I. DEFINITIONS

Non-compliance: Any failure to follow either the UW-Platteville IRB’s policies or local, state and federal regulations that relate to the protection of human subjects used in research.

There are three levels of noncompliance:

Basic: usually involves not following IRB procedures including:
- Failure to submit a protocol to the IRB prior to collecting data on human subjects
- Failing to wait for IRB approval before starting research
- Continuing to collect data after IRB approval has expired
- Changing an IRB approved consent form without informing the IRB
- Changing research procedures or enrolling subjects who were not identified on the protocol.

Serious: non-compliance that may affect the rights and welfare of participants including:
- Conducting research without submitting an IRB protocol
- Actions that compromise confidentiality of the participants
- Actions that harm the participants either physically, psychologically or emotionally
- The use of subjects from federally identified protected groups, which were not identified on the IRB protocol.

Continuing: multiple instances of non-compliance, or when a researcher does not take corrective action upon notification from the IRB of non-compliance.

II. PROCEDURES

A. All cases of non-compliance are to be reported to the IRB Chair immediately. Reports can be made by research subjects, members of the research team or anyone else familiar with the research project.

B. The IRB Chair will inform the Primary Investigator (and Sponsor, if there is one) that a non-compliance report has been made. The IRB Chair will also determine whether the report is serious enough to merit suspension of the research.

C. The IRB Chair will investigate and determine whether the non-compliance is Basic, Serious or Continuing
   a. In the case of Basic non-compliance, the IRB Chair will notify the Primary Investigator (Sponsor) of the noncompliance issue and will work with the investigators to remedy the problem.
b. In the case of Serious or Continuing non-compliance, the IRB Chair will call a meeting of the full IRB. The researcher will be given the opportunity to attend the meeting to present information, but may not be present while the IRB makes its decisions. At this meeting the following will be determined:
   i. Whether action needs to be taken, and if so what form it will take. This can include requiring changes be made to the protocol, assigning a person to monitor the remainder of the research, requiring the researcher to undergo training, or suspension/termination of the research.
   ii. A recommendation on whether any sponsoring federal agencies need to be informed.

D. For cases of Serious or Continuing noncompliance, the IRB Chair will report to the UW-Platteville Provost about the non-compliance as well as the IRB’s decisions on remedial action, including whether the IRB recommends that any sponsoring federal agencies need to be informed. In cases of continuing non-compliance, the Provost may revoke the research privileges of the individual at the University or institute other disciplinary actions. Although the IRB can suspend or terminate the research project only the Provost can suspend the researcher’s ability to conduct research.

E. The researcher may appeal non-compliance decisions. Appeals relating to Basic non-compliance can be made to the Office of Sponsored Programs and appeals pertaining to Serious and Continuing non-compliance should be made to the Provost’s office.

F. All correspondence and decisions about non-compliance will be added to the corresponding protocol file kept in IRB’s records.