

Standard Operating Procedures IRB Review of Research Subject to the Revised Common Rule

This Standard Operating Procedure (SOP) describes the variations in requirements and procedures that Ferris State University Institutional Review Board (IRB), and investigators, will adhere to for research subject to the revised Common Rule that is IRB- approved, or determined exempt, on or after **January 21, 2019**. This SOP also applies to any studies subject to the pre-2018 version of the Common Rule that Ferris IRB decides to transition to comply with the new rule. When the research invokes multiple regulatory frameworks (e.g., Common Rule, FDA, HIPAA, FERPA), all will be applied.

1. Definitions [§ .102]:

The following definitions will be applied when Ferris IRB reviews research subject to the revised Common Rule, and for exempt determinations and evaluations regarding whether a proposed activity is human subjects research when the research (or activity) is conducted or supported by a Common Rule agency. Likewise, the definitions will be applied, as applicable, to the conduct of the research, investigator responsibilities, and organizational responsibilities. Some of these definitions are unchanged from the pre-2018 rule but are included here for context.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human subject means a living individual about whom an investigator (whether professional or student) is conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be

made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research/Research study means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this rule, the following activities are deemed not to be research:

- (i) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- (ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- (iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- (iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

2. IRB Composition

The composition of the IRB is outlined in the by-laws and conform to the regulations for membership as

outlined in 45 CFR 46.107 which states:

Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. [§.107]

3. Exempt Determinations and Limited IRB Review

Determinations regarding whether research subject to the revised Common Rule qualifies for exempt status will be made by IRB Chair or IRB Administrator in consultation with members of the IRB, when necessary. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair or a Chair-designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities. [§.109(a)]

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB. [§.108(a)(3)(iii)]

Continuing review is not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its

determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter. [§.109(f)(ii), §.115(a)(3)]

3.1. Limitations on Exemptions

Children: Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children. [§ .104(b)(3)]

Prisoners: Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. [§.104(b)(2)]

3.2. Exempt Categories [§ .104(d)]

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also FDA-regulated.

1. **Research, conducted in established or commonly accepted educational settings**, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)** if at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*
3. **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject** through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7): *"When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."*

For the purpose of this provision, **benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.** Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. **Secondary research for which consent is not required:** Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
- (i) The identifiable private information or identifiable biospecimens are publicly available;
 - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 ['HIPAA'], subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**
 - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and,

if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. **Research and demonstration projects that are conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **Taste and food quality evaluation and consumer acceptance studies:**

- (i) If wholesome foods without additives are consumed, or
- (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8 always require limited IRB review and are only available when broad consent will be (or has been) obtained. **At this time, Ferris is not adopting the use of broad consent and therefore categories 7 & 8 will not be used.**

7. **Storage or maintenance for secondary research for which broad consent is required:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § .111(a)(8):

- (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § .116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
- (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § .117 (See Sections 8.6 and 8.7); and
- (iii) If there is a change made for research purposes in the way the identifiable private

information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. **Secondary research for which broad consent is required:** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § .116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
 - (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § .117 (See Sections 8.6 and 8.7);
 - (iii) An IRB conducts a limited IRB review and makes the determination required by § .111(a)(7): *“When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data”* and makes the determination that the research to be conducted is within the scope of the broad consent referenced in 8.i above; and
 - (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

4. Expedited Review

Expedited review of research subject to the revised Common Rule will be conducted using the procedures described in 45 CFR 46.110(b)(2) which states:

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in §46.108(b).

Expedited review will be conducted using the procedures described above with the following variations:

1. The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§ .110(a)]
2. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. [§ .110(b)(1)(i)] If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB
3. The limited IRB review that is required for certain exempt research (See Section 3) may be conducted using expedited review procedures [§ .110(b)(1)(iii)]
4. Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that is required and documents the rationale within the IRB record

5. Modifications to IRB-approved Research [§ .108(3)(iii)]

Investigators must promptly report proposed changes in a research activity to the Ferris IRB, and must

conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

This requirement applies to all research approved by the Ferris IRB, including any aspects of exempt research subject to limited IRB review (See Section 3), and research for which continuing review is not required (See Section 6).

The Ferris IRB will follow the procedures described in this SOP, when reviewing modifications to IRB-approved research subject to the revised Common Rule.

6. Continuing Review [§ .109(e) and (f)]

The revised Common Rule modifies when continuing review is required. Unless Ferris IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with § .110;
2. Research reviewed by the IRB in accordance with limited IRB review as described in Section 3;
3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
 - a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
 - b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

Ferris IRB may determine that continuing review is required for any research protocol that falls within the above criteria. For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations (e.g., FDA);
2. The research involves topics, procedures, or data that may be considered sensitive or controversial;
3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
5. An investigator has a history of noncompliance

When the Ferris IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

The Ferris IRB will conduct annual status reports of all IRB approved research regardless of approval category (exempt, limited exempt, expedited, and Full) at least one month prior to the proposed study expiration date as a means of checking in with the investigator(s) regarding the status of their project (ongoing - no changes; ongoing- modifications needed; ongoing - extension needed; closed).

Investigators will need to provide the following information during a status report:

1. A statement that the project is ongoing with no major changes to the protocol or study design; or

2. If the project is ongoing, but changes are requested, a request for modifications must be submitted for review along with revised documents (e.g., recruitment materials, consent, etc.) before the proposed changes may take effect; in cases where changes are made to the study team, appropriate training documentation (e.g., CITI training) and application certifications will need to be provided, as requested in the modification request form.
3. If the project is ongoing and additional time is requested, an extension request must be completed
4. If the project is ongoing and both changes and additional time are requested - both request forms (modification and extension) and appropriate supporting information must be provided; or
5. If the project is closed/ended, a Final Report should be submitted and the project will be closed.

7. Criteria for IRB Approval of Research

The Ferris IRB will apply the criteria for IRB approval to research subject to the revised Common Rule with the following variations:

Within criterion §.111(a)(3), the text describing vulnerable subjects is replaced with the following:

The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

Likewise, within criterion §.111(b), the description of vulnerable subjects is updated and now reads:

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

While pregnant women are no longer described as vulnerable within the above criteria, the IRB shall continue to apply Subpart B “Additional Protections for Pregnant Women, Human Fetuses and Neonates”. The revised Common Rule does not eliminate or modify Subpart B.

For **exempt research** subject to **limited IRB review**, the following criteria shall be applied:

1. For exempt categories 2(iii) and 3(iii) (See Section 3.2), the IRB may approve the research when it determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
2. For exempt category 7, the IRB may approve the research when it determines that the following criteria are satisfied:
 - a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §.116(a)(1) - (4), (a)(6), and (d) (See Sections 8.1 and 8.3 below);
 - b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §.117 (See Sections 8.6 and 8.7 below); and
 - c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
3. For exempt category 8, the IRB may approve the research when it determines that the following

criteria are satisfied:

- a. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
- b. The research to be conducted is within the scope of the broad consent obtained from subjects.

8. Informed Consent

When reviewing research subject to the revised Common Rule, the Ferris IRB will evaluate the provisions for informed consent as described with the below variations. Investigators conducting research subject to the revised Common Rule must adhere to these requirements.

8.1. General Requirements for Informed Consent [§ .116(a)]

The following specific requirements for consent, whether written or oral, apply to research subject to the revised Common Rule:

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR)
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR
4. The prospective subject or the LAR 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
5. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension
 - a. Generally, the beginning of an informed consent should include a concise explanation of the following:
 1. The fact that consent is being sought for research and that participation is voluntary;
 2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
 3. The reasonably foreseeable risks or discomforts to the prospective subject;
 4. The benefits to the prospective subject or to others that may reasonably be expected from the research; and
 5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

However, based upon the facts of an individual protocol, the IRB may require

that different (or additional) information be presented at the beginning of an informed consent to satisfy this requirement.

- b. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate
1. No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

8.2. Elements of Consent – add to General Requirements

In addition to the elements of informed consent, the following additional elements are required for research subject to the revised Common Rule.

Basic Elements [§.116(b)]

1. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements (must be included when appropriate) [§.116(c)]

1. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
3. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

8.3. Broad Consent [§ .116(d)]

Ferris will not implement the new regulatory "Broad Consent" option as an informed consent process at this time. Exemptions 7 & 8, which rely on Broad Consent, also will not be implemented.

8.4. Waiver or Alteration of Informed Consent [§ .116(e) and (f)]

When reviewing research subject to the revised Common Rule, the Ferris IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the revised rule and summarized below. The IRB's determination will be documented in the IRB record

and communicated to the investigator via the project approval letter.

8.4.1. General Waiver or Alteration of Consent

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an “Alteration”), under this provision the Ferris IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. 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;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions:

1. Waivers –
 - a. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in Sections 8.1 and 8.3, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alterations –
 - a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Section 8.1
 - b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 8.3.

8.4.2. Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an “Alteration”), under this provision the Ferris IRB must determine and document that the below criteria are satisfied.

1. 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:
 - a. Public benefit or service programs;
 - b. Procedures for obtaining benefits or services under those programs;
 - c. Possible changes in or alternatives to those programs or procedures; or
 - d. Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

1. Waivers –
 - a. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements in Sections 8.1 and 8.3, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
2. Alterations –
 - a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Sections 8.1 and 8.3
 - b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 8.3

8.5. Screening, Recruiting, or Determining Eligibility [§ .116(g)]

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the Ferris IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

1. The investigator will obtain information through oral or written communication with the prospective subject or LAR, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

8.6. Documentation of Consent [§ .117]

The revised Common Rule modifies the requirements for documentation of consent as described below. When reviewing research subject to the revised Common Rule, the Ferris IRB will apply the requirements summarized below.

Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF.

The ICF may be either of the following:

1. A written consent document that embodies the basic and required additional elements of

informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or

2. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by § .116(a)(5)(i) (See Section 8.1 #5.a) was presented first to the subject, before other information, if any, was provided. When this method is used:
 - a. The oral presentation and the short form written document should be in a language understandable to the subject; and
 - b. There must be a witness to the oral presentation; and
 - c. The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
 - d. The short form document is signed by the subject;
 - e. The witness must sign both the short form and a copy of the summary; and
 - f. The person actually obtaining consent must sign a copy of the summary; and
 - g. A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

8.7. Waiver of Documentation of Informed Consent [§ .117(c)]

The revised Common Rule adds a third condition under which an IRB may waive the requirement for an investigator to obtain a signed informed consent form. When reviewing research subject to the revised Common Rule, the Ferris IRB may also approve a request for a waiver of documentation of consent if it finds that:

1. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

The IRB's determination will be documented in the IRB record and communicated to the investigator.

9. IRB Review of Grant Applications

The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the Ferris IRB will no longer require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.

10. Posting of Clinical Trial Consent Forms [§ .116(h)]

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal

department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

Federal guidance or instructions regarding the implementation of this requirement was not available at the time this SOP went into effect. Until federal guidance or instructions are available, when Ferris State University is the prime awardee, the IRB office should consult with the Office of Research & Sponsored Programs regarding how to satisfy this requirement.

11. IRB Records [§ .115]

The revised Common Rule includes additional requirements for IRB records. When Ferris State University is engaged in human subjects research subject to the revised Common Rule the following records will be maintained:

1. Institutional Records –
 - a. For nonexempt research involving human subjects covered by the Common Rule (or exempt research for which limited IRB review takes place as described in Section 5.5) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)
2. IRB Records –
 - a. The rationale for conducting continuing review of research that otherwise would not require continuing review (as described in Section 6)
 - b. The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk

12. FDA Regulations

The Ferris IRB does not review investigational research projects involving the administration of investigational drugs or use of significant risk devices. Instead, these projects are deferred to a qualified, accredited external IRB for which the investigator is responsible for identification and costs. The Ferris IRB will work to establish reliance agreements with these external IRBs. Before research can begin, the FSU investigator must upload their application and supporting documents to the Ferris IRB, including external IRB approval documents.

Where FDA regulations are involved, the Ferris IRB will adhere to 21 CFR 50, Protection of Human Subjects, as appropriate for clinical investigations regulated by the FDA. See Appendix A, *Important FDA Regulatory References*, for additional definitions and processes.

Projects involving FDA-regulated drugs or devices may be referred to the Full Committee for review; ample time should be built in to allow for multiple reviews and comments by the Ferris IRB.

12.1 FDA Regulated Drugs [21 CFR 312]

An investigational drug is a substance that has been tested in the laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in people. Clinical trials test how well investigational drugs work and whether they are safe to use. An investigational drug may be approved by the FDA for use in one disease or condition but still be considered investigational in other diseases or conditions. An investigational drug may also be referred to as an experimental drug, investigational new drug (IND), or investigational agent. Supplements may or may not be considered a drug in some instances; if researchers intend to conduct human research with dietary or nutritional supplements, they should contact the IRB in advance. **When submitting an IRB application, it is the investigator's responsibility to determine if an IND application is required and provide evidence for the basis of this determination to the IRB.**

When proposing research that involves administration of non-investigational FDA approved drugs, the researcher must complete the **Drug/Biologics Information Section of the application** and provide certification to the IRB of all of the following (based on IND regulations at [21 CFR 312](#)):

1. The project is neither intended to be reported to the FDA as a well-controlled project in support of a new indication for use nor intended to be used in support of any other significant change in labeling for the drug;
2. The project is not intended to support a significant change in the advertising for the product;
3. The project does not involve a route of administration or dosage level or use in a clinical population or other factor that significantly increases the risk associated with the use of the drug; and
4. The drug is not represented in a promotional context as safe or effective for the purposes under investigation.

12.2 FDA Regulated Devices [21 CFR 812]

When submitting an IRB application, it is the investigator's responsibility to determine if the object of study meets the definition of a medical device by the FDA, as defined in Appendix A. The investigator and sponsor must determine if the device either meets the requirements for an Investigational Device Exemption (IDE) or identify the defined level of risk and also provide evidence for the basis of this determination to the IRB.

The Ferris IRB does not review investigational research projects involving significant risk devices; these projects are deferred to a qualified, accredited external IRB for which the investigator is responsible for identification and costs. In order to review projects using FDA regulated devices, the device must either:

1. Be FDA approved for the proposed indication; or
2. Have an Investigational Device Exemption (IDE) issued by the FDA; or
3. Meet abbreviated requirements at 21 CFR 812.2(b) as follows (regulatory references located in appendix).

The Investigational Device Exemptions (IDE) regulation ([21 CFR 812](#)) describes three types of device projects: significant risk (SR), nonsignificant risk (NSR), and exempt projects. NSR device studies must follow the abbreviated requirements at 21 CFR 812.2(b) which address labeling, IRB approval, informed consent, monitoring, records, reports, and prohibition against promotion. There is no need to make progress reports or final reports to the FDA with studies involving NSR devices. NSR device studies do not require an IDE application approval by the FDA. Sponsors and IRBs are not required to report the IRB approval of a NSR device study to the FDA; thus, the IRB may approve an NSR device study and the investigator may conduct the study without FDA knowledge. The IRB's NSR determination is important because **the IRB serves as the FDA's surrogate for review, approval and continuing review of the NSR**

device studies. Therefore, it is important to provide all information to the IRB that is necessary to evaluate the risk level of the device.

The Ferris IRB will consider the following when determining whether a device study poses a SR or NSR:

- the sponsor’s description of why the device is not a significant risk device
- whether the proposed NSR research study meets the definition of “significant risk”
- the proposed use of the device as well as any protocol related procedures and tests, not just the device (test article) alone. (This process is different from the IRB review process found at 21 CFR 56.111(a)(2).)
- additional information from the sponsor, if needed.

The Ferris IRB will make the SR or NSR determination about a study by reviewing relevant information at a convened meeting and document its determination in the IRB meeting minutes. The information includes the description of the device, reports of prior investigations conducted with the device, the proposed investigational plan, and subject selection criteria. **The sponsor/investigator is/are responsible for providing the IRB with the risk assessment and the rationale used in making their SR or NSR determination.** If the sponsor/investigator identifies a device as NSR, they must complete the **Device Information Section of the application** providing the IRB with an explanation of its determination (21 CFR 812.2(b)(1)(ii)) and any other information that may help the IRB in evaluating the risk of the research. For example, a description of the device, reports of prior investigations with the device, the proposed investigational plan, participant selection criteria, and other information the IRB may need in the protocol. If the FDA has determined that the study is NSR, the sponsor/investigator should inform the IRB within the application.

The IRB may agree or disagree with the sponsor’s initial NSR assessment. If the IRB determines the study is NSR, the IRB may approve the study using the criteria at 21 CFR 56.11 and the study may begin without submission of an IDE application to FDA. If the IRB disagrees with the sponsor’s NSR assessment and decides the study is SR, the IRB will inform the clinical investigator and, where appropriate, the sponsor (21 CFR 812.66). The Investigator/sponsor will be responsible to obtain IRB approval for the SR device study via a qualified, accredited external IRB and establish a reliance agreement with the Ferris IRB.

In order to determine NSR and SR, the Ferris IRB will consider the following:

1. *What is the basis for the risk determination?* The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.
2. *What is the nature of harm that may result from use of the device?* SR studies are those that present a potential for serious risk to the health, safety or welfare of a subject.
3. *Will the subject need to undergo an additional procedure as part of the investigational study, for example a surgical procedure?* The IRB will consider the potential harm the procedure could cause as well as the potential harm caused by the device.

The IRB will document its decision in the meeting minutes. The minutes will describe the IRB’s reason for its SR or NSR determination and may include FDA’s NSR determination where the agency has made the determination. **The IRB will make the SR/NSR determination before the IRB conducts its review of the study under Part 56.** The judgment about whether a study poses a significant risk or nonsignificant risk is based on the significance of the potential harm that may result from participation in the study, including the use of the device; whereas the IRB’s decision to approve a study for implementation is based on the study’s risk-benefit assessment.

If needed, the FDA is the final arbiter in deciding whether a device study poses a significant or nonsignificant risk. If FDA disagrees with an IRB's NSR decision and determines that the study poses SR, the sponsor/investigator may not begin their study until FDA approves an IDE (21 CFR 812.42). If the FDA determines that the devices study poses a nonsignificant risk, FDA will tell the sponsor in writing and the study may then be reviewed by the IRB as a NSR study.


For device studies that are exempt from the IDE regulations, the IRB does not need to determine whether the study poses a significant risk or nonsignificant risk. However, the IRB is still required to review the study in accordance with IRB regulations before the investigation may begin. Investigators are responsible to contact the FDA for the IDE exemption determination.

The IRB will refer to the most current FDA Guidance for IRBs, Clinical Investigators, and Sponsors, Significant Risk and Nonsignificant Risk Medical Device Studies, and Frequently Asked Questions About Medical Devices.

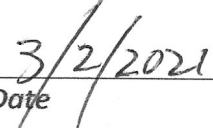
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Approved,



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Date