Five Models for Biorepositories

Model 1: Treatment/Admission Permission

- Recruitment of all patients who enter facility/clinic
- Opt-in or Opt-out to retain/obtain data and specimens
- HIPAA
- Consent
- IRB
- Specified future use/ Unspecified future use
- Human Subjects/ Not Human Subjects
- Releases to secondary users: identifiable/ not identifiable
- Type of specimen/ data
- Mechanism to update subjects records
- Return of results policy (CLIA)

Model 2: Study-based: Retention of Data and/pr Specimens Subsequent to Study

- Recruitment of subjects who are in an approved study protocol
- Opt-in or Opt-out to retain/obtain data and specimens
- HIPAA
- Consent
- IRB
- Specified future use/ Unspecified future use
- Human Subjects/ Not Human Subjects
- Releases to secondary users: identifiable/ not identifiable
- Type of specimen/ data
- Mechanism to update subjects records
- Return of results policy (CLIA)

Model 3: Dedicated Data/Tissue Research Repository

- Targeted population/ Global recruitment
- Opt-in or Opt-out to retain/obtain data and specimens
- HIPAA
- Consent
- IRB
- Specified future use/ Unspecified future use
- Human Subjects/ Not Human Subjects
- Releases to secondary users: identifiable/ not identifiable
- Type of specimen/ data
- Mechanism to update subjects records
- Return of results policy (CLIA)

Model 4: Mixed-source Repository: Uses 2 or More Models (see 1 thru 3)

- Strategy to merge repositories
- Opt-in or Opt-out to retain/obtain data and specimens
- HIPAA
- Consent
- IRB
- Specified future use/ Unspecified future use
- Human Subjects/ Not Human Subjects
- Releases to secondary users: identifiable/ not identifiable
- Type of specimen/ data
- Mechanism to update subjects records
- Return of results policy (CLIA)

Model 5: Study Based: Biospecimens Integral to Study (e.g. Genetic Study)

- Obtain data and specimens
- HIPAA for study
- Consent for study
- IRB
- Future use for study
- Releases to secondary users
- Type of specimen/ data
- Mechanism to update subjects records
- Return of results policy (CLIA)

Accessing Data from a Biorepository

Secondary Users Policy

- Establish a review board
- If identifiable, consistency with informed consent/HIPAA
- Assess scientific merit
- Does study meet biorepository policies?

Office for the Protection of Research Subjects