Grand Valley State University Human Research Review Committee	
Title: *Informed consent—general*	
Section: 810.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revisions approved 04/08/2014; 10/28/2014 Revisions Approved by HRRPPC: 04/24/2018 Revisions Approved by HRRPPC: 09/25/2018	Approved by RIO/HRPA: 02/16/2012 Revisions approved 04/08/2014; 10/28/2014 Approved by AIO/RIO: 05/14/2018 Approved by AIO/RIO: 12/19/2018
Effective Date: 12/19/2018	
Related documents: *120: Compliance with applicable laws and regulations* *710: Assessing risk to research participants* *720: Assessing risk to vulnerable participants* *730: Collection, management and security of research information* *812: Informed assent and parental permission* *813: Research involving participants with questionable consent capacity* *814: Informed consent for participants not fluent in the primary language of the study* *820: Waivers, alterations and exception to informed consent process and documentation* *G-7: Guidance on constructing an informed consent document*	

Policy

Federal regulations and HRRC policy require that, for all non-exempt research, the researcher must *obtain and document* legally and ethically valid informed consent from the subject or the subject's legally authorized representative *prior to* enrolling the subject in the research. For exempt research involving interactions or interventions with subjects, the researcher must *obtain* legally and ethically valid informed consent from the subject or the subject's legally authorized representative *prior to* enrolling the subject in the research. (Note the informed consent process used for exempt research does not necessarily require the researcher to obtain *written* consent from the subject or subject's legally authorized representative; however, a consent process must be documented in the protocol.) The prospective subject or the subject's legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

In general, this applies to all research projects that fall under expedited or full-board review [45 CFR 46.111, 116, 117]. In addition, special consent, assent and permission requirements may apply to identified vulnerable participants [45 CFR 46 subparts B, C and D]. Some conditions exist that may allow for waivers, alterations or exceptions to the standard informed consent requirements as allowed under the regulations. Consent from research participants or their legal representative must be free from coercion and undue influence, obtained in accordance with applicable laws, and acquired through culturally appropriate means.

Clinical Trials

1. For applicable FDA-regulated *clinical trials*, under 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents:

> "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

2. For federally-funded clinical trials not subject to FDA oversight, the funding agency may require that the consent form contains a statement relating to the posting of clinical trial information into a data repository. In such cases, researchers must include this statement in the consent form and, where applicable, use the specific language required by the funding agency.

Procedures

1. Non-Exempt Research: Elements of Ethically and Legally Valid Informed Consent—General requirements

    a. Informed consent shall include written and/or verbal expression of the following information components to minimize confusion or misunderstanding about the research.

        i. Name of the principal investigator;
        ii. A statement that the study involves research and an explanation of the purposes of the research;
        iii. A description of the expected duration of the total research participation, the procedures to be followed, including notice of any procedures that are experimental, and the approximate time required for each component,;
        iv. A description of any reasonably foreseeable risks or discomforts to the participant;
        v. A description of any reasonably anticipated benefits to the participant or to society;
        vi. A description of alternatives to the research including not participating;
        vii. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
        viii. Whom to contact in the event of research-related harm to the participant;
        ix. Whom to contact with questions about the research;
        x. Whom to contact with questions about participants' rights, or concerns or complaints about the research or research team members;
        xi. A statement that participation is voluntary and refusing to participate or discontinuing participation will not lead to any penalty or loss of benefits to which the participant is otherwise entitled;
        xii. A statement of what will be done with collected data if a participant withdraws from the research;
        xiii. A signature line for the statement of agreement to participate as a research subject including the participant's printed name and date;
        xiv. 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.

xv. A statement indicating the protocol has been approved by the Human Research Review Committee at Grand Valley State University and the corresponding protocol number of the study.

b. Informed consent shall include written and/or verbal expression of the following additional information *as needed* to minimize confusion or misunderstanding about the research. *Not every component is required for every study.*

i. A description of any compensation for participation or that no compensation will be provided;

ii. A description of how participants will be selected and the basis for any inclusions or exclusions;

iii. A description of the circumstances when participation may be terminated by the researcher without the participant's consent;

iv. A description of the consequences of a subject's voluntary withdrawal from the research, if any, and procedures for orderly termination of participation;

v. Disclosure of any additional costs to the subject that may result from participation in the research;

vi. A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

vii. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

c. Informed consent documents may not contain any exculpatory language; that is, language which states, suggests or implies that the participant waives any legal rights or to release the researcher, the sponsor, or the University from liability for negligence.

d. NIH-Funded Research: Informed consent documents developed for NIH-funded research are required to include a description of the issuance of Certificates of Confidentiality, as outlined in NIH Notice Number NOT-OD-17-109.

(See also: ORCI Guidance G-7: *Guidance on constructing an informed consent document*)

2. Exempt Research: Elements of Ethically and Legally Valid Informed Consent—General requirements

a. Exempt research involving interactions with research subjects requires a consent process, either verbally or in writing, that shall include the following disclosures.

i. Name of the principal investigator;

ii. A statement that the study involves research and an explanation of the purposes of the research;

iii. A description of the expected duration of the total research participation and the procedures to be followed;
iv. A statement that participation is voluntary and refusing to participate or discontinuing participation will not lead to any penalty or loss of benefits to which the participant is otherwise entitled;
v. A description of any reasonably foreseeable risks or discomforts to the participant, if any;
vi. A description of any reasonably anticipated benefits to the participant or to society, if any;
vii. A statement indicating the protocol has been reviewed by the Human Research Review Committee at Grand Valley State University and the corresponding protocol number of the study

b. A written or electronic signature documenting consent is not required for exempt research, unless additional regulations or policies requiring signature apply to the research (i.e. Family Educational Rights and Privacy Act [FERPA], Health Insurance Portability and Accountability Act [HIPAA], General Data Protection Regulation [GDPR]).
c. An active ("opt-in") consent process must be used for any research study involving the collection of GDPR-covered data. See *HRRC Policy 120: Compliance with applicable laws and regulations* for more information.

3. Long-form and Short-form Consent for Non-Exempt Research

a. If a written consent document is used it should be printed on GVSU letterhead and written at a reading level that is appropriate for all potential participants (generally 6^{th}- 8^{th} grade). Use of the long form for documenting a legally and ethically valid consent process is the default requirement for all non-exempt research. The content of the long-form is specified above and in the federal regulations under 45 CFR 46.116 (a) basic elements of consent and (b) additional elements of consent, and under section 117 (documentation requirements).

b. Unless a waiver or alteration is approved by the HRRC, researchers must acquire informed consent and document it using either a long-form or a short form process. Note that the short form process requires, in addition to producing a summary of the long form, also producing and reading the content of the long form and providing a copy of it and of the short form to the research participant or their legally authorized representative.

c. The HRRC does not require a witness to the consent when the long-form is used, though study sponsors may have different requirements. Per DHHS and FDA regulations, the long-form consent document must be signed (including in an electronic format) and dated by the participant or the participant's legal representative. For research studies subject to the International Conference of Harmonisation-Good Clinical Practice requirements, the researcher obtaining consent must also sign and date the consent form. The original

document must be kept in a secure location as described in ***HRRC Policy 730: Collection, management and security of research information*** and must be retained as described in section d below. A copy of the consent document must be given to the participant or his/her legally authorized representative to keep.

d. The short-form consent is a brief document stating that the elements of informed consent as required for the long-form have been presented orally to the participant or the participant's legally authorized representative. The short-form consent is a method that is utilized with participants who are illiterate or otherwise unable to read and/or sufficiently understand the written long-form consent document. For the requirements for utilizing the short-form process, see the Guidance section below.

4. Retaining Consent Documents

a. Documentation of participants' informed consent (either the signed [including in an electronic format] short-form and/or the long-form, or video or audio recordings of consent) are research-related records that must be retained for at least three (3) years after completion of the study, unless the HRRC waived the requirement for informed consent and/or the documentation of informed consent. For FDA regulated studies the record retention is a minimum of five (5) years.

b. If the researchers are students, study record retention is the responsibility of the principal investigator. Consent records may be preserved in hardcopy or electronically copied and retained and the paper copies destroyed. Consent records must be accessible for inspection by the HRRC or other authority. Retention of multiple copies of each record is not required.

c. If a researcher designated to retain records on behalf of GVSU leaves the institution, the researcher and the Authorizing Official should identify a successor, when applicable, who shall take over responsibility for securely maintaining the research records, either at GVSU or at another location. See ***HRRC Policy 730: Collection, management and security of research information***.

Background

Legally and ethically valid informed consent to participate in research requires a process of ongoing dialogue between the researcher and each research participant. This dialogue should result in a shared understanding about what the research involves, what the participant will be asked to do, what risks and benefits the research procedures may entail, if any, and how the results of the research are expected to be used. Informed consent is not a participant's signature on a document or his or her agreement to participate in research. It is a mutual understanding that includes an opportunity for the participant to ask questions and to receive full explanations prior to participating, throughout the research activity, and after it has been completed.