Grand Valley State University Institutional Review Board (IRB)	
Title: *IRB Protocol Review: Expedited Protocols*	
Section: 901	
Approved by IRBPPC: 02/02/2022	Approved by AIO/RIO: 02/07/2022
Effective Date: 02/28/2022	
Related Documents: *121: Review Standards for Research not Covered by Federalwide Assurance* *710: Assessing Risk to Research Participants* *720: Assessing Risk to Vulnerable Populations* *721: Protections for Pregnant Women, Fetuses, and Neonates* *730: Collection, Management and Security of Research Information* *740: Internet Based Research* *750: Recruitment, Selection and Payments to Research Participants* *810: Informed Consent: General* *812: Informed Assent and Parent Permission* *813: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives* *814: Informed Consent for Persons not Fluent in the Primary Language of the Study* *820: Waivers, Alterations, and Exceptions to Informed Consent Process and Documentation* *902: IRB Protocol Review: Full Board Protocols* *910: Continuing Review and Approval of Selected Non-Exempt Protocols* *911: Exemption Determinations and Research Ethics Standards*	

Policy

1. The IRB reviews research proposals in accordance with the applicable regulatory criteria for approval as well as state law, university policies, and IRB policies.

2. The IRB uses an expedited review process to review studies that:
    a. Adhere to the expedited applicability criteria and meet the categories adopted by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), and
    b. Involve no greater than minimal risk.

    Expedited review procedures allow one or more experienced IRB members from among the IRB voting membership (regular and alternate members designated by the Chairperson) to review and approve studies without convening a meeting of the full IRB. Collectively, these individuals are referred to as "designated reviewers (DRs)."

3. Role and responsibilities of IRB members in protocol review:
    a. IRB members are to become familiar with, and maintain, current familiarity with pertinent Federal regulations, State law and University policies related to use of human subjects in research.
    b. IRB members are to make approval recommendations and other applicable regulatory determinations on research protocols which they are assigned for

review by the deadline specified, unless prior notification to the Office of Research Compliance and Integrity (ORCI) is submitted.

c. IRB members may not participate in the review of research where they have a perceived or actual conflict of interest.

4. Role and authority of the IRB Chairperson in protocol review:
   The Chairperson will fulfill the same roles and responsibilities as the committee members as noted above. Additionally:
   a. The Chairperson may be consulted by any committee or staff member for assistance in reviewing any aspect of any protocol.
   b. The Chairperson may review and make an approval or other determination for any protocol under expedited review procedures at any time without a second reviewer, such as, but not limited to, initial submissions, revisions, amendments, and continuing review.
   c. If the DRs disagree on the proper action, the Chairperson will serve as an additional reviewer and will determine the final action taken on the protocol.
   d. As applicable, the Chairperson may request assistance with persons not otherwise affiliated with the IRB who have relevant knowledge to assist the board in the review of the protocol (*IRB Policy 150: IRB Use of Outside Expertise (Consultants).*

5. The DRs exercise all of the authority of the IRB except that the reviewers may not disapprove the research. If a DR finds the research should not be approved, the issue will be forwarded to the convened IRB for review. Only the convened IRB may disapprove a research study.

6. The convened IRB agenda is used to inform all IRB members of research studies approved using expedited review procedures. All members have access to the entire IRB file for any expedited study.

Procedures

1. Submission of Expedited Protocols
   a. The Principal Investigator (PI) makes the preliminary determination that a protocol is eligible for expedited review. The DRs make the final determination regarding whether a protocol is eligible for expedited review.
   b. The PI is responsible for submitting a completed protocol submission form in ORCI's electronic management system. This submission should also include the following documents, as applicable:
      i. The funding letter, sponsor's agreement or human subjects portion of the grant/application
      ii. Written permission from data collection sites indicating support of the research
      iii. Written recruitment materials, such as flyers, posters, emails and social media posts

iv. Written permission from the GVSU Athletic Director, if the research will target varsity athletes for inclusion
v. Written permission from the Office of Institutional Analysis, if that office will be distributing recruitment emails on behalf of the researchers
vi. Informed consent and assent documents
vii. HIPAA authorization form, if separate from the informed consent document
viii. Surveys, interview questions and data collection forms
ix. Any other documentation that may be relevant to IRB review

2. IRB members are assigned protocol submissions by the IRB Chairperson or ORCI. For review purposes, there are two designations of DRs:
    a. Trained DRs: Members who are fully trained, or selected by virtue of their experience or specialty to conduct the formal review and recommendation on the study.
    b. Reviewers-in-training: Members still in training and with less experience reviewing protocols. They are assigned protocol reviews as an additional reviewer on expedited studies until the IRB Chairperson determines that they have sufficient expertise and protocol review experience to warrant the status of Trained DR. The Chairperson and/or ORCI will provide training and mentoring for committee members as appropriate.

3. Review of Expedited Protocols
    a. With the exception of certain personnel change requests that may be reviewed and approved independently by the Chairperson (see *IRB Policy 1010: Modifications to Approved Protocols*), expedited protocols are assigned to a minimum of two DRs.
    b. DRs are provided a copy of all documents submitted by the researchers at the time the protocol is assigned for review.

4. Reviewer Actions
    a. For each expedited review, the DR will review the protocol submission, document their analysis regarding protocol-specific findings, and provide justification for the determinations.
    b. If the DR determines the research is eligible for exempt determination or qualifies as Not Human Subjects Research, the DR will document the rationale for this.
    c. For all non-exempt protocols, DRs recommend one of the following actions:
        i. **"Approve**": The initial, continuing, or modification submission meets all the criteria for approval.
            1. For initial and continuing review, include in the documentation of the review the period of approval, if applicable.
        ii. **"Approve with Conditions"**: The initial, continuing, or modification submission will meet the criteria for approval with minor or prescriptive changes or requirements that can be verified by administrative staff or Chairperson without considering the criteria for approval.

1. For initial and continuing review, include in the motion the period of approval.
2. Summarize the IRB's required modifications and reasons.

iii. **"Request Clarifications/Changes"**: The initial, continuing, or modification submission does not meet the criteria for approval, and substantial changes or additional information is needed.
1. Summarize the IRB's reasons (required clarifications and modifications) and recommendations, if any.

iv. "**Refer to Full Board**": A DR may refer the initial, continuing, or modification submission to the full board for review.
1. If the DR finds that the research should not be approved, it must be referred to the full board for review.

d. Determination of Continuing Review
i. Unless the DR determines otherwise, continuing review of approved expedited research is not required.
ii. If the DR determines continuing review is necessary upon approval of the research, the DR shall recommend the interval at which continuing review is to be conducted. This interval must be appropriate to the degree of risk, not less than once per year.
iii. The following criteria should be considered by the DR, as applicable, when determining the continuing review interval of the proposed research: the nature of the study; the degree of uncertainty of the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; and whether the study involves novel therapies.

e. If the submission includes additional required determinations, such as requests for waiving consent or the inclusion of minors in the research, these determinations will be documented by the DR in accordance with the applicable IRB policy.

5. Chairperson Actions
a. The Chairperson will review the DRs' recommended actions and determinations, and may at any time identify additional clarifications/changes that need to be addressed prior to approval of the protocol.
b. If any DR refers the study to the full board, the protocol must be reviewed by the full board (see *IRB Policy 902: IRB Protocol Review: Full-Board Protocols*).
c. If no DR refers the study to full board, the following procedures apply:
i. The Chairperson may refer a protocol to full board review at any time.
ii. If the DRs are not unanimous regarding the recommended action, the Chairperson will serve as an additional reviewer and will determine the final action taken on the protocol.
iii. If the DRs unanimously recommend Approve or Approve with Conditions:
1. The Chairperson will verify that no additional changes/clarifications are needed.

2. If additional clarifications are needed, the Chairperson will determine the final action as either "Approve with Conditions" or "Request Clarifications/Changes", depending upon the nature of the changes needed.
3. If the final action is "Request for Clarifications/Changes", the DRs will be informed of the changes being requested by the Chairperson and the rationale for the decision.

iv. If the DRs unanimously recommend Request Clarifications/Changes:
1. The Chairperson will verify the recommended clarifications and changes.
2. If the Chairperson feels that none of the DRs' recommended clarifications and changes are required to meet the criteria for approval, the Chairperson will recommend to the DRs that the action be changed to either "Approve" or "Approve with Conditions" and provide rationale for this recommendation. If, after further consideration, none of the DRs agree with the Chairperson's recommendation, the final action shall remain "Request Clarifications/Changes" or the Chairperson can refer the protocol to full board review.

d. The Chairperson will prepare the response to the PI, delineating the conditions of approval or requested changes.

6. IRB-Required Modifications and Corrections
   a. When the IRB requires modifications or clarifications to a protocol in order to comply with federal regulations, research ethics standards, or the minimization of risks to research subjects, it shall inform the researcher of the required modifications and/or clarifications in writing.

7. ORCI Actions
   a. ORCI staff do not conduct expedited reviews nor approve any modifications to previously approved expedited protocols.
   b. For protocols that have been conditionally approved: At the Chairperson's discretion, ORCI staff may verify that the conditions required for approval have been satisfied. This verification can be done without requiring further review by the DRs or the Chairperson. (Note: This is a verification process, not an "approval"; the protocol has already been determined to meet all of the criteria for approval at the time of conditional approval.)

8. IRB Approval
   a. The IRB approval letter is sent to the PI, the PI's Authorizing Official, and the Office of Sponsored Programs (if applicable).
   b. For protocols approved via expedited review, the approval date is the date of the Chairperson's approval following the DRs' completion of the review process, and the approval period (for protocols requiring continuing review), if applicable, is calculated based on this date. For protocols that are conditionally approved via

expedited review, the approval is not effective until the Chairperson or designee confirms the approval conditions have been satisfied.

Guidance

1. Expedited Categories

Categories of research that may be reviewed by the IRB through an expedited review procedure:

a. **Category 1.** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. **Category 2.** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    1. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
    2. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

c. **Category 3.** Prospective collection of biological specimens for research purposes by noninvasive means.

    Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine

prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

d. **Category 4.** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. **Category 5.** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects[45 CFR 46.101(b)(4)]. This listing refers only to research that is not exempt.)

f. **Category 6.** Collection of data from voice, video, digital, or image recordings made for research purposes.

g. **Category 7.** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101(b)(2) and (b)(3)]. This listing refers only to research that is not exempt.)

h. **Category 8.** Continuing review of research previously approved by the convened IRB as follows:

1. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
2. Where no subjects have been enrolled and no additional risks have been identified; or
3. Where the remaining research activities are limited to data analysis.

i. **Category 9.** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2. Criteria for Approval

Regulatory criteria for approval of research; applies to initial, continuing and amendment reviews:

a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
    1. Applicable protocol components: Objective, Purpose, Background, Resources available to conduct the research, Inclusion and exclusion criteria, Procedures involved in the research, and Additional protections for vulnerable populations.
    2. Questions to consider: Is there another way to do the research that will reduce risks to subjects that does not affect the science? Can less risky procedures answer the question? Can fewer procedures answer the question? Are the procedures needed at all? Can additional procedures reduce risk? Can different exclusion criteria reduce risk? Are the research staff qualified? Consider physical, psychological, legal, social, and economic risks.

b. Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. (N/A if no such procedures.)
    1. Applicable protocol components: Objective, Purpose, Background, Resources available to conduct the research, Inclusion and exclusion criteria, Procedures involved in the research, and Additional protections for vulnerable populations.
    2. Questions to consider: Are procedures that will answer the scientific question being done anyway? If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? Consider physical, psychological, legal, social, and economic risks.

c. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits subjects would receive even if not participating in the research.
    1. Applicable protocol components: Background, Inclusion and exclusion criteria, Risks to participants, Potential benefits to participants, and Additional protections for vulnerable populations.
    2. Questions to consider regarding importance of knowledge expected to result: Is the study designed in such a way that the results will likely be useful for advancing knowledge? Is there good scientific design? Are there adequate resources? What are research staff qualifications? Is there adequate time? Adequate personnel? Adequate participant pool? What will be its importance?
    3. Questions to consider regarding the overall risks and benefits: What are the risks to participants? What are the anticipated benefits? What is the importance of the knowledge that may reasonably be expected to result? Are the risks reasonable in relationship to the benefits and the importance of the knowledge that may result?

d. Selection of subjects is equitable. Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment and payment procedures.
    1. Applicable protocol components: Purpose, Background, Setting of the research, Recruitment, Inclusion and exclusion criteria, Consent process, and Additional protections for vulnerable populations.
    2. Questions to consider: Is subject selection fair, just and equal? Are burdens fairly distributed? Are benefits fairly distributed? Is a population unfairly targeted? Is a population unfairly excluded? Consider women, children, racial minorities, economically disadvantaged, non-English speaking individuals, medically uninsured, international subjects, and people with reduced autonomy.

e. Informed consent will be sought and documented from each prospective subject or the subject's legally authorized representative, or the IRB has waived or altered the requirement to obtain informed consent or documentation of informed consent.
    1. Applicable protocol components: Purpose, Background, Study design (recruitment, procedures involved in the research, and data management), Risks to participants, Potential benefits to participants, Provisions to protect the privacy interests of participants, Provisions to maintain the confidentiality of the data, Consent process, and Additional protections for vulnerable populations.
    2. Questions to consider: Will the circumstances of the consent process provide the participant sufficient opportunity to consider whether to

participate? Will circumstances of the consent process minimize the possibility of coercion or undue influence? Has the participant been provided enough information to make a decision? Will the person understand the consequences of the decision? Can the person make and communicate that decision? What language does the participant speak? Can the research team communicate in understandable language to the participants? Will written information be in the language understandable to the participants?

f. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (This criterion is generally not applicable if the research is no greater than minimal risk.)
    1. Applicable protocol components: Procedures involved in the research, Provisions to monitor the data collected to ensure the safety of subjects.
    2. Questions to consider: Who reviews the data: Investigator, internal associate, medical monitor, internal committee, independent committee (DSMB)? What data is reviewed: Safety data, untoward events, SAEs, IND safety reports, efficacy data? When and how often is data reviewed?

g. When appropriate, there are adequate provisions to protect the privacy of subjects.
    1. Applicable protocol components: Study design (data management), Provisions to protect the privacy interests of participants.
    2. Questions to consider: Will participants have an expectation of privacy? Will participants think that the information sought is any of the researcher's business? Will participants be comfortable in the research setting (consider that people may prefer to talk to the same gender; consider settings/location of interactions-office, hallway, phone; consider type of interaction-survey, physical exam, hidden camera)? What will happen to participants in the research? Will the participants be comfortable with the research situation? Privacy refers to person and their interest in controlling access to themselves.

h. When appropriate, there are adequate provisions to maintain the confidentiality of data.
    1. Applicable protocol components: Study design (data management), Provisions to maintain the confidentiality of the data.
    2. Questions to consider: Will confidentiality be pledged? Are there legal/ethical requirements? Will data release cause risk of harm? What promises have been made about the collected data? What procedures are in place to meet those promises? Consider methods for confidentiality: restricted access using locks/passwords, certificates of confidentiality, error inoculation/random responses, bracketing/top coding, ethical editing of qualitative descriptions, data brokering. Confidentiality refers to agreements with the participant about how data will be handled.

i. Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. ("N/A" if no vulnerable subjects.)
    1. Applicable protocol components: Purpose, Background, Setting of the research, Study design (recruitment and inclusion/exclusion criteria), Risks to participants, Potential benefits to participants, Consent process, and Additional protections for vulnerable populations.
    2. How to determine whether there is a vulnerable population: Is there a power differential? Are there communication issues? Are there decisional issues? Are there excessive motivating factors? Is the recruitment process acceptable? Are advertisements acceptable? Are payment arrangements acceptable? Consider fetuses, neonates of uncertain viability, non-viable neonates, prisoners, children, physical disabilities, mental disabilities, economically disadvantaged, educationally disadvantaged, students, employees, and those with life threatening diseases.
    3. Questions to consider: Is the research of importance to the vulnerable population? Can the research question be answered by using a non-vulnerable population? Is the risk-potential benefit relationship appropriate to the vulnerable population? What additional steps will be taken to minimize coercion and undue influence of the vulnerable population?