Registries and Repositories

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Registries and Repositories

- What are they?
- Things to consider beforehand
- Is IRB review required?
- Is informed consent required?
- Is a Data Use Agreement (DUA) required?
- How do I use a registry/repository?

What are they?

- Registry - A registry is a tool that identifies and tracks groups of people with similar characteristics, such as disease, genetic makeup, health behaviors, and surgical procedures. Registries can be used to provide investigators with potential study volunteers.



What are they?

- Repository - A repository is a tool that collects and stores data from individual patients for analysis purposes. Repositories can contain biological specimens.



Things to consider beforehand

- Does the data already exist?
- If so, is the quality of the data sufficient to answer the related research questions?
- Can you afford to maintain a registry/ repository?



Is IRB review required?

- It depends.
  - Is the proposed registry/repository for clinical or research purposes?
- If it will be used for clinical purposes, IRB review **is not** required.
- If it will be used for research purposes, IRB review **is** required.
- Already established clinical registries/repositories **cannot** be used for research purposes as the IRB does not grant retrospective approval.

Is informed consent required?

- It depends.
  - Will the registry/repository be sharing PHI?
    - If yes, consent is required.
    - If no, consent is not required. Instead, a waiver of consent can be requested.
- It is highly recommended that consent be obtained to increase the utility of the registry/repository.

Is informed consent required?

- A common question the IRB receives “Why do I need consent when I am only collecting data through a retrospective chart review?”
  - This activity alone would normally be reviewed as an exempt submission under category (d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimen.
  - However, when adding this data to a registry/repository, the study is required to be reviewed as an expedited submission, and thus requires either consent or a waiver.

Is informed consent required?

- The reason for this is that the data is being moved from a HIPAA protected database (usually the medical record) to a non-HIPAA protected database.
  - IRB must now perform continuing reviews to ensure participant data is continued to be protected and kept confidential.

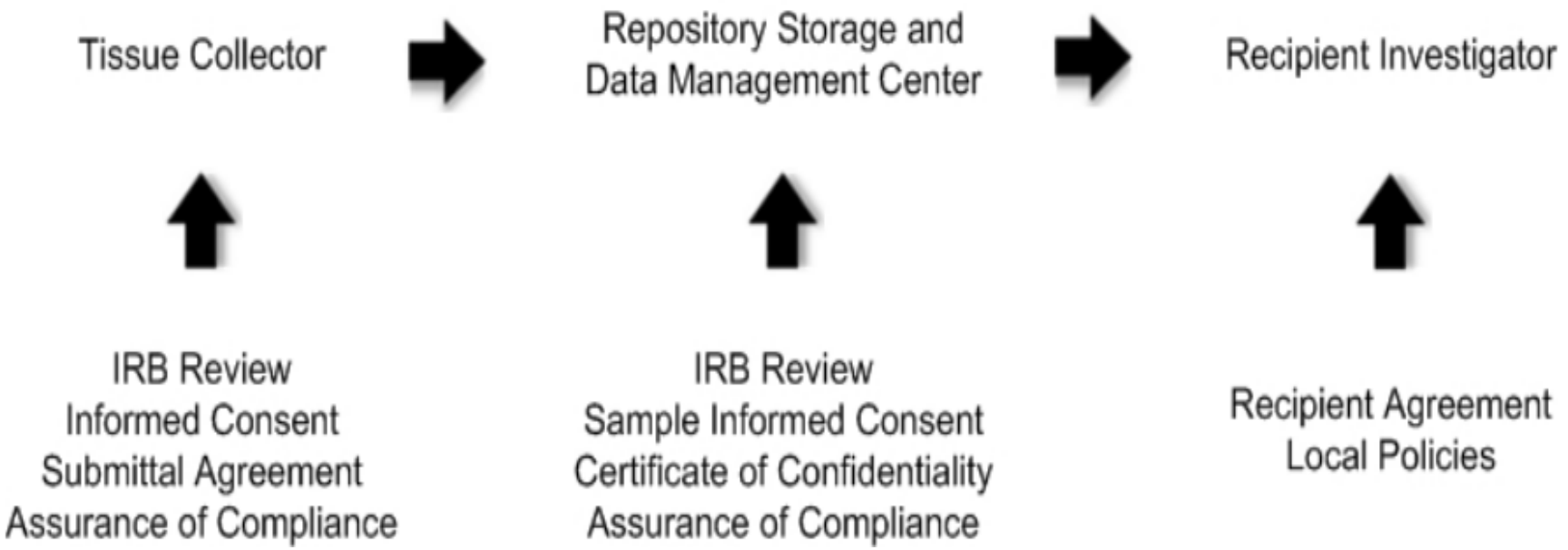
What are the two activities of a Repository submission?

- The use or disclosure of PHI for creating a research database or repository.
- The subsequent use or disclosure of PHI in the database for a particular research protocol.

How do I use a registry/repository?

- Future studies that want to utilize data from a repository will need to submit a new expedited study application.
  - The IRB will review the original registry/repository submission to ensure its stated purpose aligns with future research requests.
- If the registry/repository obtained consent for the collected data, consent does not need to be re-obtained if participants will not be contacted.
- If the registry/repository did not obtain consent, then it can only share deidentified data.

How do I use a **tissue** registry/repository?



Is a Data Use Agreement (DUA) required?

- If data will be maintained and shared within Baystate Health, then a DUA would not be required.
- If data will be shared outside of Baystate Health, a DUA may be required.



Questions?

