University of Wisconsin Colleges
Administrative Policy #56
NON-COMPLIANCE IN HUMAN SUBJECTS RESEARCH

Implemented: February 17, 2014
Approved by Chancellor: February 17, 2014
Recommended by Chancellor’s Executive Team: February 10, 2014
Recommended by UW Colleges Institutional Review Board: November 4, 2013

1. Overview:
   This policy shall apply to any student and/or employee of the UW Colleges, who is conducting an active research project which involves living human subjects, and also to the Institutional Review Board (IRB) Coordinator and/or any voting member of the IRB. Investigators, research staff, IRB members, and the UW Colleges as a whole share responsibility for the ethical conduct of research and for compliance with federal regulations, applicable state and local laws, and university policy.

2. Definitions:
   Non-compliance is an action or activity in research with human subjects at variance with the approved IRB protocol, other requirements or determinations of the IRB, UW Colleges Administrative Policy (UWCAP) #15 or other applicable policies of the UW Colleges, or relevant state or federal laws.

   Serious non-compliance could be alleged if any of the following occurs in a research study, or by UW Colleges IRB or its staff:
   • Intentional departure from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB specific to a research protocol;
   • Unintentional departure from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB specific to a research project that seriously jeopardized the rights and/or welfare of the participants;
   • Greater than minimal risk human subjects research conducted without IRB review and approval;
   • Greater than minimal risk human subjects research conducted without legally effective informed consent; or
   • Substantive modifications (changes that have the potential to affect the risk/benefit assessment of the study) to IRB-approved research, without prior IRB approval.

   Minor non-compliance is defined as an unintentional departure from established human subjects protection regulations, IRB requirements, and/or rulings of the IRB specific to a research activity that did not jeopardize the rights and/or welfare of research participants.
Continuing non-compliance occurs when the same investigator, research staff member or IRB member makes one or more additional departures from established human subject protection requirements, IRB policies or procedures, and/or rulings of the IRB, after an initial instance of non-compliance has been documented and addressed.

3. Reporting Procedure:
   Anyone (research participant, principal investigator, research staff, or any party external to the UW Colleges) can report a concern about possible non-compliance. The concern should be conveyed to the IRB unless it involves one or more IRB members or staff, in which case it should be reported to the Office of Academic Affairs.

   Principal investigators, research staff, or IRB member/staff may self-report instances of non-compliance.

   Possible non-compliance or evidence of non-compliance may also be discovered by IRB members or staff during the course of their normal duties.

4. Persons obligated to report:
   Any employee of a research project and/or the UW Colleges is ethically obligated to report possible instances of serious or continuing non-compliance. The following information should be reported to the UW Colleges IRB at irb-admin@uwc.edu within five working days (unless the allegation involves a voting member or staff member of the IRB, in which case it should be reported to the Office of Academic Affairs):
   - Name of Principal Investigator and title or topic of study
   - Name of sponsor or funding agency, if known
   - Date(s) of the non-compliance
   - Brief description of the alleged non-compliant activity or activities

   If self-reported, include this additional information:
   - Description of corrective action or modifications already taken to address the non-compliance and/or prevent its recurrence, and
   - Description of any planned future actions, along with a proposed timeline to address the non-compliance and/or prevent its recurrence.

5. Investigating Officer(s):
   If the allegation involves the IRB Coordinator and/or any voting member of the IRB, the investigation will be conducted by the Office of Academic Affairs. Further, if an allegation is made by the IRB Coordinator or Chair, then the Chair/Coordinator shall not lead the investigation.

   In all other cases, the investigation will be managed by the IRB Coordinator or delegate.
6. Investigation Procedure:

Any allegation will be initially evaluated by the IRB Coordinator and/or Chair, who will designate the allegation as a) not requiring further action or b) requiring investigation.

A report generally requires no further action if the non-compliance is:
- A factual assertion of non-compliance (generally self-reported);
- Neither serious nor continuing; and
- Addressed by the investigator through a corrective action plan to remedy the problem.

If investigation is deemed necessary, the IRB Coordinator and/or Chairperson and/or delegate first ensures that immediate action is taken if necessary to prevent unacceptable risk to research participants. For non-compliance that is potentially serious or continuing, the Coordinator or Chair shall report within five business days to the Provost and subsequently provide updates on any fact-finding and IRB review process.

The IRB Coordinator shall choose one of the following courses of action in investigating the allegation:
- Conducts the review alone
- Conducts the initial review in coordination with the IRB Chair
- Empanels a reviewing subcommittee of the IRB
- Requests that legal counsel provide advice and conduct the review
- Requests assistance from others (e.g., outside consultant or an IRB at another institution)

The individual(s) or subcommittee conducting the investigation may take any of the following actions necessary to determine whether allegations are true, and to determine the seriousness or number of occurrences of the actions:
- Reviewing written materials
- Interviewing knowledgeable sources
- Collecting relevant documentation

During the fact-finding process, the IRB Coordinator or delegate shall communicate as appropriate with the Principal Investigator or his/her representative about the progress of the review and investigation.

A factual and objective written record of findings and evidence shall be made by the IRB Coordinator or delegate and stored in the appropriate files.

If any IRB member or staff person is named or implicated in the allegation, the investigating person(s) will be named by the Office of Academic Affairs and will assume each of the responsibilities detailed herein for the IRB Coordinator or delegate.
7. Findings of non-compliance:
Allegations which, in the opinion of the IRB Coordinator (or delegate) and the IRB Chair, are supported by a preponderance of the evidence are determined to be findings of non-compliance.

If non-compliance is self-reported, it is considered to be a finding rather than an allegation.

Findings of non-compliance are assessed by the IRB Coordinator (or delegate) and the IRB Chair as to whether they are serious or continuing.

If any IRB member or staff person is named or implicated in the allegation, these judgments will be made by the investigating person(s) assigned to this case by the Office of Academic Affairs.

8. Possible consequences of a finding of non-compliance:
If the non-compliance is minor, unintentional, and did not jeopardize the rights and/or welfare of research participants, the only action required is education. The IRB Coordinator or delegate will work with the project’s Principal Investigator to develop a written plan to document and correct the situation.

All findings of minor non-compliance will be recorded by the UW Colleges IRB in a secured database and reviewed at least once per year by the IRB Coordinator. A finding of serious or continuing non-compliance shall be reported by the IRB Coordinator or delegate in writing within five working days to the Principal Investigator, IRB members, the UW Colleges Provost, and to the Office of Human Research Protection. Principal Investigators may have separate reporting responsibilities, depending on their funding source(s).

In the case of non-compliance on the part of an IRB member or staff person, the case will be reviewed and action taken as deemed necessary by the Office of Academic Affairs.

9. Possible further action by the UW Colleges Institutional Review Board (IRB):
Upon reviewing findings of non-compliance, the IRB may elect to:

- Take no further action;
- Require additional education for investigators, research staff, IRB members and/or IRB staff;
- Develop or revise IRB policies or procedures;
- Require more frequent and/or more detailed reporting to the IRB, which may include verification from sources other than the Principal Investigator that information provided is accurate;
- Suspend enrollment of subjects to the involved study or project, or to other studies of the Principal Investigator;
• Notify current participants (required when such information may relate to participants’ willingness to continue to take part in the research);
• Require modifications to the research protocol and/or consent process;
• Require that additional information be provided to past participants;
• Terminate the involved project(s) of the Principal Investigator (if subjects are to be withdrawn from the study, the IRB must utilize a process that takes into account the impact on their health and safety);
• Conduct random audits (checks for compliance with IRB requirements) of the Principal Investigator; or
• Withhold approval of future projects proposed by the Principal Investigator.
• In the case of non-compliance on the part of an IRB member or staff person, one or more of the above actions may be implemented by the Office of Academic Affairs. The Office of Academic Affairs could also choose to remove an IRB member or staff person from his/her position on the IRB if the finding involves serious non-compliance.

10. Records Retention

Records relating to review and investigation of noncompliance will be retained by the Institutional Review Board and/or Office of Academic Affairs for a minimum of three years after completion of the research or any corrective actions (whichever is longer), in keeping with federal regulations, applicable state and local law, and university policy.

11. Applicable Regulations/Guidance

21 CFR 56.108(b)(2), 21 CFR 56.113, 21 CFR 56.115(b), 45 CFR 46.103(b)(5), 45 CFR 46.113, 45 CFR 46.115(b), and “Guidance on Reporting Incidents to OHRP” (05/27/05)