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Finding Flexibility in the Regulations



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Human Research Protection Programs, Inc.[®]

Areas for Consideration

- Use of exemptions
- Use of expedited procedure
- Consent issues
 - Waiver or alteration of the consent process
 - Waiver of parental permission
 - Waiver of assent of children
 - Consent disclosures
 - Waiver of documentation of the consent process

Under Utilization or Unnecessary Restrictions on Exemptions

- Some organizations do not grant exemptions
- Some organizations add restrictions to the criteria
 - Involvement of vulnerable populations
 - Recording of identifiers
 - Collection of identifiable data
 - Use of deception techniques
 - Video/audio taping

Take Advantage of the Option to Exempt Certain Types of Research and Consider Ethical Issues

- Presents no more than minimal risk
- Equitable selection
- Consent process and disclosures
 - *May omit if no participant contact, or interferes with research and is unreasonable*
- Documentation of consent process
 - *May omit unless a legal requirement*
- Privacy interests of participants protected
 - *May omit if no participant contact*
- Confidentiality of data maintained
 - *May omit if data are anonymous*
- Protections for vulnerable populations
 - *May omit if no vulnerable populations*
- Consent process
 - Sufficient opportunity to decide
 - No coercion or undue influence
 - Understandable language
 - No exculpatory language
- Consent disclosures
 - The study involves research
 - The purposes of the research
 - The expected duration
 - Procedures to be followed
 - Extent to which confidentiality will be maintained
 - Whom to contact to ask questions
 - Participation is voluntary

Under Utilization of the Expedited Procedure

- Some organizations do not use an expedited procedure
 - Certain categories of research are eligible for review using an expedited process
 - Minor modifications to previously approved research

Use an Expedited Procedure

- Decide when the IRB will use an expedited procedure
 - For review of certain types of research studies
 - For review of minor modifications
 - Define “minor”
 - Use a procedure that involves one experienced IRB member as the reviewer
 - Have the IRB chair designate a list of experienced IRB members who may reviewer using the expedited procedure

Consent

- Waiver or alteration of the consent process
- Waiver of parental permission
- Waiver of assent of children
- Consent disclosures
- Waiver of documentation of the consent process

Not Waiving or Altering the Consent Process

- An IRB may approve a consent procedure which does not include, or which **alters**, some or all of the elements of disclosure, or waive the requirements to obtain consent provided the IRB finds and documents that:
 - The research involves no more than minimal risk to the participants
 - The waiver or alteration will not adversely affect the rights and welfare of the participants
 - The research could not practicably be carried out without the waiver or alteration
 - Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- The waiver is not inconsistent with federal, state, or local law

Another Circumstance for Waiver or Alteration of the Consent Process

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs
- The research could not practicably be carried out without the waiver or alteration

Basic Disclosures

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

Basic Disclosures

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Unnecessary Consent Disclosures

- Some disclosures are irrelevant to some types of research:
 - If disclosure element includes “any” and there is nothing that falls into the disclosure category, may consider this element not to apply
 - Any experimental procedures
 - Any reasonably foreseeable risks or discomforts
 - Any reasonably expected benefits to participants or others
 - A disclosure of appropriate alternatives, if any
 - The extent, if any, to which confidentiality will be maintained
 - For research involving more than minimal risk, ...
- No requirement to disclose what is not part of the research, not a consequence of the research, or not related to the research

Not Waiving Parental Permission

- May waive parental permission under the provisions for waiver of the consent process
- If the IRB determines that a protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children), it may waive permission:
 - An appropriate mechanism for protecting the children who will participate as participants in the research is substituted
 - Depends on the nature and purpose of the research activities, the risk, potential benefit to research participants, their age, maturity, status, and condition
 - The waiver is not inconsistent with federal, state, or local law

Not Waiving Assent of Children

- The IRB shall determine that adequate provision are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent
 - IRB shall take into account the ages, maturity, and psychological state of the children involved
 - This judgment may be made for all the children involved in the protocol or for each child, as the IRB deems appropriate
- IRB may determine that assent is not a necessary condition for proceeding with the research when:
 - The IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted
 - The IRB determines that the intervention procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research
- The IRB may waive the requirement for assent under provisions for waiver of the consent process

Not Waiving Written Documentation of the Consent Process

- An IRB may waive the requirement for the investigator to obtain a signed consent document for some or all participants if it finds:
 - That the research presents no more than minimal risk of harm to participants; and
 - Involves no procedures for which written consent is normally required outside of the research context

Waiver of Written Documentation of the Consent Process

- Research reviewed using the expedited procedure:
 - No more than minimal risk of harm and
 - Includes procedures in categories (1)-(7)
- Criteria for waiving documentation of the consent process
 - No more than minimal risk of harm and
 - In almost all cases, written consent is normally not required when procedures in categories (1)-(7) are performed outside of the research context
- Therefore, consent documentation may be waived for almost all research approved using the expedited procedure

Documentation of the Consent Process

- Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form
- Other potential options:
 - Video or audio taping and providing a copy of the audio or video tape
 - Clicking “I agree” on a Web site