University of Kentucky Specimen Banking/Repositories Informed Consent Resources 3/2014

Informed consent is one of the most important ethical issues involved in biobanking. The UK Office of Research Integrity (ORI) has updated guidance and consent language to help investigators and organizations develop a process that fits the unique characteristics of the repository or banking study.

Because of the extensive variation in the design and operation of research repositories, a "one size fits all" template is not feasible. The ***Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future*** **Use [PDF]** presents issues for consideration, sample template language, and optional approaches for the consent process.

The ***Sample Consent to Participate in a Research Repository or Individual Study Banking Material for Future Use*** **[WORD]** is a pre-fabricated version of the consent language from the Issues document. Investigators may copy or customize applicable portions of the sample template which includes elements of informed consent, a section for banking sub-studies, and authorization language if the repository involves use and disclosure of protected health information.

The following illustrates just a few examples of the diversity in purpose and procedures that may account for the vast variation in consent which may range from an interactive process where the donor has extensive and ongoing say regarding use of their sample, to situations where informed consent may be waived by the IRB.

Relationship between subject and PI when collection is in conjunction with research or an optional sub-study of an individual clinical trial.	Relationship between patient and institution when collection for an organized research repository that systematically stores and shares material and associated information.
Banking by a clinical division for a single specific purpose such as oncology research in a core lab.	Banking for future unspecified research in which material will be shared with researchers within or outside the institution.
Secondary use of de-identified specimens by recipient researcher under agreement not to re-identify.	Secondary use of coded specimens matched with medical record information utilizing human and/or computerized honest broker systems.
Banking blood sample left over from clinical lab analysis.	Collection of specimens, health questionnaires, and ongoing access to medical records.
Collections of tissue leftover from a clinical procedure.	Collection of extra tissue from a clinical procedure or collection of tissue solely for research purposes.
Whole genome sequencing to identify germline variants.	Anonymous genetic data placed in open access internet database.

Informed consent for repositories and specimen banking is typically broad to allow for a wide range of potential future uses in research. However, the consent document should be specific enough to inform subjects about concepts that may apply, such as ownership of donor tissue, secondary unspecified future research, privacy protections, unlimited medical record access, incidental findings, and large-scale data sharing. Ultimately, research conducted by recipient investigators who access material from a repository should be consistent with the uses described at the time of consent.

In addition to the consent document, repositories may choose from a variety of consent approaches. Literature describes a number of consent approaches to enhance donor comprehension, autonomy, and personal control over future use of donated material. Dynamic consent is a novel approach using modern communication strategies such as ongoing, interactive web-based consent. Repositories may choose a tiered approach to allow participants to "opt-in" or "opt-out" of select uses as long as systems are in place to ensure participant's wishes are followed. Another streamlined approach involves a simplified consent containing key issues, used in conjunction with supplemental material such as glossaries or FAQ pamphlets. This option is particularly useful where non-research personnel are trained to obtain consent in a clinical setting.

Such variability influences not only informed consent, but also the determination whether or not the banking activity involves human subject research. Designation as "not human subject research" involves more than just use of de-identified specimens. For the applicable criteria, see the **UK Guide For Determining When Protocols Involving Coded Private Information or Biological Specimens Meet the Federal Definition of "Human Research" [PDF].**