

REGIS UNIVERSITY

Non-Compliance with Regulations of Institutional Research Committees & Plant Operations Biosafety

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Non-Compliance with Regulations of Institutional Research Committees & Plant Operations Biosafety

I. PURPOSE

The institutional research committees BPO - Biosafety in Plant Operations of the Regis University, Institutional Review Board for the Protection of Human Subjects in Research (IRB), Institutional Animal Care and Use Committee (IACUC), and Biosafety in Plant Operations (BPO) – are charged with the protection and safety of the University community according to Federal regulations. To mitigate risk and liability, it is critical that staff, subjects, and all interested parties have a means of communicating information about the conduct of a researcher or research project directly to the appropriate institutional officials. It is vital that IRB members, IACUC members, and the BPO office, department heads, and other institutional officials with responsibility for oversight of research have access to the highest levels of authority within the institution and can count on ethical handling of research misconduct and non-compliance.

The purpose of this policy is to describe guidelines on review of non-compliance allegations, what administrative bodies will perform reviews, and what may be the possible consequences of such non-compliance with policies, procedures and/or decisions of the institutional committees.

This policy applies to all research submitted to Institutional Committees and/or covered by Biosafety in Physical Plant Operations.

II. DEFINITIONS

Adverse event: Occurrence or situation during the course of a research project that was (1) harmful or (2) increases the probability of harm to subjects.

Assurance: Authority granted to the Institutional Committees and Plant Operations from the appropriate Federal agency to oversee research activities within the University.

BioSafety in Plant Operations: The Assistant Director of Plant Operations in the Regis University Physical Plant is responsible for control of all materials or supplies considered a BioSafety risk including hazardous waste. Plant Operations is charged with review of research involved biological materials that may represent hazards to individuals and/or the environment. Plant operations will also assure research being carried out on the Regis University Campus meets Federal, State, and local regulations for use of hazardous materials and supplies.

Assistant Director of Plant Operations (Physical Plant): The Assistant Director of Plant Operations in Physical Plant is responsible for Biosafety. The Assistant Director is responsible for directing initial inquiry by Biosafety. The Assistant Director is also involved in events from the inquiry through resolution of the situation as responsible party for Biosafety.

Institutional Committee Chair: Chair of the pertinent Institutional Committee. The Chair is responsible for directing initial inquiry by the Institutional Committee. The Chair is also involved in events from the inquiry through resolution of the situation as a voting member of the Institutional Committee.

Compliance Committee Chair: The Chair is responsible for directing events from the inquiry through resolution of the situation.

Compliance Committee: The University committee charged with resolving allegations of serious non-compliance. At the beginning, the Compliance Committee works with the University Institutional Committees and Biosafety in developing action plans when noncompliance is detected. The Compliance Committee will meet as necessary. Voting members shall include the Institutional Official (Vice President for Academic Affairs, or designee, who will chair the Compliance Committee), the appropriate Dean, the appropriate department Chair, and the Chair of the appropriate institutional committee or Assistant Director of Plant Operations in the case of biosafety. Non-voting members shall include the Director of the Office of Academic Grants, a representative from the Office of Internal Audit, and University Counsel. Decisions of the Compliance Committee must be supported by positive vote of all voting members, with signature of the President.

Institutional Committee: The institutional research committees of the Regis University – Institutional Review Board for the Protection of Human Subjects in Research (IRB), Institutional Animal Care and Use Committee (IACUC).

IRB: Institutional Review Board for the Protection of Human Subjects in Research. The committee mandated to review all research involving human subjects in research.

IACUC: Institutional Animal Care and Use Committee. The committee overseeing activities involving any live, vertebrate animal used or intended for use in research, research training, teaching, experimentation or biological testing or for related purposes.

I.O.: Institutional Official. The Vice President for Academic Affairs, the signatory on the Assurances submitted to the Federal offices in charge of research compliance activities of the Committees, and Chair of the Compliance Committee.

Non-compliance: Conducting research in a manner that disregards or violates Federal regulations governing such research as approved by the Institutional Committees. This can include but not limited to willful failure to comply with Federal requirements and guidelines, failure to obtain Institutional Committee approval for research involving human or animal subjects or Biosafety procedures, inadequate procedures for obtaining informed consent from human subjects, inadequate supervision of research, failure to report adverse events or proposed protocol modifications to insure safety of subjects, and ongoing failure to provide progress reports.

OBA: Office for Biotechnology Activities, the Federal unit responsible for regulating use of biohazardous materials such as recombinant DNA.

OHRP: Office of Human Research Protection, the Federal unit responsible for regulating the IRBs.

OLAW: Office of Laboratory and Animal Welfare, the Federal unit responsible for regulating the IACUCs.

OAR: Office of Academic Grants, the University office responsible for providing administrative support for the Institutional Committees.

P.I./P.D.: Principal Investigator/Program Director, the person (staff, student, or faculty member) responsible for the conduct of a research project, whether funded or not.

Protocol: The plan presented to the Institutional Committee or BPO for the conduct and methodology of the proposed research project.

III. POLICY

- Institutional Committees and BPO shall review all relevant research regardless of funding source, to ascertain that rights, welfare and regulations are protected and/or followed according to Federal regulations and University policies. The authority of the Institutional Committees and BPO is derived on Federal regulations, University policies, community standards, etc., and is based on the approved assurances on file with the appropriate Federal agencies. Institutional Committee authority is independent of other University authority.
- PIs/PDs shall be required to certify compliance with the submission of each protocol (active, continued, or modified) for Institutional Committee review. They must also acquire permissions and certify compliance with the BPO. Anyone conducting and/or supervising such studies or experiments without approval of the appropriate Institutional Committee(s) or BPO may be personally responsible for legal or other liabilities that may consequently arise. In addition, the research may be subject to disciplinary action by the University.
- Allegations of non-compliance with institutional committee or BPO process or non-compliance with the approved protocol shall be directed to the following:
 - For incidents of an administrative nature only: Chair, IO, and Director of Academic Grants.
 - For incidents involving adverse events or continuing disregard of approved protocols: Full Compliance Committee.
 - The Compliance Committee Chair shall inform and discuss non-compliance incidents with the appropriate Institutional Committee.
- Resolutions of non-compliance shall be signed by the IO and President.
- When appropriate the Director of Academic Grants shall report such incidents and their resolutions to the appropriate Federal agency and sponsor (if funded).

IV. PROCEDURES

Investigation of non-compliance may often be the result of communication difficulties; therefore the IO will refer allegations to the Institutional Committee. The institutional committee will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of subjects may be jeopardized.

If it becomes known that a P.I. has deviated from approved protocols or plans, the following will occur:

- The Institutional Committee Chair or Assistant Director of Plant Operations shall request a written explanation from the P.I. regarding the non-compliance issue.
- In the Chair's absence, an Acting Chair will be designated and will initiate the process.
- The Chair of the appropriate Institutional Committee or Assistant Director of Plant Operations will review the written explanation and the protocol and report conclusions and recommendations in writing to the IO. The IO will ask that the Compliance Committee be convened and the Non-Compliance Committee Chair will contact the Academic Grants Director, the P.I.'s Chair and Dean. In the case of a student researcher, the advisor (and department, school, or college) bears the burden of the responsibility and discipline of the student.

If it becomes known that a P.I. has not submitted an application to the Committee or cleared their activity with Plant Operations **prior to** conducting research, the same procedure is followed. In addition, the Institutional Committee Chair determines:

- The level of risk posed from the research activity.
- The consent procedures followed, if any.
- The details of the conduct of the research.

Following the Directors or Institutional Committee Chair's review, a memo is sent stating the conclusions of the review, along with recommendations to the IO. If appropriate the IO, or designee will forward the review to the Non-Compliance Committee Chair who will then contact the Academic Grants Director, the P.I.'s Chair and Dean.

Depending on the seriousness of the non-compliance, the BPO or Institutional Official, in consultation with the Compliance Committee, communicates recommendations or requirements that may include one or more of the following:

- If the data are intended for publication, the investigator must disclose to the publication editor(s) that the data were collected without the approval of the appropriate Institutional Committee.
- If the study is ongoing, experiments must cease until the Institutional Committee has reviewed and approved all study procedures.

- Investigator may be required to complete a training program.
- The investigator may be required to inform subjects of lack of compliance with Regis University procedures.
- The P.I. agrees NOT to publish the results of the research.
- The P.I. agrees to discard data collected during the period of noncompliance.
- The P.I. agrees NOT to present the research as having had IRB approval.
- Student is required to fulfill degree requirements without a publication option.
- If there are multiple instances of noncompliance in a specific department, college or school, the unit will be required to formulate a plan to assure that its investigators comply with compliance regulations and procedures, and inform the Institutional and Compliance Committee of the plan in place.
- When the lack of compliance results in risk of, or actual harm to subjects, the Director of Academic Grants is required to report the situation to OHRP, OLAW, and/or OBA as required by Assurances. This action may result in investigation of the University's management of research compliance and possible suspension of all funded research until a resolution is reached.