IRB Member Minute

Informed Consent Key Information for Banks & Repositories

The informed consent process and form(s) should begin with a concise summary of Key Information, which zeros-in on the most important reasons one might or might not want to participate in the research.

For a bank that may share specimens for genetic research or genomic data sharing, the possibility of a bruise from the needle stick is probably not the best choice for the "might not want to" portion of the Key Information.

The risk of re-identification in genetic or genomic research could have significant consequences for the individual and family members (e.g., insurability, employability, family distress).

Likewise, the protections and safeguards employed to prevent re-identification (e.g., secondary researcher agreements, the Genetic Information Nondiscrimination Act), may be key reasons an individual would choose to participate.

While choosing what to include in the Key Information is a judgment call, the IRB can ask an investigator's basis for his/her choice(s) and request changes where necessary. The participant-centered movement has prompted considerable empirical research on participant perceptions, which may be consulted for guidance.

See the ORI Sample Applications page for examples of Key Information including a Research Biobank, Comparative Effectiveness Research, and others.