Policy and Procedure for Reporting Protocol Non-Compliance

A. Policy for Reporting Noncompliance

In compliance with 45 CFR 46.103(5) the CCIAO will report promptly to the CCI, appropriate institutional officials, the Office for Human Research Protections (OHRP), and any other sponsoring Federal department or agency head:

1. Any serious injuries to human subjects or other unanticipated problems involving risks to subjects or others,
2. Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
3. Any suspension or termination of IRB approval.

B. Reporting Procedure for Noncompliance

1. When a matter of possible non-compliance is identified or brought to the attention of the CCI Administrator (CCIA), the CCIA will discuss the matter with the Principal Investigator. If the CCIA cannot resolve the problem, it will be referred to the CCI Chair.

2. If the CCI Chair cannot resolve this and determines that the matter requires further investigation, the CCIA will inform the CCI Executive Committee, the Associate Dean for Academic Affairs, and legal counsel. The CCIA also will inform the Principal Investigator of this action.

3. Depending on the gravity of the issue and risk to research subjects, the CCI Chair may either request a preliminary investigation by a CCI Executive member and two other CCI members, or after conferring with the CCI Executive Committee, request that the CCI Subcommittee for Investigative Review be convened. The CCIA will inform the Principal Investigator of the action taken.

If a preliminary investigation is conducted and the issue is resolved, a report is made to the CCIA and the CCI Chair. The CCIA provides a copy of the report to the Principal Investigator.

If the preliminary investigation is conducted and the issue is determined to require further review, such findings are sent to the CCIA and the CCI Chair, who then convene the CCI Subcommittee for Investigative Review. The CCIA notifies the Principal Investigator of this action.

The membership of the CCI Subcommittee for Investigative Review is appointed by the CCI Chair, with the advice of the Executive Committee, and may include: The CCI Chair, the CCI Vice Chairs, CCIA, YU legal counsel, Associate Dean for Academic...
Affairs, Assistant Dean for Clinical Affairs, Associate Dean for Clinical Research, Assistant Dean for Research Development and other members of the faculty who have expertise in the area of concern.

The Principal Investigator will be provided an opportunity to present information to the Subcommittee.

4. If the issue is resolved at this point, the CCIA will document in the CCI file, the issue, the CCI's decision, and the individuals involved in the decision. The CCIA will notify the Principal Investigator of the action of the CCI Subcommittee for Investigative Review.

5. Should it be determined that this matter needs to be referred to the CCI Full Committee, the CCIA will provide the Principal Investigator with a copy of the report of the CCI Subcommittee for Investigative Review and will notify the Principal Investigator of his/her opportunity to provide additional information to the CCIA. The CCI Subcommittee for Investigative Review will review the Principal Investigator's information, and then submit all findings and recommendations to the CCI Full Committee, Associate Dean for Academic Affairs and YU legal counsel. The CCI Full Committee will review the matter and prepare a report, including findings and recommendations. The CCIA will provide the Principal Investigator and the Associate Dean for Academic Affairs with a copy of the CCI Full Committee report.

6. The Associate Dean for Academic Affairs will submit the CCI Full Committee's findings to the Dean. The Dean in consultation with legal counsel, will determine whether a report needs to be filed with the Office for Human Research Protections (OHRP), and any other sponsoring Federal department or agency, in compliance with 45 CFR 46.103(5), and/or another committee of the medical school, as appropriate.

7. At any point during the above procedure, should it be determined by the CCI that research subjects are being placed at additional risk due to matters identified during the investigation, the CCI may take steps to suspend or terminate the research protocol.