Grand Valley State University Human Research Review Committee	
Title: *Waivers, alterations and exceptions to informed consent process and documentation*	
Section: 820.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011 Revisions approved on 04/08/2014 Revisions approved by HRRPPC: 04/24/2018	Approved by RIO/HRPA: 09/23/2011 Revisions approved on 04/08/2014 Revisions approved by AIO/RIO: 05/23/2018
Effective Date: 05/23/2018	
Related documents: *710: Assessing risk to research participants* *720: Assessing risk in vulnerable participants* *810 Informed consent – general* *812: Informed assent and parental permission* *814: Informed consent for persons not fluent in the primary language of the study*	

Policy

In some circumstances, the HRRC may approve for a non-exempt, minimal risk protocol a consent procedure that alters or excludes some or all of the elements of informed consent, or may waive the requirement to document consent (obtain a signed consent form) for some or all participants. For situations in which documentation of informed consent is waived, the HRRC may still require the researcher to provide participants with a written information statement regarding the research. The HRRC must document its justification for any waiver or alteration to the standard requirements for informed consent.

Procedures

1. Approval of Waivers

    a. Any waivers of documentation or alterations to informed consent must be voted on separately from the vote for approval of the protocol for both expedited and full-board protocols under review. For protocols under expedited review, all reviewers, as well as the Chair reviewing the protocol, must vote to approve the waiver. For protocols under full-board review, the HRRC must approve the waiver by majority vote.

    b. For FDA-regulated research, the HRRC may determine that a waiver or alteration of informed consent is permissible for clinical investigations involving no more than minimal risk to participants, consistent with the FDA guidance on this topic published July 2017.

2. Use of Deception

a. When deception is a necessary and integral part of a study design, preliminary consent must still be obtained whereby the researcher informs the participant about the research. Deception generally requires that after the research interventions have been completed, the researcher explains the nature of and need for the deception to the participants and then seeks their post-facto approval of the deception. The participant's acceptance or refusal of the explanation provided should be recorded in the researcher's notes, but does not require a signature of the participant.

b. If an individual participant refuses to accept the explanation provided and requests that any information collected from or about him or her be destroyed, the researcher should comply with this request to the extent feasible.

c. If a preponderance of participants do not accept the explanation offered of the need for deception, even if they are willing to continue to participate in the research, a report of an unexpected problem in the research must be reported to the HRRC. Any other unexpected problems that arise from the use of deception also must be reported to the HRRC in a timely manner. Debriefing participants of the use of deception may be done after each individual participant or after the entire group of participants have completed the research procedures, depending on the study design.

Guidance

1. HHS regulations at 45 CFR 46.116(d) and FDA guidance on waiving informed consent published July 2017 require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. For expedited reviews, these findings can be documented by the designated reviewers or HRRC chair. For research reviewed by the convened IRB, these findings must be documented in the meeting minutes. The required findings are:

    a. The research involves no more than minimal risk to the subjects;
    b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
    c. The research could not practicably be carried out without the waiver or alteration; and
    d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2. **Waiver of parental permission and 46.408(c) and (e)** ***Requirements for permission by parents or guardians for assent by children***
    408 (c): The HRRC may waive the requirements for obtaining parental or guardian permission if either of the following 2 conditions is met:
        1. The HRRC makes and documents the required findings under either 45 CFR 46.116 (c) or (d) [the "practicability conditions"], OR

2. The HRRC determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) AND the following two additional criteria are also met:

(a) An appropriate mechanism is in place to protect the children

(b) The waiver is not inconsistent with federal, state or local law.

The choice of an appropriate substitute mechanism (for example, appointing a child advocate or assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

Note that the HRRC may waive the requirement for obtaining parental or guardian permission under 45 CFR 46.408(c) even if the research involves more than minimal risk to the child subjects. 408(e): When the HRRC determines that assent is required, it shall also determine whether and how assent must be documented.

3. Exclusions of or Alterations to Elements of Informed Consent:

"An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent…or waive the requirements to obtain informed consent provided the IRB finds and documents that:

i. The research involves no more than minimal risk to the subjects;
ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
iii. The research could not practicably be carried out without the waiver or alteration; and
iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation" (45 CFR 46.116(d)).

4. **Waiver of Documentation of Informed Consent**:

"An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

v. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
vi. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context" (45 CFR 46.117(c)).