Grand Valley State University Institutional Review Board	
Title: *Research Noncompliance*	
Section: 1030.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised by HRRPPC: 04/24/2018 Revised by IRBPPC: 11/20/2020 Revised by IRBPPC: 11/30/2021 Revised by IRBPPC: 01/31/2023 Revised by IRBPPC: 10/20/2023 Revised by IRBPPC: 04/30/2024 Revised by IRBPPC: 09/09/2024 Revised by IRBPPC: 11/17/2025	Approved by RIO/HRPA: 02/16/2012 Revisions approved by AIO/RIO: 05/23/2018 Revisions approved by AIO/RIO: 11/30/2020 Revisions approved by AIO/RIO: 12/21/2021 Revisions approved by AIO/RIO: 02/07/2023 Revisions approved by AIO/RIO: 11/06/2023 Revisions approved by AIO/RIO: 08/30/2024 Revisions approved by IO: 10/25/2024
Effective Date: 11/17/2025	
Related documents: *050: Records Retention and Destruction* *730: Collection, Management and Security of Research Information* *1010: Modifications to Approved Protocols* *1020: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events* *1040: Post-Approval Compliance Review* *1050: Suspension or Termination of Research Activities* *1060: Closure of Approved Research Studies* *1070: Responding to Concerns and Complaints About Human Subjects Research Activities* *OP-3: GV Procedures for Responding to Allegations of Research Misconduct* *G-03: IRB Noncompliance Flowchart*	

Policy

1. All members of research teams involved in research on living human subjects must comply with applicable federal, state, and local laws, research ethics standards and the determinations, policies and directives of the Institutional Review Board (IRB), or other oversight authority such as study sponsors, or collaborating educational and private institutions as appropriate. The study Principal Investigator (PI), all members of research teams, and the protocol authorizing official are responsible for reporting known or suspected incidents of noncompliance to the GVSU Office of Research Compliance and Integrity (ORCI), IRB, and/or Institutional Official (IO).

2. The IO, the GVSU IRB, and the ORCI are responsible for investigating cases of potential noncompliance in human subjects research involving GVSU researchers and/or for which GVSU serves as the reviewing IRB. This includes studies which have already received GVSU IRB approval/exempt determination as well as studies in which GVSU IRB review was required but not obtained. Research activities that are not subject to GVSU IRB oversight do not fall under the domain of this policy.

3. Research misconduct and research noncompliance are distinct and separable violations of required research protections. Research noncompliance may be non-serious or serious, and isolated or continuing. Federal regulations require reporting to the IRB findings of either serious or continuing noncompliance (45 CFR 46.108(a)(4)(i)). Allegations of research misconduct are

handled under a separate university policy and procedure (42 CFR 93; *OP-3: GV Procedures for Responding to Allegations of Research Misconduct*).

Definitions

1. *Research Misconduct*. In the GVSU policy and procedures on Research Integrity (revised, 2012), research misconduct (RM) is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, and/or engaging in ordering, advising or suggesting that subordinates engage in misconduct in research, scholarship or creative activities. RM does not include honest error or differences of opinion. The RM offenses are defined as:

    a. *Fabrication*: making up data or results and recording or reporting them.
    b. *Falsification*: manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record.
    c. *Plagiarism*: the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

2. *Research Noncompliance*. Noncompliance is defined as failure by any member of the research team to comply with applicable federal, state, or local laws, research ethics standards or with the determinations, policies and directives of the IRB, or other oversight authority such as study sponsors, collaborating educational or private institutions, etc. Noncompliance may be serious or minor, and isolated or continuing. Refer to Guidance section below.

    a. *Serious Noncompliance*. Noncompliance is serious when the action or omission poses a greater than minimal risk to research participants. This could include, but is not limited to, actions or omissions that increase risks to participants, compromise participants' rights and welfare, significantly decrease potential benefits, and/or compromise the integrity of the research/data or the human research protection program. Actions that are determined to be flagrant or intentional violations of IRB requirements may also constitute serious noncompliance.

        Examples of serious noncompliance include, but are not limited to:
        - Failure to obtain IRB approval or determination prior to initiating research activities.
        - Allowing untrained individuals to perform research activities.
        - Failure to obtain informed consent.
        - Implementing unapproved changes to research activities that increase risk to participants or adversely affect their rights, safety, or welfare.
        - Instructing or knowingly allowing protocol personnel to engage in activities that are in violation of IRB or institutional policies or regulatory requirements.

    b. *Continuing Noncompliance*. Noncompliance is continuing if it 1) includes repeated actions that have previously been reported and/or 2) demonstrates a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect

research participants or the validity of the research and/or suggests the potential for future noncompliance without intervention. Examples of continuing noncompliance include, but are not limited to:

- Multiple instances of serious or minor noncompliance. This could include multiple instances on a single protocol or separate incidents on multiple protocols.
- Continuing to engage in noncompliant activities after being notified that the activities were not in compliance.
- Failure to respond to incidents of noncompliance or failure to adhere to required corrective actions.

c. *Minor Noncompliance*. Noncompliance may be considered minor when the action or omission does not pose a greater than minimal risk to research participants. This typically includes, but is not limited to, administrative oversights or non-substantive unapproved changes.

Examples of minor noncompliance include, but are not limited to:

- Failure to submit an amendment to add personnel to the protocol, provided those individuals have completed all required training and the changes don't alter the qualifications of the overall research team.
- For non-exempt protocols, making minor edits to recruitment and/or consent materials without obtaining prior IRB approval, so long as the changes made do not change the meaning of the information provided or result in any required element(s) of consent.
- Enrolling participants who do not meet the inclusion criteria, so long as their participation does not increase their risk or compromise the rights, safety, or well-being of the participant.

Procedures

1. Reports of Noncompliance

a. Any person with direct knowledge or reasonable suspicion of research noncompliance must report that information to the ORCI, and/or IRB Chairperson, and/or IO. Alternatively, GVSU's anonymous online reporting system may be used to report an incident.

b. If willing, the person with direct knowledge of potential research noncompliance may also report that information to the PI. If reported to the PI, the PI shall take immediate corrective action to reduce or eliminate any imminent risk to participants that is posed by the potential reported noncompliance.

c. Self-reporting of noncompliance is encouraged and will be considered when determining corrective actions.

2. Resolution of Minor Noncompliance by the ORCI

a. The ORCI may resolve instances of minor noncompliance when the noncompliant incident is a one-time or isolated event. Examples may include, but are not limited to:
    i. Unapproved changes to personnel, other than the PI, when the new personnel have completed required and appropriate training before involvement with participants and participants' identifiable data.
    ii. For non-exempt protocols, making minor edits to recruitment and/or consent materials without obtaining prior IRB approval, so long as the changes made do not change the meaning of the information provided or result in any changes in required element(s) of consent.
    iii. For non-exempt protocols, unapproved changes in the type of compensation when the change does not alter the amount of compensation and/or the plans for pro-rating compensation.
    iv. For non-exempt protocols, changing the transcription method used without prior IRB approval when the change does not increase the level of data security risk.

b. The following steps will be taken by the ORCI for resolving specific minor noncompliance:
    i. Check IRB records to verify the incident is a one-time or isolated incident.
    ii. Inform the PI/researchers of the minor compliance and remind them that IRB approval is required for the change they are wanting to make.
    iii. Instruct the PI to promptly obtain IRB approval of the change, if they have not already done so, and to adhere to the approved protocol until the amendment request is approved (if appropriate).
    iv. Document the instance in the IRB's electronic document management system.

c. The ORCI will provide a summary report of all minor noncompliance resolved by the ORCI, to the IRB as part of the next regularly convened meeting.

3. Noncompliance Investigations and Determinations

a. For all instances of noncompliance that are not initially resolved by the ORCI, the following procedures will be followed.

b. Initial Assessment
    i. The ORCI, the IRB Chairperson, and/or the IO will conduct an initial assessment of the reported noncompliance to determine if the activity falls under the purview of the GVSU IRB and, if so, to determine the immediate procedural steps required to reduce or eliminate any risk to currently enrolled or future research study participants. If the reported noncompliance does not fall under the purview of the GVSU IRB, the ORCI and/or IO will attempt to contact the appropriate authority overseeing the activity on behalf of the complainant. If the reported noncompliance affects an active IRB-approved study and the risk minimization procedures include suspension or termination of some or all research-related procedures and

interventions, the IRB Chair and IO shall inform the PI. See *IRB Policy 1050: Suspension or Termination of Research Activities*.

ii. The ORCI, IRB Chairperson, and/or the IO will respond to the report of noncompliance consistent with *IRB Policy 1070: Responding to Concerns and Complaints About Human Subjects Research Activities*. Reports of noncompliance related to research activities that lack IRB approval will be forwarded as information to the IO.

iii. After discussion of the initial assessment, if the IRB Chairperson, IO, and ORCI determine the incident does not constitute noncompliance, this determination is documented, and if necessary, the PI will be notified. No further action is necessary.

iv. If the IRB Chairperson, IO, and ORCI determine the incident is determined to be a one-time or isolated incidence of minor noncompliance, the ORCI will follow the steps outlined in Procedures 2b above to resolve the incident.

v. For all other noncompliance situations, the subsequent procedures will be followed.

c. Administrative Inquiry

i. A formal administrative inquiry will commence. The purpose of the administrative inquiry is to develop a written summary of findings of fact.

ii. The IO shall issue a written statement summarizing the initial assessment and the inquiry plan (if any) to the PI, the PI's Authorizing Official, the Chairperson of the IRB, and other individuals as deemed appropriate by the IO.

iii. At the direction of the IO, the formal administrative inquiry, if required, will be completed by the ORCI. The ORCI will consult with the PI and others as appropriate (e.g., other protocol personnel, the IRB Chairperson, other members of the IRB, etc.) to complete the inquiry.

iv. Following the completion of the formal administrative inquiry, the ORCI shall provide the IO with a written report summarizing the proceedings and findings of the formal inquiry. The IO will review the report and, if needed, seek clarifications and/or additional information from the ORCI; if needed, the ORCI will amend the report to address the clarifications and missing information. If desired, the IO may forward the report to the IRB Chairperson and/or other members of the IRB for additional review.

v. The IO shall forward the draft of the written report summarizing the formal inquiry proceedings and findings to the PI. The PI's Authorizing Official will be notified that the PI has received the draft report. The PI will have seven business days to provide a written response, if desired. The written response is to be submitted to the

IO. If the PI fails to respond to the IO within seven business days, the report will be accepted as final.

vi. If the IO determines changes are required to the report, the IO will coordinate with the ORCI to incorporate the changes, and the ORCI shall prepare an amended report, and the review process outlined in Procedures 3.c.v is repeated.

vii. The IO will forward the final report to the PI, the IRB Chairperson, the PI's Authorizing Official, and other individuals as deemed appropriate by the IO. At the discretion of the IO, the PI's response(s) to the draft report, if any, and any supporting documents, may also be forwarded to the recipients of the final report prior to IRB review.

d. IRB Review of Noncompliance

i. The IRB Chairperson will review the final report and determine if the noncompliance does or might constitute serious and/or continuing noncompliance. If desired, the Chairperson may consult with other members of the IRB for assistance in making these determinations.

1. If the noncompliance is neither serious nor continuing, the rationale for this decision is documented, and the report does not require review by the convened IRB. The IRB Chairperson notifies the IO of this determination, and the IO then conducts a final review and determines appropriate administrative actions, if any (Procedures 2.d).
2. If the noncompliance does or might constitute serious or continuing noncompliance, the report requires review by the convened IRB. The IRB Chairperson will determine if an emergency meeting of the IRB is necessary or if the review can occur at the next scheduled meeting of the IRB.

ii. The convened IRB will review the report and make the appropriate determinations. The IO, at their discretion, can additionally choose to supply the IRB with a copy of the PI's written response(s) to the report (Procedures 2.b.v), either in full or in part.

1. The IRB may table the report and request that additional facts be collected or that a further investigation be conducted if necessary for its determinations. If this occurs, the following actions will be taken:
    a. The additional inquiry will be conducted, and the ORCI will prepare an addendum outlining the information collected and conclusions drawn from the additional inquiry. This addendum will be attached to the original report and sent to the IO.
    b. The IO will provide a copy of the addendum to the PI, and the PI will be given seven business days to provide a written response to the addendum, if desired. The written response is submitted to the

IO. If changes are required to the addendum, the IO will coordinate with the ORCI to incorporate the changes, and the ORCI shall prepare an amended addendum. If the PI fails to respond to the IO within seven business days, the addendum will be accepted as final.

c. The addendum and the PI's response, if any, will be provided to the IRB in advance of the next convened meeting.

2. The IRB will determine if the noncompliance is serious and/or continuing. The rationale for this decision shall be documented in the meeting minutes.
3. The IRB will consider what, if any, appropriate corrective actions are necessary. The actions to be taken—which can be taken for one specific protocol or for multiple research protocols associated with the PI—will depend upon the circumstances of the noncompliance and may include the following:
    a. Suspend or terminate IRB approval
    b. Require additional information from the PI with a plan for corrective action
    c. Transfer research to another investigator
    d. Modify the protocol
    e. Modify the informed consent form and/or information disclosed during the consent process
    f. Provide additional information to active participants whenever the information may affect their willingness to continue participation
    g. Provide additional information to past participants
    h. Require current subjects to re-consent
    i. Increase the frequency of continuing reviews
    j. Observe the research and/or the consent process
    k. Require additional training of the investigator and/or research team
    l. Allow continuation of some research activities under the supervision of an independent monitor
    m. Require additional follow-up of participants
    n. Consider whether changes made without prior IRB review and approval were consistent with ensuring the participants' continued welfare
    o. Other actions as deemed appropriate by the IRB.

iii. The IRB will consider if the serious or continuing noncompliance might also meet the definition of an unanticipated problem. See *Policy 1020: Reportable Events: Protocol Deviations, Unanticipated Problems and Adverse Events*.

iv. The IRB is responsible for making determinations and determining corrective actions, if any, related to the human subjects regulations, GVSU IRB policies, and the IRB protocol(s) affected by the noncompliance. The rationale for all decisions made by the IRB is documented in the meeting minutes, and the IRB will issue the PI a formal letter, outlining the determination(s) made and any subsequent actions by the IRB. The IRB will send a copy of this letter to the IO.

e. IO Review of Noncompliance

i. Independent of any IRB review and any IRB required corrective actions, subsequent administrative actions may be determined by the IO, either independently or in consultation with university counsel and other individuals as deemed appropriate by the IO.

ii. The IO will issue a final letter indicating the matter has been reviewed and outlining the results of the investigation, including any corrective or administrative actions as determined by the IO. This final letter will be issued to the PI, the PI's Authorizing Official, the Chairperson of the IRB, and other individuals as deemed appropriate by the IO. The IO will monitor the PI's completion of any identified corrective or administrative actions.

iii. The IO will send a copy of the final report and the final IO letter to the PI's Appointing Officer. The IO may send other supporting documents at their discretion.

f. External Reporting
   i. Failure by GVSU-affiliated individuals and/or IRB protocol personnel to follow federal and GVSU regulations, guidelines, policies, and procedures may require reporting to the appropriate institutional, local, state and/or federal agencies.

   ii. If external reporting is necessary, the IRB Chairperson, ORCI staff, and IO will prepare the necessary report(s) as appropriate and within the required timeframe. The report(s) should include a full description of the violation(s) and the appropriate corrective actions that have been taken and/or are planned. A timeline for the implementation of future planned corrective actions should be included as appropriate. The IO is responsible for submitting the report(s) to the appropriate institution or agency.

g. Confidentiality
   i. All discussions of the IRB members related to a noncompliance investigation (both during and outside of convened IRB meetings) are confidential and should not be referenced in non-IRB-related matters.

   ii. Information about the noncompliance inquiry will only be shared as deemed appropriate by the IO or as required by law or court order.

h. Documents relating to the inquiry, including but not limited to the findings, determinations, recommendations, and the reports of administrative actions by the IO, will be retained per *IRB Policy 050: Records Retention and Destruction*.

Guidance

1. Unapproved research is considered a form of research noncompliance.

2. *Unapproved research* is defined as the commencing of any research activity involving living human participants that requires approval from the IRB but has not received such approval. This includes research:

    a. For which no protocol has been submitted to the IRB;
    b. For which a protocol was submitted, but not approved;
    c. That was initially approved, but for which continuing review has lapsed;
    d. That differs from what was approved by the IRB, if the changes implemented required, but did not receive, IRB approval; and/or
    e. That required, but did not receive, approval from another IRB or was outside of what was approved by another IRB, even if the protocol was approved by the GVSU IRB.