Group Exercise on Informed Consent;

Please read and pick a topic. Then please pick the question(s) you would like to discuss in your group.

Vulnerable Populations

1. You are working with children ages 2-18 in a study on how psychological and medical conditions affect relationships with caregivers. Although you have the required parental permission, in some cases it's hard to tell whether the child really wants to participate in the study. Discuss the regulatory considerations regarding assent in these situations.
2. Discuss what to do if you discover your study has enrolled a pregnant woman or a prisoner or a child and the study was only reviewed under subpart A. Under what conditions would you conduct a pregnancy screen for all participants? Ask questions about incarceration? Age?
3. How do you determine who is vulnerable in international research and how does that affect the informed consent procedures and processes?
4. Share ideas with your table on techniques/tools for enhancing informed consent with vulnerable populations.

Internet Research*

(*Note, OHRP has not issued specific guidance on internet research. Please discuss regulatory/IRB considerations and best practices for the following scenarios.)

1. Is internet research automatically exempt because there is no "reasonable expectation of privacy" on the internet? What is observation of public behavior in the online setting? Must you get consent before doing any research on internet fora?
2. Is an internet data miner conducting research? Is a survey host (i.e., "survey monkey") engaged? How would you consent participants? How do you ensure you are not dealing with vulnerable populations (e.g., children, prisoners, pregnant women) in internet research?
3. Share ideas with your table on techniques/tools for enhancing informed consent in internet research.

When to Waive?

1. An investigator proposes to conduct a study of spousal abuse. The investigator will interview women and obtain private identifiable information from them about their abusive spouse. Because of this, the abusive spouses are now subjects. The investigator is seeking a waiver of informed consent for the abusive spouse. Discuss what determinations an IRB must make in order to waive informed consent and/or documentation of informed consent.
2. When determining whether informed consent can be waived under 45 CFR 46.116(d), discuss what factors would satisfy the criterion that "the research could not practicably

be conducted without the alteration or waiver." Consider whether in the following examples, the research could not practicably be conducted without the alteration or waiver of informed consent:

- Prospective study of 100 individuals being treated for HIV infection. The medical records will be reviewed periodically and data will be collected and recorded with identifiers.
- Several years after graduation, an investigator wants to search the institution's databases to determine whether there is a correlation between math grades and graduation of students enrolling with a major in the institution's elementary education program. The investigator wants to record student names, grades, and graduations status. Records indicate that the program included 5000 students entering the program.
- We need 100% participation of the targeted study population to avoid self-selection bias.

3. Share ideas with your table on techniques/tools for best practices and ethical considerations when waiving consent.

Repositories

1. Describe informed consent best practices for: (a) "secondary use" of previously collected research data retained by the investigator and (b) excess biological specimens stored in a pathology laboratory's archives.
2. You are conducting a study on cancer that offers the possibility of benefit for participants. As a condition of participation, the study sponsor would like to require the subject to agree to authorize the use of his/her tissues for any future research projects. Discuss the ethical and regulatory implications of this consent procedure.
3. You are conducting a study on a variety of genetic factors and are planning to store tissue. For some genetic factors, the clinical significance is currently unknown, but you are expecting the researchers in your study may make discoveries that could affect current participants or their descendents. Discuss ethical, consent and best practices.
4. Share ideas with your table on techniques/tools for enhancing informed consent with repositories.

Informed Consent and the use of the Short Form

1. Describe the procedures for seeking and documenting legally effective informed consent from subjects who are:
    a. Blind
    b. Illiterate
    c. Physically unable to sign their name.
2. Describe the procedures for seeking and documenting legally effective informed consent from subjects who are not fully fluent in English.
3. Share ideas with your table on techniques/tools for enhancing informed consent using the short form.