

Policy and Procedures for Addressing Allegations of Non-Compliance with Valdosta State University's Research Participant Protection Program

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1.0 POLICY STATEMENT

Valdosta State University is committed to excellence in teaching, research, and public service. Concomitantly, the University is committed to the conduct of these activities with the highest possible ethical standards. Accordingly, VSU expects any faculty, staff member, student, or member of the general public who suspects noncompliance with ethical principles, human research participant protection regulations, or institutional policy or procedures governing human research to report such concerns to the University. The University's Institutional Review Board (IRB) for the Protection of Human Research Participants is responsible for promptly addressing such allegations so that participants' rights are protected and their safety and well being are assured, the integrity of the research is not compromised, and all parties are given due process.

2.0 ADMINISTRATIVE PROCEDURES

(Substantive revisions to be made by the Institutional Review Board as required; non-substantive edits to be made by the IRB Administrator as required)

2.1 Purpose

As part of its mandate to ensure protection of the rights and welfare of humans participating in research in accordance with the highest ethical standards, the Valdosta State University Institutional Review Board (IRB) reviews, approves, and monitors human research activity carried out under its auspices for conformance with all applicable laws, regulations,

policies, and procedures. This comprehensive program is hereinafter referred to as the Research Participant Protection Program. The IRB is also responsible for reviewing and, if warranted, fully investigating any allegations of non-compliance with the Research Participant Protection Program raised by the employees, students, or the public. The purpose of these administrative procedures is to ensure reporting of suspected noncompliance, to define the roles of all parties, to establish standard methods of addressing such allegations, to specify possible sanctions, to close cases and report cases, and to deal with malicious allegations, all while providing due process and protecting the rights and reputations of all parties to the extent possible.

2.2 Jurisdiction of the Institutional Review Board

- 2.2.1 The IRB is an administrative body established to protect the rights and welfare of human research participants recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy.
- 2.2.2 The IRB functions independently of, but in coordination with, other committees. For example, an institution may have a research committee that reviews protocols to determine whether the institution should support the proposed research. The IRB, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not research participants are adequately protected.
- 2.2.3 The IRB has jurisdiction over the approval of research as defined by Federal regulation, which includes "all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency" that has adopted the human subjects regulations (45CFR46.101(a)) unless the research is exempt from review under the criteria specified in 45CFR46.101(b). (Examples of research involving human participants that is exempt from review include educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.)
- 2.2.4 In accordance with 45CFR46.103(b)(1), Valdosta State University policy has extended the IRB's jurisdiction to include the approval of all research involving human participants that does not meet the exemption criteria specified in 45CFR46.101(b), regardless of whether the research is conducted or supported by a federal department or agency.

- 2.2.5 Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB (45CFR46.112). Furthermore, approved research is subject to continuing IRB review and must be reevaluated at least annually (and more frequently, if specified by the IRB) (45CFR46.109(e)).

2.3 Definition of Terms

- 2.3.1 *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45CFR46.102(d)).
- 2.3.2 *Research participant* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, and/or identifiable private information (45CFR46.102(f)).
- 2.3.3 *IRB* means an institutional review board established in accordance with the Code of Federal Regulations, Chapter 45 Part 46.
- 2.3.4 *Research Participant Protection Program* means the body of laws, regulations, policies, and procedures adopted by the IRB to ensure the protection of the rights and welfare of individuals participating in research conducted under the auspices of Valdosta State University.
- 2.3.5 *Noncompliance* means failure of the investigator involved in human research activity to meet the requirements of the University's Research Participant Protection Program, regardless of whether or not the noncompliance is accidental or willful and regardless of whether or not participants are placed at increased risk as a result of the noncompliance. Noncompliance with the VSU Research Participant Protection Program may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious violations, which pose risk to subjects and/or violations of their rights and welfare.
- 2.3.6 *Serious noncompliance* is defined as knowingly disregarding or violating federal regulations or institutional policies and procedures applicable to human participant research, which, in the judgment of the IRB, may impact participant safety, make a substantial alteration to risks to participants, or any factor determined by the IRB Chair or any IRB member as warranting review of the violation by the convened IRB. Examples of serious noncompliance include, but are not limited to, the following:
- Implementing recruiting procedures and/or initiating contact with prospective participants before receiving IRB approval;

- Failure to obtain required informed consent (i.e., there is no documentation of informed consent, or informed consent is obtained after initiation of study procedures);
- Enrollment of a participant who did not meet all the inclusion/exclusion criteria;
- Over-enrollment of participants in research that is of greater than minimal risk;
- Modifying the research protocol without IRB approval (including, but not limited to, changing the purpose or specific aim of study, the principal investigator, the maximum number of participants, the recruitment process, the consent process and/or form, data collection tools [including survey forms and approved interview questions], and data collection techniques;
- Failure to timely report to the IRB (and, if applicable, the sponsor) and/or suspend a study when it becomes apparent that unanticipated problems have arisen and/or participants are suffering adverse reactions or are being placed at unanticipated additional risk;
- Continuing activities involving research participants after protocol approval has been suspended or expired; and
- Failure to adhere to the educational and administrative requirements of the IRB.

2.3.7 *Minor noncompliance* is defined as violation of federal regulations or institutional policies and procedures applicable to human participant research that does not impact participant safety and/or does not substantially alter risks to the participants. Examples of minor noncompliance include, but are not limited to, the following:

- Missing original signed and dated consent form (only a photocopy available);
- Missing pages of an executed consent form
- Inappropriate documentation of informed consent, including:
 - missing participant signature,
 - missing investigator signature,
 - copy not given to person signing the form,
 - someone other than the participant dated the consent form, and
 - individual obtaining informed consent is not listed in the approved IRB protocol;
- Use of invalid consent form (i.e., consent form that does not bear the IRB approval stamp and/or is outdated/expired);
- Failure to submit continuing review application to the IRB before study expiration;
- Failure to submit a final report at no later than the expiration date of the study.

2.3.8 *Continuing noncompliance* is defined as a pattern of recurring or ongoing instances of actions or omissions which indicates an underlying deficiency in knowledge of the regulations and IRB requirements or an unwillingness to comply with them.

2.3.9 *Unanticipated problem* means any incident, experience, or outcome that meets all of the following criteria:

- It is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents, (such as the

IRB-approved research protocol and informed consent document) and the characteristics of the subject population being studied;

- It is related, or possibly related, to participation in the research (i.e., the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- It suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

2.3.10 *Adverse event* means any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. (Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.)

2.3.11 *University official*, for the purposes of this policy, means the person receiving the allegation of non-compliance. He/she may be a faculty member, department head, academic dean, an IRB member, or a member of the Office of Sponsored Programs & Research Administration staff.

2.3.12 *Allegation* means any written or oral statement or other indication of possible noncompliance with VSU's Research Participant Protection Program made to a university official.

2.3.13 *Good faith allegation* means an allegation made with the honest belief that noncompliance may have occurred. An allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

2.3.14 *Informant* means the person who makes an allegation of noncompliance.

2.3.15 *Respondent* means the person against whom an allegation of noncompliance is directed or the person whose actions are the subject of a preliminary review and/or investigation. There can be more than one respondent in any preliminary review or investigation.

2.3.16 *Preliminary review* means the first step in addressing an allegation of noncompliance. The purpose of the preliminary review is to ensure that frivolous or uninformed accusations are dismissed and that differentiation is made between willful noncompliance and carelessness or incompetence.

2.3.17 *Investigation* means the second step in addressing an allegation of noncompliance. It is undertaken when results of the preliminary review indicate that the allegation

appears justified in order to determine if indeed such noncompliance has occurred and, if so, to recommend appropriate actions.

2.3.18 *Sanction* means any penalty or coercive action taken by the IRB to help ensure compliance with applicable regulations, policies, and procedures for the involvement of human participants in research.

2.3.19 *Retaliation* means any action taken by the University or an employee of the University that adversely affects the employment or other institutional status of the informant who has made a good faith allegation of noncompliance or of any other person who has cooperated in good faith in the review and/or investigation of such allegation.

2.4 Rights and Responsibilities of the Parties

2.4.1 Responsibilities of the Institutional Review Board (IRB)

2.4.1.1 The IRB has primary responsibility for implementation of the procedures set forth in this policy, including conducting preliminary reviews and investigations, specifying remedial measures to be undertaken by investigators when appropriate, and imposing and recommending sanctions when investigators have been found to have failed to comply with VSU's Research Participant Protection Program.

2.4.1.2 Procedures for addressing allegations of noncompliance have been designed with recognition that determination of why, or even if, noncompliance has occurred may be difficult and that the process of review and/or investigation must be sufficiently flexible to be terminated when it becomes clear that charges are unjustified or that the issue can be resolved appropriately by other means. It is understood that persons conducting the preliminary review and/or investigation must possess the special knowledge necessary to judge the situation and can have no immediate personal interest in the case.

2.4.1.3 The IRB's actions in response to review and/or investigation of allegations of noncompliance cannot be grieved, as the IRB has statutory and institutional authority in these matters.

2.4.1.4 The IRB is administratively assisted in its work by the Office of Sponsored Programs & Research Administration.

2.4.2 Rights and Responsibilities of the Informant

2.4.2.1 Any individual, whether internal or external to the institution, who observes or suspects noncompliance with the VSU's Research Participant

Protection Program has a legal and ethical obligation to report the suspected activity.

- 2.4.2.2 The informant will be given an opportunity to testify during preliminary review and/or investigation. He/she will be informed of the findings of the preliminary review and/or investigation and will be given the opportunity to comment on portions of reports of findings pertinent to his/her allegation or testimony.
 - 2.4.2.3 The institution will protect the identity of the informant who reports noncompliance in good faith to the maximum extent possible. For example, if the informant requests confidentiality, the institution will make an effort to honor the request during the preliminary review within applicable policies and regulations and state and local laws. The informant will be advised that, if the matter is referred for investigation and his/her testimony is required, confidentiality may no longer be guaranteed.
 - 2.4.2.4 In all cases, the institution, through the Office of the Provost & Vice President for Academic Affairs, will undertake diligent efforts to protect the position and reputation of the informant making a good faith allegation, including assuring that he/she will not be retaliated against in the terms and conditions of employment or other status at the institution.
 - 2.4.2.5 The informant is responsible for immediately reporting any alleged or apparent retaliation to the Provost & Vice President for Academic Affairs directly or through the Office of Sponsored Programs & Research Administration.
- 2.4.3 Responsibilities of University Officials
- 2.4.3.1 Any faculty member, department head, dean, or staff member who receives an allegation of noncompliance with VSU's Research Participant Protection Program has a legal and ethical obligation to report such allegations in accordance with the procedures herein.
 - 2.4.3.2 The IRB Administrator and/or IRB staff who become aware of possible noncompliance are authorized to enact administrative cures as necessary, inform the IRB Chair of the situation, and/or recommend to the IRB Chair that a preliminary review be undertaken.
- 2.4.4 Rights and Responsibilities of the Institutional Review Board
- 2.4.4.1. The Chair of the IRB has the authority to immediately and indefinitely suspend a research activity involving human participants, in full or in part, upon receipt of an allegation of noncompliance with VSU's Human Research Participant Protection Program in order to ensure the rights and welfare of participants until the allegation of noncompliance is resolved.

2.4.4.2 If the allegation of noncompliance is received and found by the Chair of the IRB to warrant preliminary review, the Chair and the Vice-Chair, providing they have no conflict of interest, will serve as the two-member preliminary review team. If the preliminary review findings warrant a full investigation, the Chair of the IRB will appoint a voting member of the IRB, who has no conflict of interest, to chair an investigative subcommittee.

2.4.5 Rights and Responsibilities of the Respondent

2.4.5.1 The respondent has the right to due process. Preliminary review and/or investigation of an allegation of noncompliance with VSU's Research Participant Protection Program will be conducted promptly and expeditiously and with full attention to the rights of all individuals involved. The preliminary review and/or investigation will be conducted in a manner that will ensure fair treatment and confidentiality to the extent possible without compromising the rights and welfare of the research participants or the ability of the IRB to thoroughly carry out its responsibilities.

2.4.5.2 The respondent will be informed in writing of the allegation of noncompliance when a preliminary review is initiated. He/she will have the opportunity to be interviewed and present evidence and to review and comment on draft reports during the preliminary review. He/she will be notified in writing of the final determinations and resulting actions.

2.4.5.3 If the matter is referred for investigation, the respondent will be informed of this action in writing. At that time, his/her cognizant administrators (which, depending on the employment status of the respondent may be a dean, department head, unit director, principal investigator, and/or faculty advisor) will be informed of the impending investigation and will be reminded of the need for confidentiality. If the research is externally funded, notification of the sponsor of the impending investigation will be made in accordance with the sponsor's requirements. The respondent will have the opportunity to be interviewed and present evidence and to review and comment on draft reports. He/she may also consult with legal counsel or a non-lawyer personal advisor (who may not be a member of the IRB or a principal or witness in the case), and he/she may bring the counselor or advisor to interviews or meetings on the case. However, the counselor or advisor may attend in an advisory capacity only and may not actively participate in the investigative process.

2.4.5.4 The respondent will be informed in writing of the final determination of the investigation and resulting actions. A copy of the final report, indicating the results of the investigation and the sanctions imposed, if any, will be sent to the respondent, the respondent's cognizant administrators, and any external sponsor agency previously alerted to the problem in accordance with the sponsor's rules and regulations. The respondent will

receive a copy of the report, and the person making the allegation will be informed of the investigative subcommittee's findings.

2.4.5.5 Persons found to have been noncompliant cannot grieve the IRB's decision or the sanctions imposed that are within the IRB's purview, as the IRB is given statutory and institutional authority.

2.4.6 Responsibilities of Other Persons

2.4.6.1 All employees and students of Valdosta State University have an obligation to cooperate with the IRB and institutional officials in the preliminary review and/or the conduct of investigations of allegations of noncompliance with the University's Research Participant Protection Program and to provide relevant evidence about such allegations upon request.

2.4.7 Responsibilities of the Vice President for Academic Affairs

2.4.7.1 The Vice President for Academic Affairs, who is the designated Institutional Official for the University's Research Participant Protection Program, is responsible for reviewing all reports of alleged retaliation and taking appropriate action to protect the position and reputation of the informant making a good faith allegation. Such protections will also be extended to other persons who testify or otherwise offer evidence during the preliminary review and/or investigation. In the event an employee is found to have made a malicious allegation, the Vice President for Academic Affairs will take appropriate disciplinary action. Any student found to have made a malicious allegation will be referred to the Student Government Association Judicial Council or the VSU Judicial Committee, as appropriate, for disciplinary action. Finally, the Vice President for Academic Affairs or the Vice President for Student Affairs may be called upon to impose sanctions that are recommended by, but outside the authority of, the IRB.

2.5 Procedures for Addressing Allegations of Noncompliance

2.5.1 Reporting Possible Noncompliance

2.5.1.1 Suspected noncompliance may be reported confidentially by any employee, student, or member of the general public to any university official.

2.5.2 Receiving the Allegation

2.5.2.1 Although written allegations are encouraged, they are not required. If an allegation is made verbally, or if the informant opts to not make a written allegation, the university official initially receiving the report of suspected

noncompliance should document it in writing, with as much detail as possible, to fully ensure that the issues are clear and to prevent misunderstandings. Details may be elicited from the informant by asking such questions as: "Did you see this yourself?," "When did this happen?," "Where did this happen?," etc.

2.5.2.2 The university official receiving the allegation and/or the person making the allegation are encouraged to consult informally with the IRB Chair and/or the IRB Administrator to clarify what constitutes noncompliance. If, after such consultation, the informant and/or the university official are assured that noncompliance has not occurred, no further action is necessary.

2.5.2.3 If the university official determines that the allegation is likely made in good faith and that noncompliance is a possibility, he/she must immediately (within the same day) report the allegation to the Chair of the IRB and/or the IRB Administrator. Allegations found substantive by the IRB Chair and/or the IRB Administrator will be referred for preliminary review.

2.5.3 Immediate Action

2.5.3.1 Upon receipt of an allegation, depending on the seriousness of that allegation and the potential for harm to the research participants, the IRB Chair (or the Vice-Chair in the absence of the Chair) may immediately and indefinitely suspend the research activity, either in full or in part, pending preliminary review and/or investigation, in order to assure the protection of the rights and welfare of the participants. Consideration of the allegation will then be initiated and will be made as necessary in two distinct and consecutive phases.

2.5.4 Preliminary Review Phase

2.5.4.1 When an allegation of noncompliance with VSU's Human Research Participant Protection Program is received, the IRB Chair will initiate a preliminary review. The Chair and the Vice-Chair of the IRB will serve as the preliminary review team. The purpose of the preliminary review is to ensure that frivolous or uninformed accusations are dismissed and that differentiation is made between noncompliance and carelessness or incompetence. The time between receipt of an allegation and completion of the preliminary review will be as short as practicable but will not exceed fifteen (15) days. (At the request of the respondent, with documentation of extreme extenuating circumstances, and with approval of the preliminary review team, the period of time for the preliminary review may be extended to give the respondent reasonable time to respond to the allegation.)

- 2.5.4.2 If either the IRB Chair or Vice-Chair has a conflict of interest, he/she will be replaced by another voting member of the IRB who will be selected by the officer without the conflict. If both the Chair and the Vice-Chair have a conflict of interest, they will together appoint two other voting members of the IRB to conduct the preliminary review. The two-member preliminary review team may consult with the informant, the respondent, potential witnesses, other IRB members, and/or IRB administrative staff during the preliminary review to the extent necessary to determine the merits of the allegation, always keeping in mind the need for confidentiality. The review team will also immediately (within one business day) notify the respondent in writing of the allegation when preliminary review is initiated. If the respondent is not the principal investigator, the principal investigator of record, the respondent's immediate supervisor, and/or, in the case of a student respondent, the faculty advisor, will also be notified. The respondent will have five (5) working days to answer the allegation.
- 2.5.4.3 If no evidence or grounds for a charge of noncompliance are found during the preliminary review, no further investigation is required. However, if evidence of carelessness or incompetence is noted, the review team may recommend corrective action. This may include a requirement for procedural changes and/or protocol modification before the research activity can resume, referral of the investigator to printed and web resources, consultation and/or instruction from IRB members and/or administrative staff, ongoing monitoring of procedures, and/or other appropriate interventions. The preliminary review team will prepare a confidential written report that will be forwarded to the Office of Sponsored Programs and Research Administration where it will be sequestered for a minimum of three (3) years. Copies of the report on the preliminary review will also be given to the respondent and his/her immediate supervisor and/or the faculty advisor as appropriate. The informant will also be notified of the outcome of the preliminary review.
- 2.5.5 Formal Investigation Phase
- 2.5.5.1 If the preliminary review indicates sufficient evidence and justification for additional study of the matter, a formal investigation will be initiated. The purpose of the formal investigation is to determine if noncompliance with VSU's policies and procedures has occurred and, if so, to recommend appropriate actions. The investigation will begin immediately and will be completed as soon as practicable but will not exceed more than thirty (30) days. (At the request of the respondent, with documentation of extreme extenuating circumstances, and with approval of the investigation team, the period of time for the investigation may be extended to give the respondent reasonable time to respond to the allegation.)
- 2.5.5.2 The IRB Chair will promptly notify in writing the respondent and his/her cognizant administrators of the initiation of the formal investigation. At

that time, all additional necessary administrative actions will be taken by the IRB, on behalf of the University, to ensure the rights and welfare of research participants, the integrity of the research, the observance of legal requirements and responsibilities, and the rights and, inasmuch as possible, the confidentiality of the informant and the respondent. Consideration will be given to a review of all research conducted by the respondent that involves human participants. If the alleged noncompliance involves externally sponsored research, the IRB Chair will first inform the Vice President for Academic Affairs (the Institutional Official), and then, if required by the sponsoring agency, will report the impending formal investigation to the agency according to its rules and regulations. (The sponsoring agency may reserve the right to initiate an investigation of its own.) The IRB may also consult with the University's General Counsel to develop and initiate any other procedures appropriate to the circumstances.

- 2.5.5.3 The formal investigation will be conducted by an IRB investigative subcommittee comprised of not less than three (3) and not more than five (5) voting IRB members appointed by the IRB Chair. The IRB Chair will appoint a chair of the investigative subcommittee. Any IRB member who has personal involvement in the issue at hand may not participate on the subcommittee.
- 2.5.5.4 The investigative subcommittee will seek all relevant materials and documents, including, but not limited to, research tools and data, information, proposals, publications, electronic and paper correspondence, and memoranda of telephone calls. If, during the investigation, the subcommittee finds the roles of any of the respondent's co-workers or supervisors suspect, those individuals will be advised of the concerns and, if appropriate, the subcommittee will request a separate preliminary review for each person involved according to the procedures outlined herein.
- 2.5.5.5 Whenever possible, interviews will be conducted by the investigative subcommittee with all individuals involved either in making the allegation or against whom the allegation is made, as well as with other individuals who might have information regarding key aspects of the allegation. A complete summary of each interview will be prepared by the investigative subcommittee and provided to the interviewed party for comment or revision before it is included in the confidential investigation file.
- 2.5.5.6 Throughout the investigation, the respondent will be advised by the chair of the investigative subcommittee and/or the IRB administrator of the progress of the investigation and will be afforded the opportunity to respond and to provide additional information. At all times, diligent effort will be made to maintain confidentiality of deliberations.

- 2.5.5.7 If the investigative subcommittee fails to confirm that noncompliance has occurred, the case against the respondent is closed. As necessary, however, the investigative subcommittee may recommend for IRB approval actions that should be taken to protect the rights and welfare of the research participants. Such actions may include a requirement for procedural changes and/or protocol modification before the research activity can continue or resume, referral of the investigator to printed and web resources, consultation and/or instruction from an IRB member and/or the IRB Administrator, ongoing monitoring of procedures, and and/or other appropriate interventions. A final case report will be filed and distributed as specified below.
- 2.5.5.8 If the investigative subcommittee finds that noncompliance has occurred, the subcommittee will recommend appropriate sanctions to the IRB for consideration, modification, and/or approval. Sanctions approved by the IRB will be communicated in writing to the respondent and to his/her cognizant administrators. Suspension of a previously approved protocol, in whole or in part, will be reported and described in detail as required to the U.S. Department of Health and Human Services Office of Research Participant Protection Programs and the sponsoring agency as required by law or regulation.

2.6 Sanctions

- 2.6.1 Sanctions to be imposed by the IRB must be proposed, discussed, and voted on at a convened meeting of the IRB at which a quorum is present and with a majority of the members approving the sanctions.
- 2.6.2. Sanctions to be imposed by the IRB will be determined on a case-by-case basis. Factors that will be considered include the seriousness of the noncompliance, the past record of the investigator, and the level of cooperation that the investigator exhibits during the preliminary review and investigation.
- 2.6.3 Sanctions that may be imposed by the IRB include, but are not limited to, the following:
- Written warning for non-compliance (may or may not be forwarded for entry into the official personnel file);
 - Written reprimand for non-compliance (may or may not be forwarded for entry into the official personnel file);
 - Requirement for additional investigator training before interaction or intervention with research participants can continue;
 - Ongoing monitoring of recruitment, informed consent, and experimental procedures by the IRB or representatives of the IRB;
 - Requirement to add research staff or consultant(s);
 - Suspension of any or all of the investigator's human research protocols;

- Permanent suspension of privileges to conduct human participant research;
- Filing of a scientific misconduct complaint under the University's Scholarly Misconduct Policy; and/or
- For student investigators, referral to the Vice President for Student Affairs, the Student Government Association Judicial Council, or the VSU Judicial Committee, as appropriate, for disposition.

The IRB may also make recommendations for sanctions that are outside its authority to the Vice President for Academic Affairs or the Vice President for Student Affairs for implementation (for example, suspension/termination of employment or dismissal of a student, respectively). If the Vice President determines that more complete documentation is necessary before the recommended sanction can be imposed, the matter may be returned to the IRB investigative subcommittee.

2.7 Case Closure and Reporting

- 2.7.1 The case will be considered closed after all sanctions determined by the IRB, the Vice President, and/or the Judicial Council or Judicial Committee have been implemented.
- 2.7.2 At closure, the case file will be forwarded to the Office of Sponsored Programs & Research Administration where it will be sequestered for a minimum of three (3) years. A copy of the final report, indicating the results of the investigation and the sanctions imposed, will be sent to the respondent, the respondent's cognizant administrators, and any sponsoring agency previously alerted to the problem in accordance with the agency's rules and regulations.
- 2.7.3 The informant will be advised of the investigative subcommittee's findings and the disposition of the case.

2.8 Malicious Allegations

- 2.8.1 If the informant is a VSU employee and is determined during preliminary review or investigation to have made the allegation maliciously or with intentional dishonesty, the IRB investigative subcommittee will refer the matter to the Vice President for Academic Affairs for disciplinary action. If the informant making a malicious or dishonest allegation is a student, the matter will be referred to the Vice President for Student Affairs and/or the Student Government Association Judicial Council or the VSU Judicial Committee, as appropriate, for resolution.