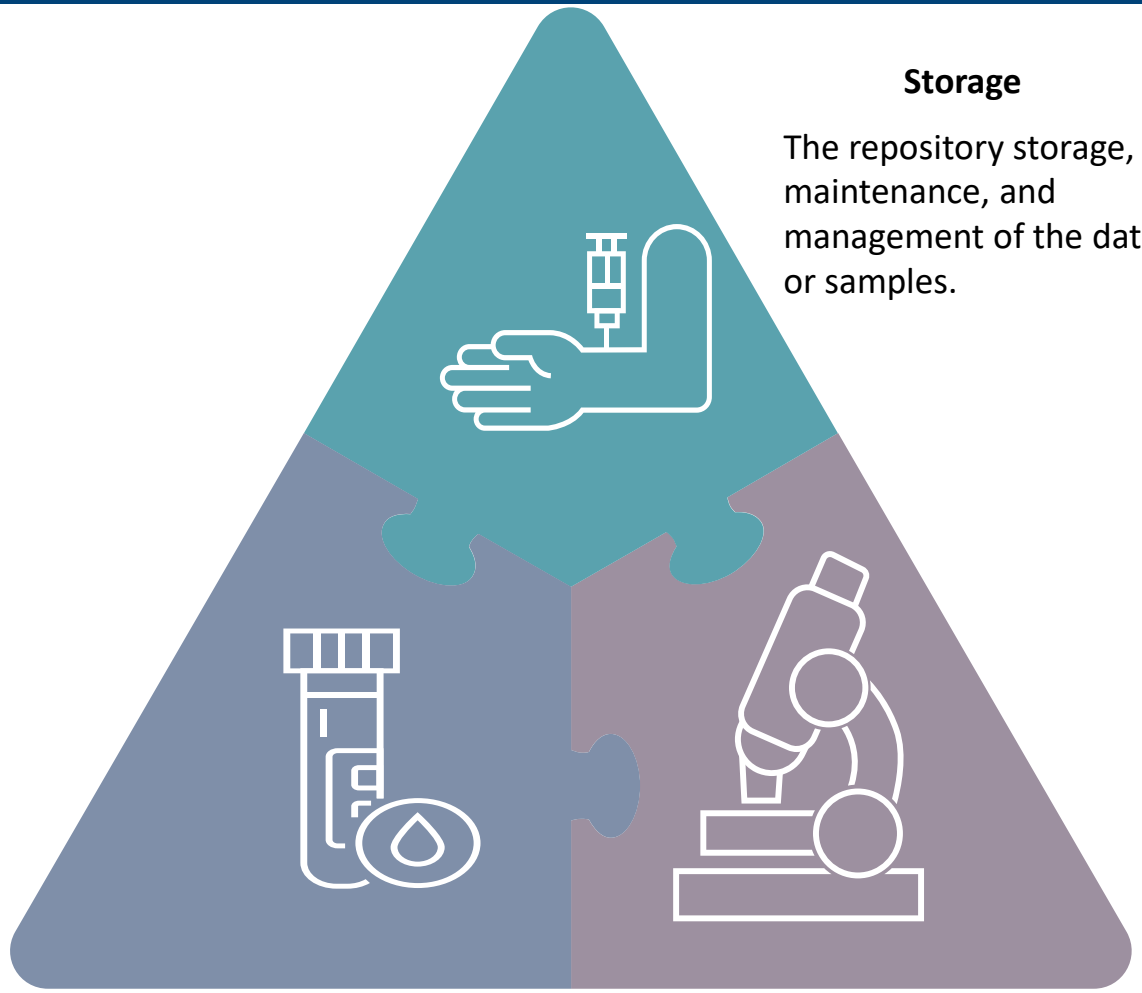
Overview of Presentation



What is a repository?

Is a system or facility that collects, stores, and distributes data or biological samples obtained from living persons for research use. This research use is facilitated through the repository's established plans for sharing, either with the repository investigators who collected the data or samples, or with other investigators. Repository activities involve three components.

What is a repository?



Storage

The repository storage, maintenance, and management of the data or samples.

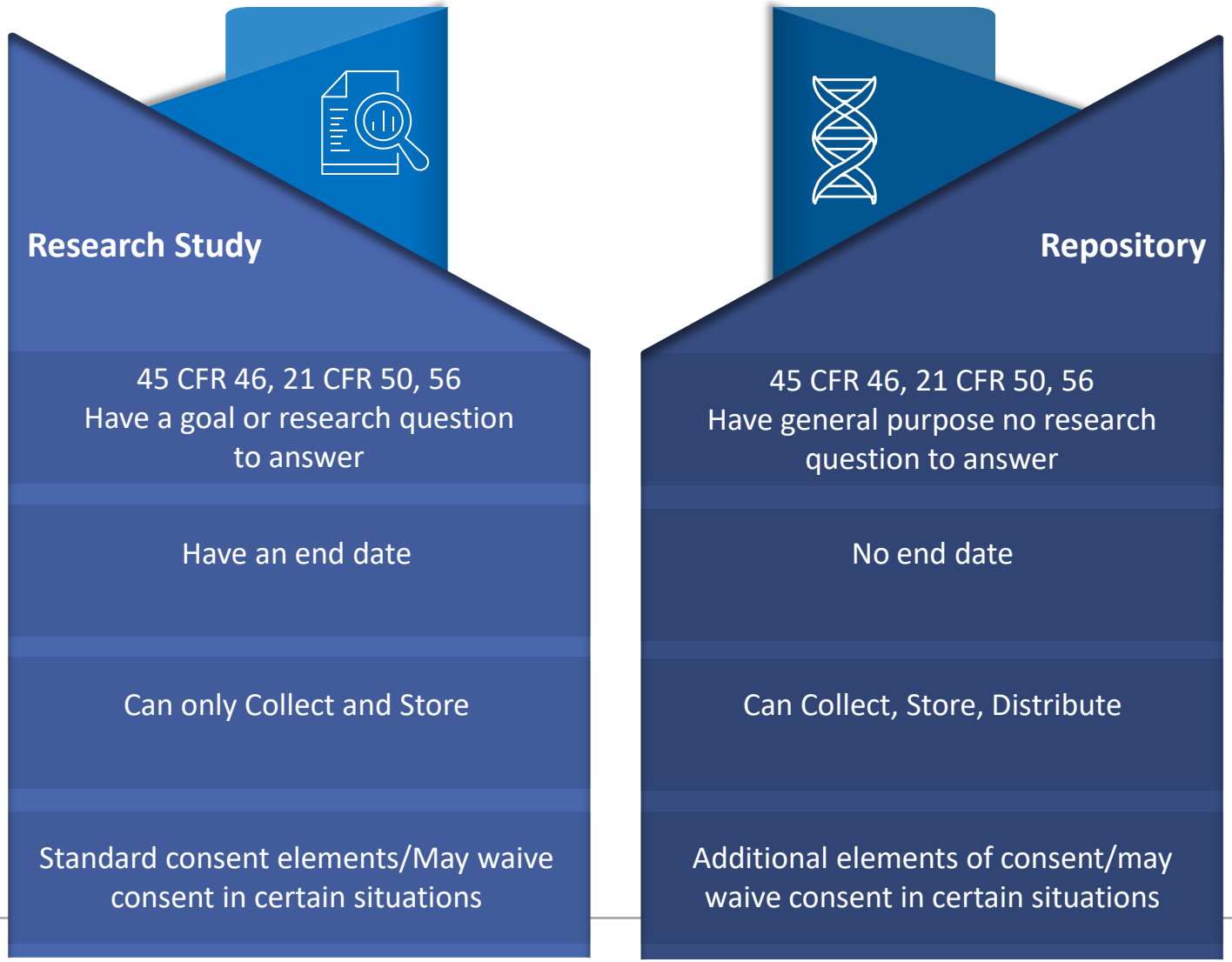
Collection

The collection of the data or biological samples.

Distribution

The plans and activities for use or sharing for research.

Research Study versus Repository



Types of Repositories

Data

- Data bank
- Data registry

Specimen

- Biorepository
- Biobank
- Specimen Bank

Data & Specimens

- Includes both data and specimens

Applicable Regulations - OHRP

Is it research?

1. Is a **systematic investigation** (including development, testing, and/or evaluation, designed to contribute to **generalizable knowledge**
2. Systematic Investigation – a careful or detailed inquiry or examination of information that involves a system, method, or plan.
3. Generalizable knowledge – widely applicable

Does it involve Human subjects?

1. A **living individual** about whom an investigator (whether professional or student) is conducting research:
2. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
3. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable

Applicable Regulations - FDA

- 21 CFR Part 50 (Informed Consent) and 21 CFR Part 56 (IRB Review)
  - If there are plans to conduct a clinical trial - involves a human who participates in research either as a recipient of the FDA regulated test article or as a control
  - Subject is an individual **on whom** or **on whose specimen** an investigational articles is used

Applicable Regulations- HIPAA

Use or disclosure of data to create the research repository database

- With Informed Consent/HIPAA Authorization of the participant
- With a HIPAA waiver from the IRB

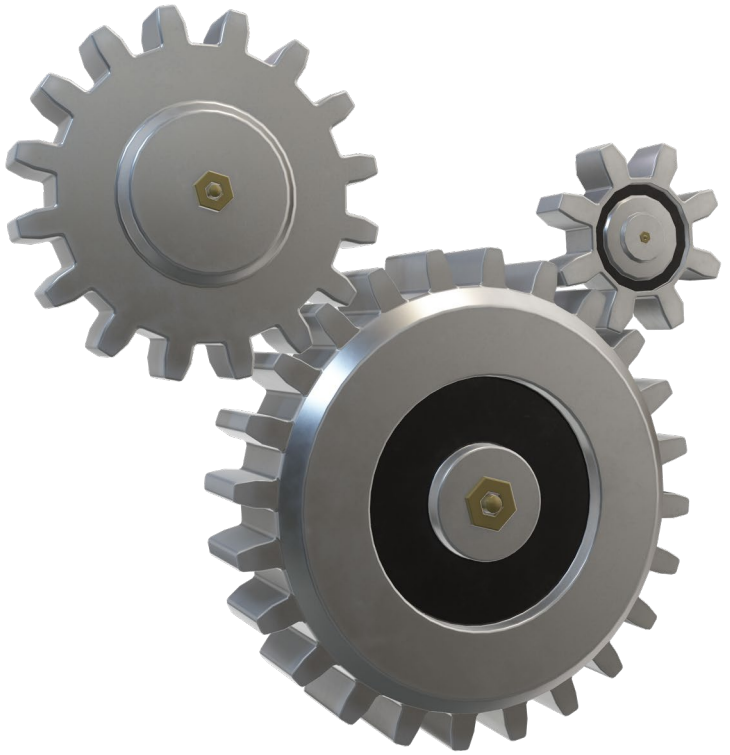
Subsequent use or disclosure of data in the database for a particular research protocol

- Depends upon what type of data is being requested

Other Regulations and Protections

- Genetic Information Non-Discrimination Act (GINA)
  - Protects individuals against discrimination based on their genetic information in health coverage and in employment. Title I of GINA prohibits discrimination based on genetic information, determined to be health information.
  - Prohibits the use and disclosure of genetic information by covered health plans for underwriting purposes, which include eligibility determinations, premium computations, applications of any pre-existing condition exclusions, and any other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.
  - Language regarding GINA protections are included in the consent form.

- Certificates of Confidentiality
  - Protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations.
  - Automatically granted for federally funded research
  - May be obtained if repository activities are not federally funded.



REPOSITORY PROCEDURES/ACTIVITIES

Collection

Existing/Prospective Clinical Materials	Existing/Prospective Identifiable Research Materials	Prospective collection for this repository	Deidentified data collection
Leftover specimens	Must provide originating study details	Additional specimen collected during clinical/research procedure (e.g., collect extra 10ml blood during SOC draw)	Public, clinical, or research materials provided anonymized to repository staff
Data collected from medical records	Consent from other study should list this repository/purpose (i.e., health condition)	Specimen collected for procedure only being done for research (CSF collection – spinal tap only for repository)	
IRB considerations same for all research	Consent should include options for opting in/out to storage in the repository	Collection of data only for storage in the repository (QOL surveys, physical examination, gait analysis, depression index, etc.)	

Storage

External Repository

Repository materials sent to a non-UTSW/Affiliate location

Local Repository

Repository materials stored at UTSW/Affiliate location

Distribution Activities

Deidentified data distribution to non-repository staff

- *IRB approval not required*
- *May obtain existing repository data and new data if collected by repository staff*

Note: Will require Modification to repository to add new data points

Best practice is for recipient investigator to obtain a Non-Human Determination from the IRB

Deidentified data distribution to repository staff

- *IRB approval not required*
- *Must be re-coded to deidentify*
- *May only obtain existing repository data (no new data)*

Best practice is for recipient investigator to obtain a Non-Human Determination from the IRB

Identifiable data distribution

- *IRB approval/Determination required*
- *Exempt - Data only with HIPAA waiver*
- *Expedited*
  - *Data only if HIPAA is N/A*
  - *Specimens included*
  - *Waiver of consent and authorization required*
  - *Recontact only if repository consent explicitly allowed it*
  - *Purpose of recipient research should be consistent with purpose of repository (e.g., breast cancer research)*
  - *PI must have request process in place*

Repository Models

Local Repository

Central Repository – with Local PI as Lead

Central Repository – with non-Local PI as Lead

Informed Consent

- Repository informed consent should ***also*** include a clear description of:
  - the operation/location of the repository;
  - the specific types of research to be conducted with materials in future;
  - conditions under which data and specimens will be released to recipient-investigators (e.g., identifiable, with IRB approval, or only deidentified); and
  - procedures for protecting the privacy of subjects and maintaining the confidentiality of data
- Where human genetic research is anticipated include information about the risks of genetic research (typical for biorepositories)

Waiver of Consent/HIPAA

Consent and authorization may be waived only if the regulatory criteria for a waiver of consent and waiver of HIPAA authorization are met, **AND**

- The protocol includes a plan for allowing subjects to opt-out of the repository or certain aspects of the repository*, **OR**
- It involves materials (data, documents, records, or biospecimens) that have been collected, solely for non-research purposes such as medical treatment or diagnosis, **OR**
- It involves existing materials (data, documents, records, or biospecimens) that have been collected for research purposes under another IRB-approved research study, however consent and authorization for future research use could not/cannot be obtained.

*This is *not* regulatory – this is institutional policy

Waiver of Documentation of Consent/HIPAA Alteration

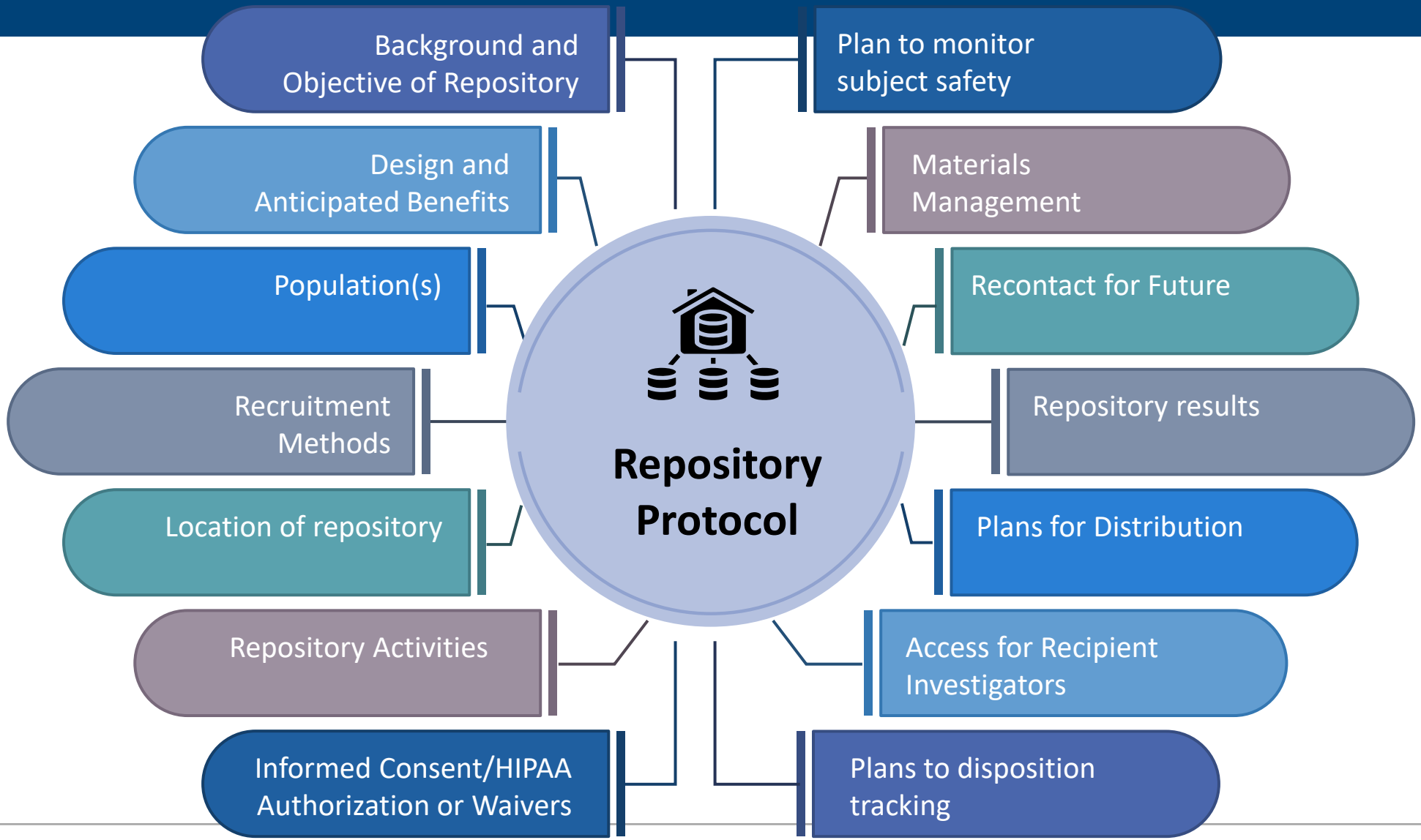
Waiver of Documentation of Consent

- All elements of consent are provided in an information sheet
- Waiving the requirement to obtain a signature on the consent form
- Waiver of documentation criteria is met
- Consent is verbal and documented in the research record

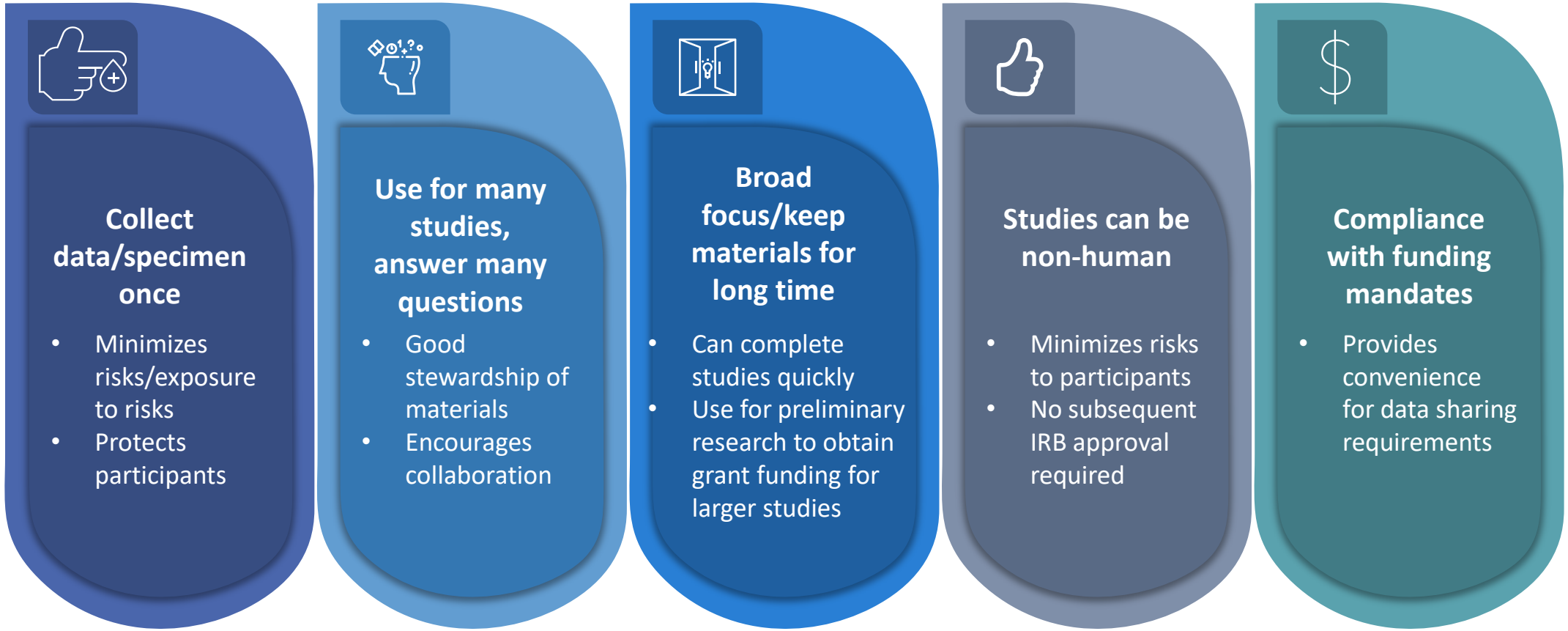
HIPAA Alteration

- Include all elements of HIPAA Authorization
- Waiving the requirement to obtain written authorization when criteria is met
- Authorization is verbal and documented in the research record

Protocol Details



Benefits of Repositories



Repository Best Practices

Establishing an Honest Broker

Stewardship planning

Approval for recipient investigators to use repository materials

Recipient investigator quantity

Who receives priority

Offer ability for research subjects to opt-out or withdraw from the repository

Keeping participants informed

Changes to repository location, PI, etc.

Incidental findings – how should they be communicated

See RM presentation from October 2023

Maintain records of distribution activities

Honest Broker

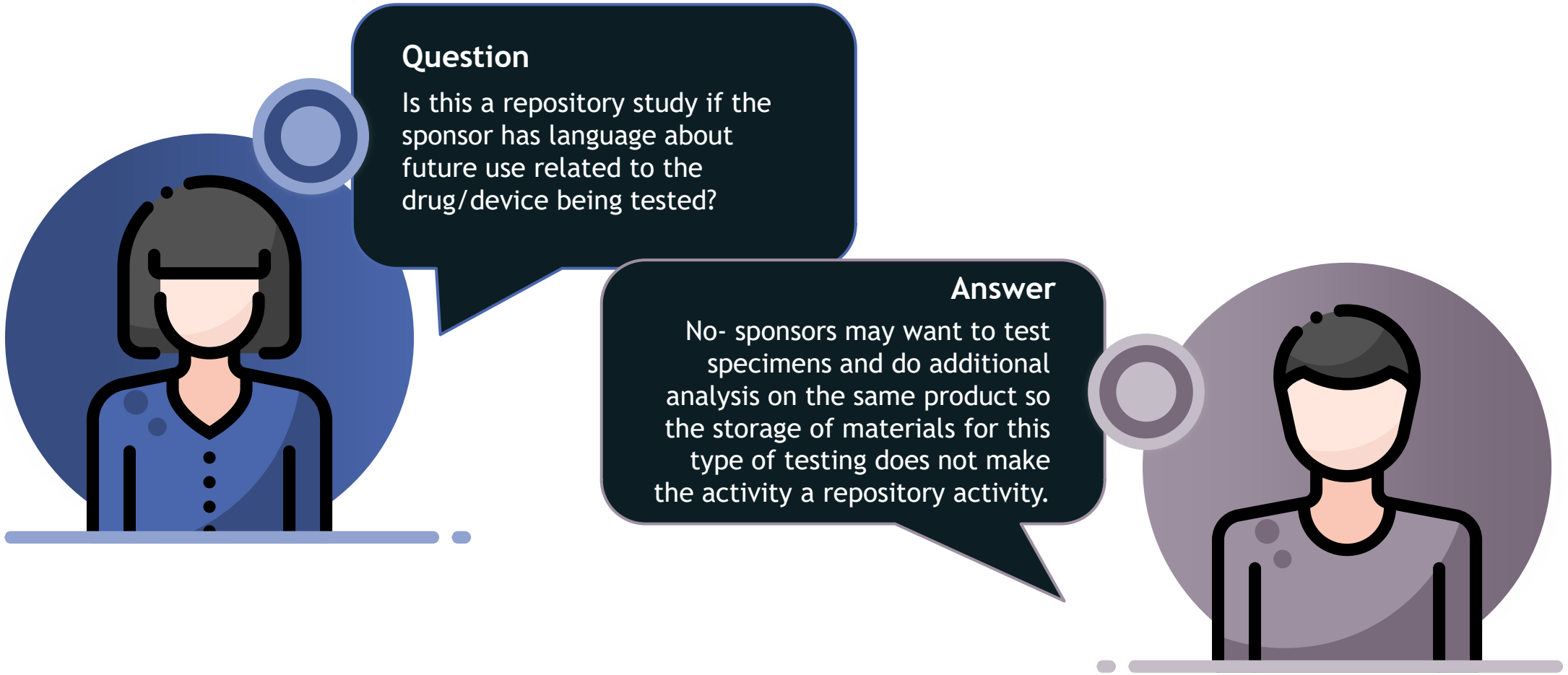
An honest broker acts as an intermediary between the researchers and the data subjects. They ensure that the researchers do not have access to any identifying information of the participants, thus protecting their confidentiality and privacy.

By managing access to data and ensuring that only de-identified data are provided to researchers, an honest broker helps maintain the integrity of the dataset. This reduces the risk of unintended disclosure or misuse of sensitive information.

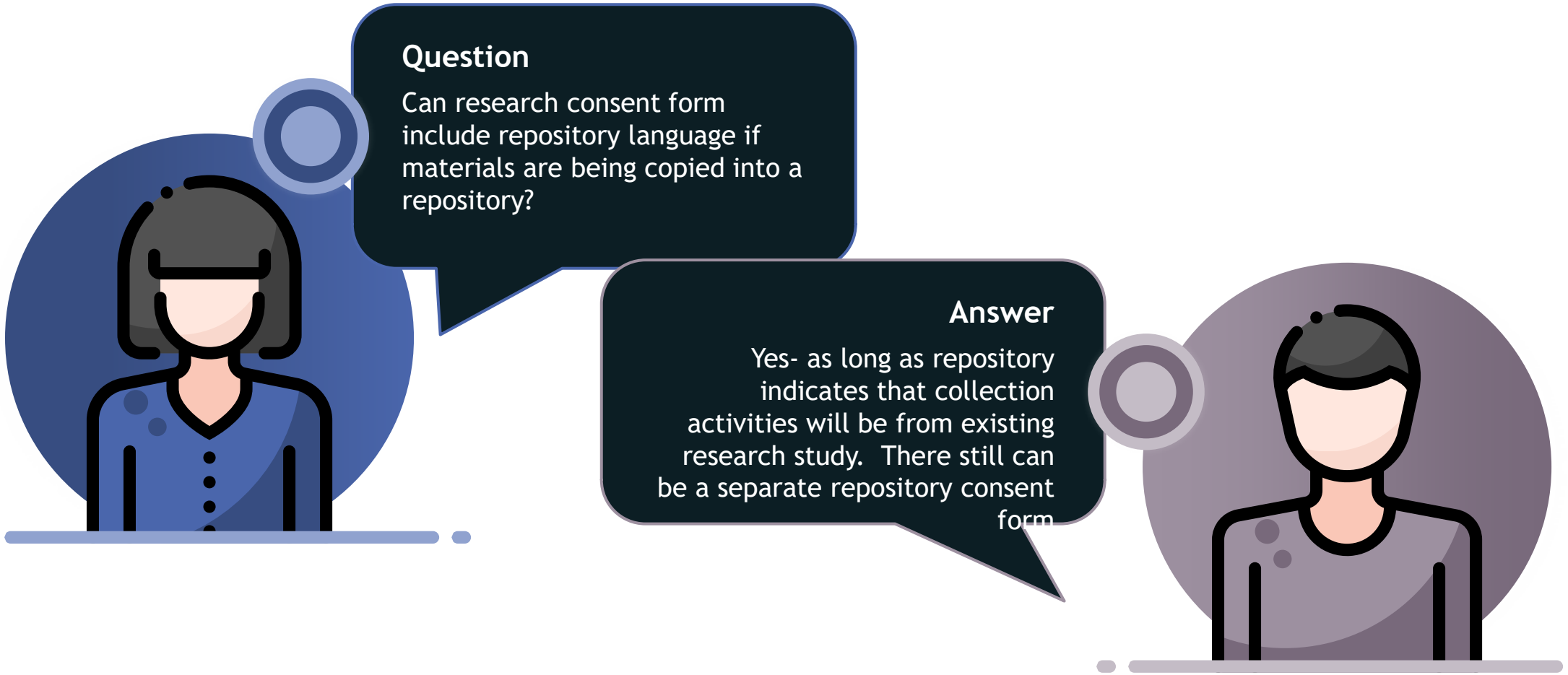
With an honest broker managing data access and sharing, researchers can collaborate more effectively across different institutions or research projects. The broker can streamline the process of accessing data while ensuring compliance with relevant regulations and policies.

Data received through Honest Broker is typically de-identified making subsequent research non-human in nature

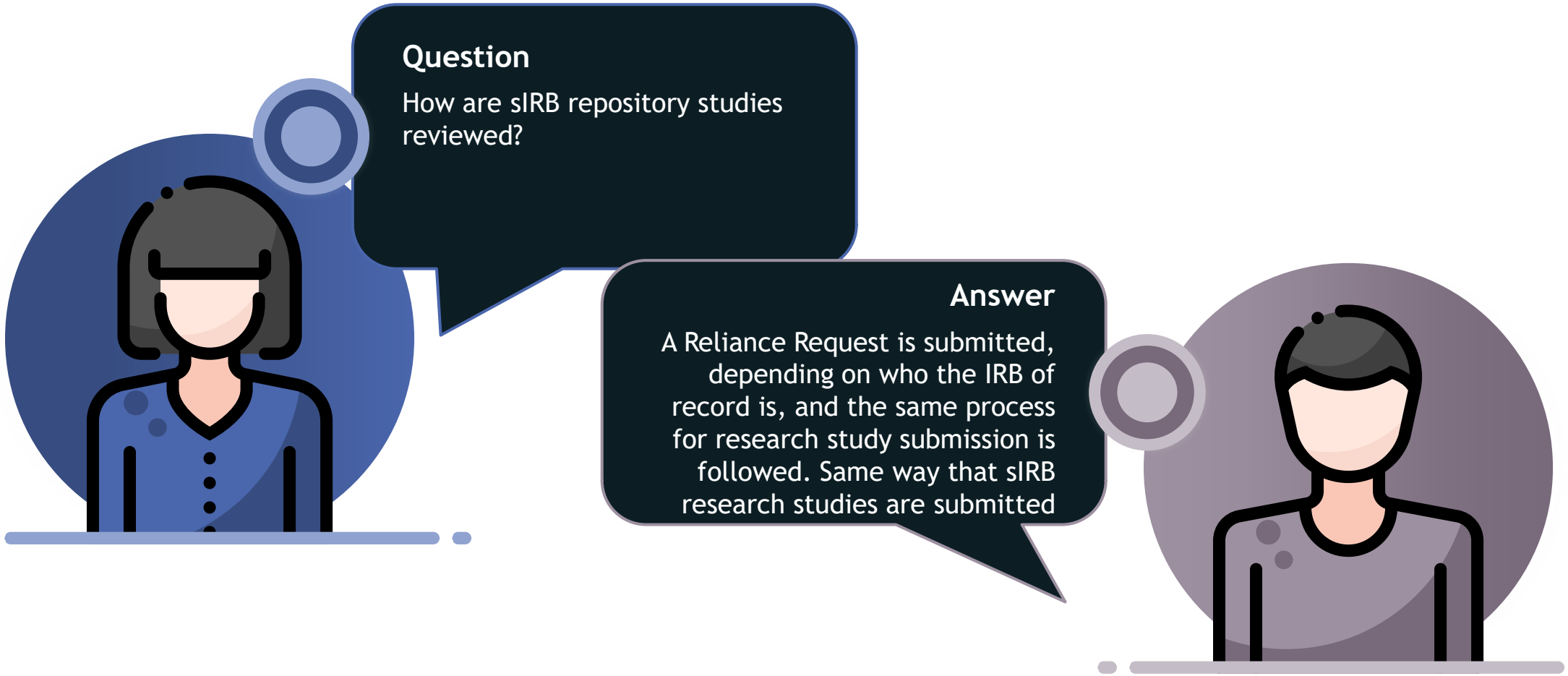
FAQs


Question
Is this a repository study if the sponsor has language about future use related to the drug/device being tested?
Answer
No- sponsors may want to test specimens and do additional analysis on the same product so the storage of materials for this type of testing does not make the activity a repository activity.

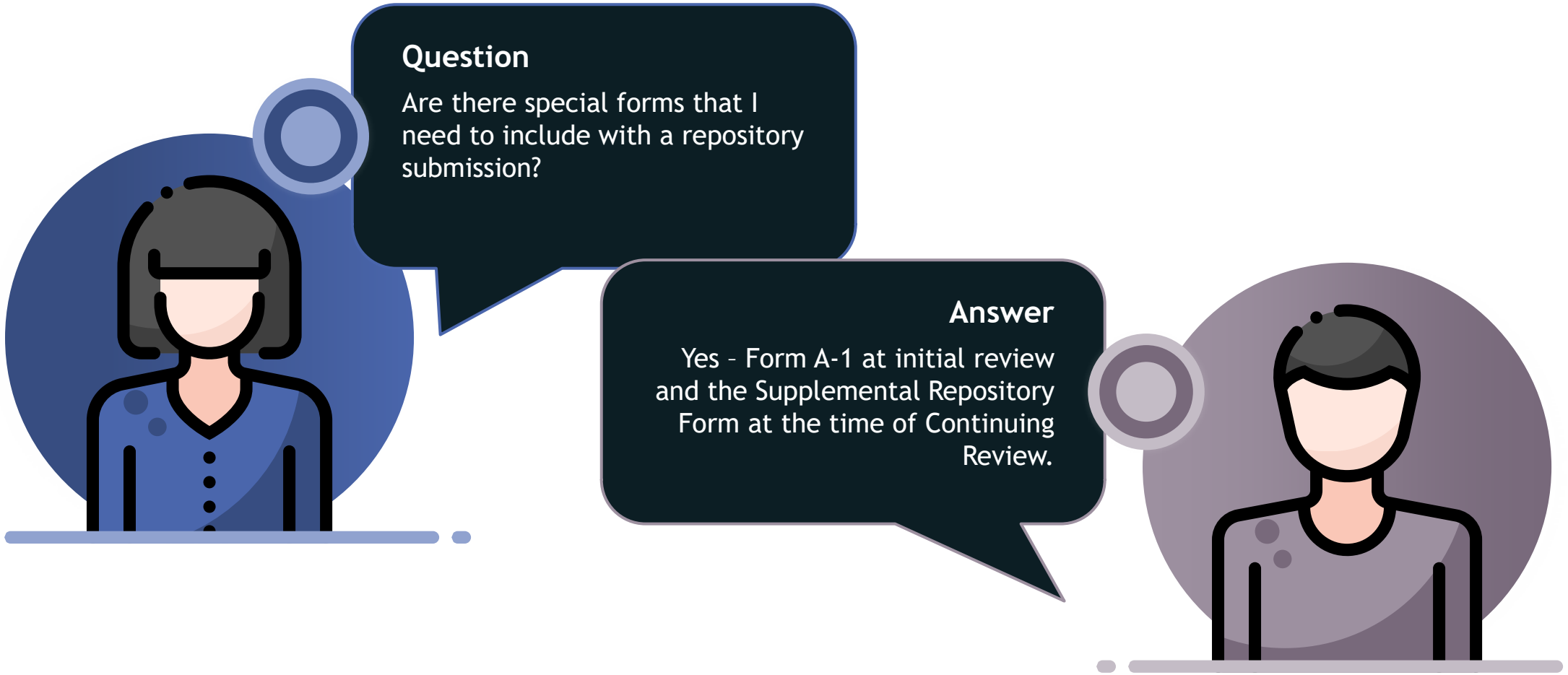
FAQs


Question
Can research consent form include repository language if materials are being copied into a repository?
Answer
Yes- as long as repository indicates that collection activities will be from existing research study. There still can be a separate repository consent form

FAQs


Question
How are sIRB repository studies reviewed?
Answer
A Reliance Request is submitted, depending on who the IRB of record is, and the same process for research study submission is followed. Same way that sIRB research studies are submitted

FAQs


Question
Are there special forms that I need to include with a repository submission?
Answer
Yes – Form A-1 at initial review and the Supplemental Repository Form at the time of Continuing Review.

FAQs

Question

What if my department has a clinical database and I have a study that I'd like to conduct by using the available data in the clinical database?

Answer

It depends upon what information is stored in the clinical database.

- If PII/PHI is stored along with the materials, you require for your study - SUBMIT AN EXEMPT STUDY
- If there is no PII/PHI stored along with the materials, you require for your study (de-identified database) - YOU MAY SUBMIT A FORM Y1 – FOR A NON-HUMAN RESEARCH

FAQs

Question

What is the difference between a clinical database and a research repository?

Answer

- Clinical databases are use of a variety of electronic health record information which are intended for diagnosis, treatment, billing, marketing, and quality improvement/control purposes.
- Research repositories are a bank of materials created with the sole purpose of being able to conduct research without having to create and manage a new study.

Questions

Thank You!

- **We'd love to hear your feedback.** We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

- Visit: https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW