Grand Valley State University Institutional Review Board (IRB)	
Title: *Waivers and Alterations to Informed Consent Process and Documentation [Revised Common Rule Version]*	
Section: 820b.	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 Revisions approved by IRBPPC: 09/27/2019 Revisions approved by IRBPPC: 03/24/2025	Approved by RIO/HRPA: 09/23/2011 Revisions approved on 04/08/2014 Revisions approved by AIO/RIO: 05/23/2018 Revisions approved by AIO: 09/30/2019 Revision approved by AIO/RIO: 3/16/2020 Revision approved by IO: 06/15/2025
Effective Date: 06/15/2025	
Related Documents: *710: Assessing Risk to Research Participants* *720b: Assessing Risk in Vulnerable Participants [Revised Common Rule Version]* *760: Research Utilizing HIPAA-Protected Health Information* *810b: Informed Consent: General [Revised Common Rule Version]* *812: Research Involving Children* *814: Informed Consent for Persons Not Fluent in the Primary Language of the Study* *1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events* *G-15: Guidance on the Use of Deception and Incomplete Disclosure in Research*	

Policy

1. For certain non-exempt studies, the IRB may approve 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.

2. For situations in which documentation of informed consent is waived, the IRB may still require the researcher to provide participants with a written information statement regarding the research.

3. The IRB must document its determination for any waiver or alteration to the standard requirements for informed consent.

Procedures

1. Approval of Waivers and Alterations

    a. Waivers 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.

    b. For protocols being reviewed under expedited review procedures, all reviewers, as well as the Chair reviewing the protocol, must vote to approve the waiver.

c. For protocols being reviewed under full board review, the IRB must approve the waiver or alteration by majority vote and document this determination in the IRB meeting minutes.

2. Use of Deception

a. When deception is a necessary and integral part of a study design, preliminary consent should 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 them 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 IRB. Any other unexpected problems that arise from the use of deception also must be reported to the IRB 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.

3. Criteria for Approving a Waiver or Alteration to Informed Consent

a. General waiver or alteration of consent: When the IRB approves 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, the following elements must be satisfied.

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 requested waiver or alteration;
iv. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation; and
v. For studies reviewed under HHS regulations, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

b. Research involving public benefit and service programs conducted by or subject to the approval of state or local officials.

    i. In order for the IRB to waive or alter consent under this category, the IRB must find and document that:
        a. 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; and
        b. The research could not practicably be carried out without the waiver or alteration.
    ii. The Investigator must provide the IRB with written documentation from an appropriate government official indicating the project is endorsed by the state or local government agency, and the project meets one of the above criteria.

c. If a waiver of consent is approved, the IRB must document the waiver. If an alteration of consent is approved, the IRB must document the specific elements of the consent documentation/process that have been altered.

4. Waiver of Documentation of Informed Consent:

    a. The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

        i. The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participants wants documentation linking the subject with the research, and the subject's wishes will govern;
        ii. 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; or
        iii. If the subjects or legally authorized representatives are members of a district cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an

appropriate alternative mechanism for documenting that informed consent was obtained.

b. If none of the above applies to the research, the IRB may approve an alteration of consent following the criteria outlined in Procedures 3.a above, where the alteration is to not require documentation of consent.

c. If a waiver of documentation of informed consent is approved, the IRB must document the waiver.

5. Waiver of Parent Permission

   a. The IRB may waive the requirements for obtaining parent or guardian permission if either of the following conditions is met:

      i. The IRB makes and documents the required findings under section 3 above, OR
      ii. The IRB determines that the research is designed to study conditions in children or a subject population for which parent 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, AND
         b. The waiver is not inconsistent with federal, state or local law.

   b. 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.

   c. The IRB may waive the requirement for obtaining parent or guardian permission under Procedures 5.a.ii, even if the research involves more than minimal risk to the child subjects.

6. Use of Identifiable Information for Screening and Recruitment Activities

   a. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

      i. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, OR
      ii. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

b. The research protocol should include information about how potential subjects will be identified and recruited in order for the IRB to be able to determine whether informed consent for these activities is required.

c. The use of identifiable records protected by FERPA for screening and recruitment is dependent upon how the educational institution holding the records interprets and applies the FERPA regulations. The use of identifiable records for this purpose may not be permissible.

d. For identifiable records protected by HIPAA, a waiver or alteration of HIPAA authorization will also need to be considered.