

# IRB Noncompliance

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## Summary

Federal regulations require the reporting of serious and continuing noncompliance to the IRB, institutional officials, and certain federal agencies and department heads. This document describes the campus policy regarding noncompliance, how the term is defined, and requirements for IRB review.

## Definition of Noncompliance

The University of Wisconsin-La Crosse (UWL) defines noncompliance as any failure to follow (1) federal regulations, state laws, or institutional policies relevant to human subjects research, or (2) the requirements and determinations of the reviewing IRB.

When noncompliance has occurred, federal regulations and UWL policy require the IRB to determine whether the incident is minor, serious, continuing, or a combination. The level of noncompliance is dependent upon intent, context, and other circumstances taken into account by the IRB.

Examples of **noncompliance** may include, but are not limited to, the following:

- failure to obtain informed consent or inadequate procedures for obtaining informed consent from subjects
- conducting human subjects research without a UWL IRB approved protocol or exemption
- inadequate supervision of research that involves potential risks to subjects and others

- conducting research, including enrollment of subjects, when a UWL IRB approval has expired or has been suspended or terminated
- initiating changes to the research protocol without prior IRB approval unless the change is necessary to eliminate apparent immediate hazards to the subject (Note: Both the discovery of unforeseen risk and a request to update the protocol must be reported to the IRB as soon as possible.)
- failing to adhere to the conditions of approval of a protocol as specified by the UWL IRB
- starting research under a protocol before meeting the conditions required by an IRB and receiving an IRB notification of approval
- failing to take UWL-required CITI human subjects protection training
- enrolling significantly more subjects than approved by IRB
- enrolling subjects from populations not previously approved by IRB
- enrolling subjects who should have been screened out from the project based on the defined exclusion criteria approved by IRB
- failing to have research participants sign a new consent form when new and relevant risks are discovered or failing to provide this new information to participants
- altering an IRB-approved consent process or an IRB-approved recruitment process without prior IRB approval
- using the online IRB Exempt Decision Tool to document an IRB exemption for non-eligible projects (see [tool guidance](#) for details)

## Categories of Noncompliance

The IRB will categorize incidents of noncompliance using the following categories. The level of noncompliance is dependent upon intent, context, and other circumstances taken into account by the IRB.

### **Minor Noncompliance**

Minor noncompliance is neither serious nor continuing and is an occasional instance of noncompliance that does not affect the rights and welfare of participants or put participants at risk of harm.

Examples include a single instance of failure to submit a continuing review progress report to the IRB in time to prevent the lapse of approval, failure to secure IRB approval before beginning research or introducing protocol changes when those changes constitute minimal or no risk to the participants, or first occurrences that are believed to be the result of ignorance and/or misinterpretation of the IRB regulations.

These occurrences should be reported to IRB and corrected as soon as possible. Data collected during the lapse must be excluded from reportable results unless approval is sought and received from the IRB Coordinator and/or committee as appropriate.

## **Serious Noncompliance**

Serious noncompliance is noncompliance that affects the rights and welfare of participants or that may put participants at risk of harm. This involves one or more of the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others, decreases potential benefits, or compromises the integrity of the human research protection program.

Examples of **serious noncompliance** include:

- one or more instances of conduct defined above as noncompliance that exposes subjects or others to risks of harm that are not an inherent part of the approved research protocol
- conduct defined as noncompliance above, even though subjects or others have not been exposed to risks of harm not inherent in the approved protocol, where the IRB finds that the lack of risk exposure was incidental
- misrepresentation of information related to the human subjects research protocol or performance of the research
- conducting non-exempt research without IRB approval
- making substantive changes to a previously approved protocol without IRB approval
- conduct that adversely affected the integrity or effectiveness of human subjects protections or subjects rights or welfare

Whether the conduct was inadvertent, careless, reckless, or intentional may be taken into consideration by the IRB in a determination of seriousness.

## **Continuing Noncompliance**

Continuing noncompliance is multiple or repeated instances of noncompliance, particularly after written notice from the IRB that the investigator must take action to correct noncompliance. The multiple or repeated instances of noncompliance may occur on one or more protocols and may occur simultaneously or independently. The IRB will determine if the continuing noncompliance also constitutes serious noncompliance.

## **Unanticipated Problem Involving Risks to Subjects or Others**

If the IRB determines that there was no negligence on the part of the investigator(s) and that all IRB approved procedures were followed, Unanticipated Problems Involving Risks to Subjects to Others do not constitute noncompliance.

To be categorized as an Unanticipated Problem, the issue must meet the following conditions:

- Is unexpected (in terms of nature, severity, or frequency) given: (a) the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document), (b) the

characteristics of the human subject population being studied, AND (c) known risks of study drugs/procedures.

- Is related or probably related to participation in the research (probably related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research).
- Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

These occurrences should be reported to IRB via the [Attachment C](#) and corrected as soon as possible.

## Reporting IRB Noncompliance

Any person who witnesses or suspects any noncompliance with IRB requirements is encouraged to report their concerns. **No adverse action will be taken against anyone making a report.**

The following is a list of ways you may report your concerns:

- Contact the investigator, faculty mentor, IRB Coordinator, ORSP, Research Integrity Officer (RIO), or IRB Committee Chair.
- Email your concerns to the IRB at [irb@uwlax.edu](mailto:irb@uwlax.edu).
- Anonymous/confidential Qualtrics survey: [Survey | Qualtrics Survey Software](#)

Reports will be forwarded to the IRB Coordinator and/or the Research Integrity Officer (RIO) for evaluation in collaboration with ORSP. Reports may be referred to the IRB Committee for further review and action.

## IRB Determinations about Noncompliance

If a report of alleged noncompliance is referred to the IRB Committee, the committee will review the report and any supporting information to determine whether it meets the definition of a noncompliance and, if so, the extent of noncompliance. Reports determined to be incidents of noncompliance will be categorized by the IRB using the Categories of Noncompliance outlined in preceding section.

Student PIs, student Co-PIs and faculty mentors share accountability for upholding ethical standards, mitigating risk, and following approved protocol requirements. In the event that a student is the PI/Co-PI in a project under investigation for noncompliance, the student and faculty will be separately contacted to gather information related to the investigation. Research misconduct investigations are handled separately from academic misconduct issues. Academic misconduct will be handled per university policy.

If the IRB makes an initial assessment of the noncompliance report as representing potentially serious or continuing noncompliance as defined above, it may be referred to the procedure outlined in the UWL Scientific Misconduct policy. Additionally, sponsor

reporting requirements, disciplinary actions, and legal consequences may apply if required by project terms and conditions or applicable regulations.

## IRB Committee Review Process & Timeline

Reports of alleged noncompliance referred to the IRB committee will be reviewed according to the following process and timeline:

1. The IRB Coordinator, Chair, and/or RIO will reach out to the investigator(s), and faculty mentor(s) when applicable, to gather additional supporting information about the alleged noncompliance. At this point, a determination will be made as to whether noncompliance has occurred, and if appropriate will be referred to the IRB Committee for further review.
2. The investigator(s), and faculty mentor(s) when applicable, will be notified an alleged noncompliance report has been referred to the IRB committee for review within 7 business days of its referral to the committee.
3. The committee will meet within 30 business days or at the next regularly scheduled meeting after receiving the initial noncompliance report to review the report and any supporting information. The investigator(s) may be invited to participate and/or submit additional materials for consideration.
4. The committee will render a preliminary determination and, if applicable, required resolution and/or action plan, which will be communicated to the investigator(s) and Research Integrity Officer (RIO) within an additional 15 business days.
5. The investigator(s), and faculty mentor(s) when applicable, is then provided with an opportunity to respond to this finding and required resolution/action plan (if applicable) within 15 business days and provide, in writing to [irb@uwlax.edu](mailto:irb@uwlax.edu), additional relevant information or detail any potential mitigating circumstances that might not have previously been considered. If no appeal is made, the RIO and Provost will be notified of the final finding and required resolution/action plan (if applicable).
6. The IRB will review this response and make a final determination regarding the noncompliance, notifying the investigator(s), and faculty mentor(s) when applicable, the RIO, and Provost of the determination in writing within 30 additional business days.
7. If the IRB makes a final determination that a report constitutes serious and/or continuing noncompliance, federal regulations or sponsor terms & conditions may require that such instances be reported to the Office of Human Research Protections (OHRP) and to the sponsor(s). Other relevant personnel, such HR, investigator's chair/unit director, dean/division director, Provost, and/or Chancellor, may also be notified.
8. If there is a required resolution/action plan issued by the IRB, completion of the prescribed actions will be overseen in collaboration by the IRB Coordinator, IRB, and RIO. Documentation of completed actions will be kept on record in ORSP.

## Corrective Actions

Actions prescribed by the IRB related to the protocol can include, but are not limited to, the following:

- Requiring the investigator(s) make modifications to the protocol
- Requiring more frequent review of the protocol
- Requiring the investigator(s) modify the consent process or consent documents
- Requiring the investigator(s) to provide additional information to current and/or past participants or re-consenting to participation
- Requiring further corrective actions by the investigator(s), and faculty mentor(s) when applicable
- Requiring an investigator oversight plan for the study team
- Requiring additional education for the investigator(s) and/or study team
- Reconsideration of IRB approval
- Implementation of monitoring of the research
- Implementation of monitoring of the consent process
- Restricting or disallowing use of data collected while the protocol was non-compliant
- Restricting or suspending future human subjects research activities
- Suspension of the research
- Termination of the research
- Referral of the matter to the Research Integrity Officer (RIO) for further consideration
- Referral of the matter to the Scientific Misconduct in Research process
- Recommendation for further administrative actions

Unanticipated problems and noncompliance determined to involve no or minor risk to participants or first occurrences that are believed to be the result of ignorance or misinterpretation of the IRB regulations may still be subject to internal scientific misconduct investigation, sanctions, requirements for education/training, or retroactive IRB review determination.

The IRB may require corrective actions, such as those listed above, even without a finding of serious or continuing noncompliance. Sponsor reporting requirements may apply if required by project terms and conditions or applicable regulations.

**NOTE: Although the IRB can suspend the research study, only the Provost and Chancellor have the authority to suspend an individual's privileges to conduct research.**

## Completion of Resolution/Action Plans

Upon completion of a mandated IRB resolution/action plan, investigators are required submit documentation that all required resolutions/actions have been fulfilled.

Documentation must be emailed to [irb@uwlax.edu](mailto:irb@uwlax.edu). It will be forwarded by IRB to the

Research Integrity Officer (RIO) and IRB Coordinator for review and approval. Additional information or documentation may be requested of the investigator to confirm completion. Confirmation of final approval will be sent to the investigator and maintained in ORSP records.

## IRB Retrospective Review & Approval

IRB retrospective approval, as addressed in this section, does **not** include retrospective review of projects that do not initially meet the definition of human subjects research. Examples include programmatic evaluations, consulting arrangements, and some oral history projects. Individuals conducting these activities may later determine that the data acquired has utility for their research and may submit materials to the IRB for retrospective review and approval to use the data in research and/or disseminate the data (e.g., conference presentations, publications).

Data **may not** be used for research or dissemination unless IRB approval is granted. Approval is not guaranteed. Requests for retrospective review of activities that do not initially meet the definition of human subjects research are not considered noncompliance.

Requests for IRB retrospective review are processed as follows:

1. The investigator should submit a request to [irb@uwlax.edu](mailto:irb@uwlax.edu) in accordance with the [IRB Researcher's Guide for Submission of Protocols](#). The submission must indicate it is a request for retrospective review and provide a justification for the request (e.g., description of data for which approval is requested, intended use(s) of the data, justification for the request, justification for why the data cannot be obtained through other means). (Note: These approvals are **not** allowed to be processed through the online IRB Exempt Decision Tool.)
2. The submission is reviewed by the IRB Coordinator, who determines whether the project is exempt or requires further review by the IRB committee.
3. The IRB Coordinator (if the project is exempt or, in some cases, requires expedited review) or IRB committee (if the project requires full review or requires expedited review with committee input) will review and determine whether the data has approval for use in research and/or dissemination, including any conditions on the timeframe or type of data that can be used.
4. The decision will be documented and sent to the investigator in an IRB determination letter outlining the specific conditions of the approval.

The following considerations are applied by the IRB to requests for retrospective review and approval:

- The initial activity must not have met the definition of human subjects research, and thus did not require initial IRB review.
- Considerations related to participant vulnerability, risk, and informed consent, including but not limited to:

- There is no or minimal risk from data being used now (e.g., if someone knew a participant had been a part of this group, there would be no issues on aggregated information being presented).
  - Participants knew they were completing a survey and did so voluntarily.
- Review of the investigator-provided justification for the request, e.g., description of data for which approval is requested, intended use(s) of the data, justification for the request, justification for why the data cannot be obtained through other means
- Data use limitations, including but not limited to:
  - No quotes may be used from individuals surveyed, as permission was not given by participants for the proposed use, the proposed use could identify individuals, and participants may have responded differently.
- Associated data collection timeframes
  - Generally, data collected up to 3 years prior to the submission of a request may be approved for use. However, data from earlier periods may be considered for approval with appropriate justification.