

Handling Complaints and Allegations of Potential Non- Compliance with Human Subject Protection Regulations

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POLICY:

- A. For reports involving changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects of changes, the IRB also decides whether the change was necessary to eliminate apparent immediate hazards to the subject, and whether there was insufficient time for IRB review. If these conditions are both false, the incident represents a protocol violation.
- I. Federal regulations [45 CFR 46 .103(b) (5); 21 CFR 56.108(b), and 38 CFR 16.103(b) (5)] require each institution to have "*...written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) ... any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.*" This document describes UIC's policy and procedures for addressing complaints and allegations of potential non-compliance with Federal and State regulations, with University policies regarding research, and with the requirements of the HSPP.
- II. It is UIC policy that investigators, research team members, faculty and staff must report any allegations or observations of apparent serious or continuing non-compliance in human subject research. Complaints or allegations of noncompliance may be directed to the OPRS, IRB, OVCR Associate Director for Research Compliance, HPA or IO. Research subjects and individuals not directly involved with conducting or overseeing the research are also encouraged to report suspected non-compliance.
- III. This policy is applicable to all human subject research activities of UIC faculty, staff, students, or others within the jurisdiction of the UIC HSPP. The policy extends to adjunct and/or volunteer faculty when their appointment is listed among the investigator's credentials in study documents.

DEFINITIONS:

- I. **NON-COMPLIANCE:** Conducting research involving human subjects in a manner that intentionally or unintentionally fails to comply with federal or state regulations, VHA Handbook 1200.05, UIC HSPP policies, or the requirements or determinations of the IRB. Examples include, but are not limited to, initiating research prior to IRB approval, implementing changes in the IRB-approved protocol without prior IRB approval, using inadequate procedures for informed consent, failing to meet education and training requirements and lapses in IRB approval.
- II. **PROTOCOL VIOLATION:** Any deviations, whether accidental, unintentional or intentional, from the IRB-approved protocol that are implemented prior to IRB approval. **Major protocol violations** are those that cause harm to subjects or others, place them at increased risk of harm, impact the scientific integrity of the research, compromise the human subject protection program, have the potential to recur or represent possible serious or continuing non-compliance. Major protocol violations require prompt reporting and are reviewed as potential serious noncompliance. **Minor protocol violations** are those not meeting at least one of the criteria in the preceding sentence and do not require reporting to the IRB. They should be reported to the sponsor as described in the protocol and written documentation of their occurrence filed with the investigator's study records.
- III. **SERIOUS NON-COMPLIANCE:** Non-compliance that results in either substantive harm (or genuine risk of substantive harm) to the safety, rights or welfare of human subjects, research staff or others, substantively compromises the effectiveness of the HSPP or substantively impacts the integrity of the research.
- IV. **CONTINUING NONCOMPLIANCE:** Persistent failure to conduct research in compliance with federal or state regulations, VHA Handbook 1200.05 (if applicable), or requirements or determinations of the IRB.
- V. **EXAMPLES** of apparent serious or continuing noncompliance are provided in the addendum of this policy.

PROCEDURE:

- I. Reporting occurrences or allegations.
 - A. Investigators are required to promptly report to the IRB using the *Prompt Reporting to the IRB* form all findings and allegations of apparent serious or continuing noncompliance, including major protocol violations, subject complaints, and changes to the protocol made without IRB approval to

eliminate apparent immediate harm to subjects. The timeframe for reporting is within 5 working days of becoming aware of the event.

- B. Non-compliance may be uncovered by the IRB, the OPRS, Associate Director for Research Compliance (e.g., during ongoing review or monitoring of research or through audits or other quality assurance activities) or JBVAMC Research Compliance Officer (RCO). These findings are forwarded through the OPRS to the applicable IRB.
 - C. Allegations of non-compliance may also be reported by members of the research team, UIC faculty, staff or administrators, sponsors, study participants, participating organizations, or other knowledgeable parties. The complaints or allegations may be provided to the Director of OPRS, OPRS staff, IRB Chair (or designee), the HPA, or IO. To facilitate reporting, informed consent documents provide a contact phone number and e-mail to discuss concerns or complaints with the research with OPRS staff. The OPRS website also provides telephone and e-mail contacts for OPRS staff members and administration, including the IO and HPA.
- II. Receipt and initial review of allegations of non-compliance.
- A. When complaints or allegations of non-compliance are received via telephone, in person or e-mail by OPRS staff from sources outside of the research team, the information is recorded on the *Complaint/ / Unanticipated Problem/Event Record - Transcription Form* and forwarded to the Assistant Director of the relevant IRB.
 - B. The Assistant Director performs an initial review of the allegation including examination of the complaint form and IRB protocol file (i.e., protocol, consent documents) and, if warranted, conducts discussions with the investigator, other research team members and complainant.
 - C. If the Assistant Director, in consultation with the Associate Director/Director and IRB Chair, determines that the allegation has no basis in fact or the complaint is a minor administrative issue that is able to be resolved by the Assistant Director and does not represent non-compliance (e.g., isolated subject payment complaint), no further action is taken.
 - D. Complaints and allegations that are found not to be non-compliance, including minor administrative issues resolved by the Assistant Director, are entered into a log. A compilation of these complaints is provided to the IRB, the Assistant Director of Quality Assurance/ Quality Improvement, and the OVCR Associate Director for Research Compliance annually to make them aware of issues and/or recurring concerns that may require new or revised policies and procedures.
 - E. If the Assistant Director determines that the allegation represents potential non-compliance, the Assistant Director compiles any collected information for subsequent review by the Chair (or designee).
 - F. If the investigator is asked to provide a response to the complaint, this information is included with the material provided the Chair.
 - G. Complaints or allegations of non-compliance received directly by the IO or HPA are referred to OPRS and handled as described above and may also be

referred directly to the HSEIC for investigation based on the assessment of the IO or designate, the HPA.

- III. Receipt and initial review of investigator reports of non-compliance (including protocol violations) or changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects.
 - A. Investigator reports of non-compliance are submitted to OPRS via the *Prompt Reporting to the IRB* form and forwarded to the Assistant Director of the relevant IRB.
 - B. The Assistant Director reviews the report for completeness, contacts the investigator if necessary for additional information and makes a preliminary assessment of whether the event represents non-compliance.
 - C. The report is then forwarded to the IRB chair or designee.
 - D. Changes to the protocol to eliminate apparent immediate harm to subjects: the AD considers whether the change was necessary to eliminate apparent immediate hazards to the subject and whether there was insufficient time for IRB review.
 1. If these conditions are both true, the incident is referred to the convened IRB for a final determination.
 2. If these conditions are **not** both true, the incident represents a major protocol violation (i.e., serious noncompliance) and is forwarded to the IRB chair or designee.
- IV. Receipt of JBVAMC RCO Reports of Apparent Serious or Continuing Noncompliance
 - A. The JBVAMC RCO must directly report to the facility Director within 5 business days of identifying apparent serious or continuing noncompliance based on an informed consent audit, regulatory audit or other systematic audit of JBVAMC research.
 - B. A copy of this report is provided simultaneously to the IRB as well as the ACOS for R&D and R&D committee.
 - C. The Assistant Director of the relevant IRB reviews the report for completeness and contacts the RCO if necessary for additional information.
 - D. Reports consistent with the examples of apparent serious or continuing noncompliance provided in subparagraphs 7.f. and g. of VHA Handbook should be referred to the convened IRB for a final determination to be made.
 - E. The report is then forwarded to the IRB chair or designee.
- V. IRB Chair (or designee) review.
 - A. The minimum materials provided to the IRB chair (or designee) to facilitate their review and evaluation of the non-compliance event:
 1. Original report of non-compliance;
 2. Any follow-up information gathered about the non-compliance issue;
 3. Current approved research protocol;
 4. Current approved consent document; and
 5. Access to the complete research protocol file.

- B. Determinations that may be made by the Chair (or designee) are:
1. The event does not represent non-compliance;
 2. The event represents non-serious and non-continuing non-compliance and no action is required;
 3. The event represents non-serious and non-continuing non-compliance and corrective action is required; or
 4. The event represents apparent serious and/or continuing non-compliance and the allegation or report of non-compliance is referred to the convened IRB for the final determination to be made.
 5. The event likely represents a **change to the protocol to eliminate apparent immediate harm to subjects** and is referred to the convened IRB.
- C. When the non-compliance is non-serious or non-continuing, corrective actions implemented by the chair (or designee) may include, but are not limited to:
1. Oversight or educational measures;
 2. Changes to the protocol or consent process to prevent future occurrences of non-compliance;
 3. More frequent monitoring of the research; or
 4. Modification of the continuing review schedule.
- If the investigator is unable or unwilling to work with the IRB Chair, then the noncompliance is handled as continuing non-compliance.
- D. When the non-compliance is judged likely to be serious or continuing, the chair (or designee) will determine if immediate action is needed to protect the rights and welfare of human subjects until the meeting of the convened board. Immediate actions to be considered include:
1. Suspension of part (e.g., new subject recruitment) or all of the research (refer to UIC policy *Administrative Hold, Suspension, or Termination of IRB Approval*);
 2. Notification of currently enrolled subjects when information related to the compliance issue may relate to the subject's willingness to continue to participate in the research.
- E. If the Chair (or designee) deems that further investigation of the matter is warranted, they may request the HPA to convene the HSEIC (composition and function described below) for this purpose at any time in the process. The written request will include, at a minimum, the AD's report and a charge for the inquiry (i.e., why the matter is being referred, what additional information the IRB is requesting to be obtained during the inquiry).
- F. Documentation and PI notification of IRB Chair (or Designee) review and determinations.
1. For events determined to be neither serious nor continuing, the finding of the chair (or designee) is documented in writing and copies provided to the investigator, Academic Department Head, other relevant UIC oversight committees (e.g., investigational drug service, radiation safety, cancer center), UIC HPA, JBVAMC R&D Committee (if JBVAMC is a performance site), NU OPRS (if NU is a performance

- site) and UIC OPRS protocol file. The IRB is notified of the Chair's actions at the next scheduled meeting via the agenda.
2. For events being referred by the Chair to the convened IRB, the investigator is notified of the determination, including any immediate actions taken by the Chair (i.e., suspension) and solicited by the Chair or IRB staff for any updated information.
 3. For events being referred by the Chair to the HPA to convene the HSEIC, the investigator is notified by OPRS on behalf of the Chair of the determination and informed of the HSEIC process.

VI. Convened IRB review.

- A. When apparent serious or continuing non-compliance is reviewed by the convened IRB, two primary reviewers are assigned to conduct a thorough review of the packet of information and present the compliance issue to the full board. The IRB members receive at a minimum:
 1. Original report of non-compliance;
 2. Follow-up information gathered about the non-compliance issue;
 3. Protocol summary;
 4. HSEIC/HSIC/Appeals Committee findings and recommendations (as applicable);
 5. Current approved research protocol (primary reviewers only);
 6. Current approved consent document;
 7. Other relevant research materials (e.g., recruitment materials; surveys, audit reports, sponsor monitoring reports, continuing review application); and
 8. Access to the complete research protocol file.
- B. The IRB may determine that further inquiry of the non-compliance is warranted before making the determinations below and request the HPA to convene the HSEIC or HSIC (described below) to investigate and review the allegation of non-compliance, with a final report and recommendation provided to the IRB. The written request will include, at a minimum, the AD's report and a charge for the inquiry (i.e., why the matter is being referred, what additional information the IRB is requesting to be obtained during the inquiry). For research approved by the JBVAMC/NU/UIC Collaborative IRB (UIC IRB#4), the EC serves as the HSEIC. The IRB refers to the HSEIC report in making its determination of whether the non-compliance is serious and/or continuing and of an appropriate corrective action plan.
- C. For reports involving changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects, the IRB should consider whether the change was necessary to eliminate apparent immediate hazards to the subject, and whether there was insufficient time for IRB review. If these conditions are both true, the incident does not represent noncompliance. If these conditions are not both true, the incident represents a major protocol violation (i.e, serious noncompliance).
- D. The IRB may make any of the following determinations:
 1. No non-compliance has occurred;

2. Non-compliance has occurred, but the non-compliance is neither serious nor continuing (refer to V.C. for possible corrective actions);
 3. Non-compliance has occurred that is serious and/or continuing.
- E. When the non-compliance is determined by the convened IRB to be serious and/or continuing, the IRB considers whether to implement one or more of the following actions:
1. Suspension of research approval (refer to UIC policy, *Administrative Hold, Suspension, or Termination of IRB Approval*);
 2. Termination of research approval (refer to UIC policy, *Administrative Hold, Suspension, or Termination of IRB Approval*);
 3. Notification of currently enrolled subjects when information related to the non-compliance issue may relate to the subject's willingness to continue to participate in the research.
- F. Other actions the IRB may take include, but are not limited to:
1. Imposition of ethics and/or human subjects research education for the investigator and/or research staff;
 2. Modification of the protocol;
 3. Modification of the consent process;
 4. Providing information to past participants;
 5. Requiring re-consent of current participants;
 6. Modification of the continuing review schedule;
 7. Monitoring of the research;
 8. Monitoring of the consent process; and/or
 9. Referral to other UIC officials or committees for possible review.
- G. The corrective action plan should include timelines for the investigator to respond to the IRB and follow-up evaluation of the implementation and completion of the actions by the investigator.
- H. Review of the non-compliance issue is documented in the IRB meeting minutes.
- I. A communication documenting the IRB's determination, the reason for the determination and the corrective action plan is generated and sent to the investigator within 10 working days of the convened IRB's determination. Copies of the communication are sent to the Director of OPRS, Academic Department Head, HPA, other relevant UIC oversight committees (e.g., investigational drug service, radiation safety, cancer center), JBVAMC R&D Committee (if JBVAMC is a performance site), EC (UIC IRB#4), NU OPRS (if NU is a performance site), relevant IRB and the UIC OPRS protocol file.
- J. Serious or continuing non-compliance is reported by the Director of OPRS to appropriate IOs and federal agencies as described in the policy, *Reporting of Unanticipated Problems/Events, Suspensions, Terminations, and Non-compliance*.
- K. Reports to IOs, OHRP, FDA and other federal agencies will be made promptly. In the event a situation requires extended time to investigate or resolve, a preliminary report will be sent and followed by a final report. In no event will a preliminary report to IOs, the supporting agency head, or OHRP

be delayed beyond 30 days of the OPRS receiving notice of a reportable event.

L. JBVAMC RESEARCH: Special Reporting Considerations

1. When the IRB determines that serious or continuing noncompliance has occurred, the Chair or designee must report the problem or event directly (without intermediaries) to the JBVAMC facility Director within 5 business days of the determination. Copies of this communication are sent to the JBVAMC ACOS for R&D and R&D Committee. The UIC Human Protection Administrator (HPA) serves as the chair's designee for this reporting.
2. The JBVAMC facility director must report the determination to the appropriate ORO RO, with a simultaneous copy to the VISN Director and ORD, within 5 business days after receiving notification from the IRB.
3. If the IRB requires additional time beyond the first convened meeting after receiving the report to investigate or resolve whether serious or continuing noncompliance occurred, an initial report should be sent to the facility Director that a report of apparent serious or continuing noncompliance has been received and provide a preliminary determination or indicate the disposition of the matter has not been determined.
4. The IRB must reach a determination that serious or continuing noncompliance did or did not occur within 45 days after receiving the report of apparent noncompliance.
5. Any remedial actions must be completed within
 - a) 90-120 days after the IRB's determination for noncompliance involving a specific study or research team.
 - b) 120-180 days after the IRB's determinations for programmatic noncompliance.

VII. Non-Compliance investigation committees and their function.

A. Human Subject Executive Inquiry Committee.

1. Composition. The HSEIC includes the HPA (Chair) or designee, Director of the OPRS, Associate Director of the OPRS, Associate Director for Research Compliance, and may include (at the option of the HPA) the Chair or Vice-Chair of the responsible IRB, University legal counsel, and other individuals deemed of usefulness to the inquiry and appointed by the HPA. In the absence of the HPA, or when there may be a perceived conflict of interest, the IO may also convene the HSEIC and shall be able to assume the other duties under this policy that are normally ascribed to the HPA. No individual on the HSEIC should have a real or perceived conflict of interest with the research or review of the non-compliance issue under evaluation. The Executive Committee Supporting the Collaborative IRB serves as the HSEIC when the allegation of noncompliance involves research performed at the JBVAMC and approved by UIC IRB 4.
2. Process. Upon receiving an allegation or report of non-compliance to investigate from the HPA and/or IRB, the HPA or designee will send

notice to the respondent (i.e., investigator) that a complaint of non-compliance has been made and will be investigated by the Committee. In addition, the HSEIC shall:

- a) Determine whether to initiate an investigation or refer to the HSIC;
- b) Once a preliminary evaluation is complete, give the respondent the opportunity to respond in writing to the complaint or allegation of non-compliance;
- c) Send acknowledgement to the complainant, if applicable, that the allegation has been received and is either being investigated by the HSEIC or referred to the HSIC.

The HSEIC reviews the allegation, the response from the respondent, and other information needed to determine whether further investigation is warranted. The HSEIC may, at its discretion, interview the respondent and any other individuals who may have relevant information, and collect other information appropriate to the inquiry; however, it is not obligated to do so. If new allegations emerge or the scope of the initial allegation broadens, the investigator will be informed promptly and given an opportunity to respond.

If the HSEIC determines that the allegations raise serious and immediate concerns for the safety and welfare of human research subjects or others, the Committee may recommend that the IRB or IO, whichever entity is appropriate to the type of non-compliance complaint or issue, suspend the research or that other immediate actions be taken to protect the rights and welfare of the subjects.

Generally, the inquiry process should be completed within 30 working days from the time the HSEIC is convened. The HPA may grant an extension of time if warranted.

3. Recommendations. Following the completion of the HSEIC's evaluation, the Committee provides the respondent and the IO with its findings and recommendations. After providing the respondent an opportunity to appeal (see Appeals Committee process - section VI.2.C. below), the HSEIC issues its findings and recommendations in writing to the IO, the IRB, the respondent, the HSIC (if it is being referred to the Committee), other IOs as deemed appropriate, and, if appropriate, legal counsel. Recommendations may include, but are not limited to:
 - a) Dismissal of the allegation as unjustified, without merit or unfounded;
 - b) Resolution through corrective actions, such as an educational intervention or the addition of safeguards to the research, including the submission of the information to the IRB for approval of a protocol specific corrective action plan;

- c) Increased monitoring where the transgression was minor and easily remedied;
- d) Referral to the HSIC for a formal investigation when the alleged complaint is founded and is of a potentially serious nature;
- e) Referral of non-protocol specific sanctions for consideration by the IO;
- f) Referral to the appropriate UIC officials or committees for resolution (e.g., grievance, research misconduct), if necessary.

Based on the HSEIC report, the IO or IRB Chair may institute immediate corrective actions prior to review by the convened IRB to protect the rights or welfare of the subjects, preserve the integrity of the study, or protect the integrity of HSPP.

B. Human Subject Investigative Committee.

1. **Composition.** The HSIC includes a minimum of five faculty members, appointed by the IO, and at least one IRB Chair or IRB member. The HPA or designee serves as the non-voting Chair, and the OPRS Director or Associate Director, the Associate Director for Research Compliance, and University legal counsel serve as ex-officio members. Other individuals may be appointed to the HSIC by the HPA or IO or serve as *ad hoc* consultants as appropriate. No individual on the HSIC or serving as an *ad hoc* consultant should have a real or perceived conflict of interest with the research or review of the non-compliance issue under question.
2. **Process.** The HSIC shall:
 - a) Receive allegations of non-compliance or harm referred from the HSEIC;
 - b) Review the respondent's written response to the complaint or allegation;
 - c) Request and review other information, data, and materials relevant to the matter;
 - d) Interview individuals with information relevant to the research or instance of non-compliance at issue, including, but not limited to, the complainant, if identified, research staff, and other investigators as needed; and
 - e) Seek other institutional resources or external consultants to provide expertise beyond that available on the HSIC as needed.

The HSIC, convened at the request of the HSEIC, the HPA, the IO or IRB will conduct an investigation. One or more members of the HSEIC will be available for consultation to the HSIC. The Chair of the HSIC and the IO shall determine if additional consultants with special needed expertise should be appointed to the HSIC.

The respondent will be given an opportunity to submit written comments or appear personally before the Committee. During any personal appearance, the respondent may be accompanied by an advisor of his/her choice. The person may advise, but not represent

the respondent. When another individual will accompany the respondent, the HSIC must be notified at least five working days prior to the meeting and identify whether the advisor is an attorney. If the respondent chooses an attorney for this purpose, a representative from the Office of University Counsel will be invited to be present to advise the HSIC. The respondent may also present relevant information and recommend additional individuals to be interviewed.

At the conclusion of the investigation, the HSIC shall issue a written report summarizing the information examined, stating its conclusions and recommending the actions that the Committee deems appropriate. If the Committee decision is not unanimous, the report shall include a summary of the dissenting opinion(s). Generally, the HSIC investigation process should be completed within 60 working days from the time that the HSIC is convened.

If during its investigation, the HSIC determines that it has not been able to adequately investigate the allegation of non-compliance, the HPA will be notified.

3. Recommendations. Following the completion of the HSIC's investigation, the Committee provides the respondent and the IO with its findings and recommendations. After giving the respondent an opportunity to appeal (see Appeals Committee process - section VI.2.C. below), the HSIC issues its findings and recommendations in writing to the IO, the IRB, the respondent, other IOs as deemed appropriate, and, if appropriate, legal counsel. Recommendations may include, but are not limited to:

- a) Dismissal of the allegation as unjustified, without merit or unfounded;
- b) Resolution through corrective actions, such as an educational intervention or the addition of safeguards to the research, including the submission of the information to the IRB for approval of a protocol specific corrective action plan;
- c) Increased monitoring where the transgression was minor and easily remedied;
- d) Referral of non-protocol specific sanctions for consideration by the IO;
- e) Referral to the appropriate UIC officials or committees for resolution (e.g., grievance, research misconduct), if necessary.

Based on the HSIC report, the IO or IRB Chair may institute immediate corrective actions prior to review by the convened IRB to protect the rights or welfare of the subjects, preserve the integrity of the study, or protect the integrity of HSPP.

C. Appeals committee.

1. Composition. The Appeals Committee includes a minimum of three members; at least one IRB Chair, at least one faculty member and an

IRB Vice-chair, none of whom participated on the HSEIC or HSIC. An IRB Chair or Vice-Chair of a non-affected IRB will serve as the Chair of the Appeals Committee. The HPA, OPRS Director or Associate Director, and the Associate Director for Research Compliance are available, if requested, to provide information to this Committee, but these individuals must recuse themselves from any final discussions or voting of the Appeals Committee. The Committee may consult University legal counsel as appropriate. Other members may be appointed by the IO to the Appeals Committee as appropriate. No individual on the Appeals Committee should have a real or perceived conflict of interest with the research or review of the non-compliance issue under question.

2. *Process.* Once the HSEIC or HSIC completes its evaluation, the Committee's findings and recommendations are provided to the IO and to the respondent, the respondent has have 10 working days upon receipt of this report in which to appeal in writing to the HSEIC or HSIC.

The Appeals Committee reviews an appeal by the respondent and issues its recommendation as to whether reconsideration of the decision is warranted to the HPA, and IO. In the appeal, the respondent must provide a reason for the appeal, including the provision of new information and/or a request for a meeting with the Appeals Committee. The grounds for appeals by the respondent are limited to the following situations:

- a) The respondent has new information that was unavailable at the time of the investigation;
- b) The procedures outlined in this policy were not followed;
- c) The sanctions are considered to be excessive.

The Appeals Committee will review the written appeal received from the respondent. If the respondent claims new, previously unavailable information was not considered, the Committee shall consider the information in conjunction with the report of either the HSEIC or the HSIC. The Appeals Committee may meet with the respondent, the HSEIC or the HSIC in making its determination. The respondent shall have an opportunity to appear before the Appeal Committee if requested in writing. During any personal appearance, the respondent may be accompanied by an advisor of his/her choice. The person may advise, but not represent the respondent. When another individual will accompany the respondent must notify the Appeals Committee at least five working days prior to the meeting and identify whether the advisor is an attorney. If the respondent chooses an attorney for this purpose, a representative from the Office of University Counsel must be invited to be present to advise the Appeals Committee. The respondent may present relevant information and recommend additional individuals to be interviewed. Generally, the Appeals Committee will make its final

determination within 30 working days of receiving the respondent's request for reconsideration.

3. Outcome.
 - a) Recommendation that the appeal should be denied. If the Appeals Committee denies the appeal, the committee will recommend that the IO accepts the recommendations of the HSEIC or the HSIC as final.
 - b) Recommendation that the appeal be granted.
 - (1) If the Appeals Committee recommends reconsideration, the Appeals Committee may recommend that the IO direct the HSEIC or the HSIC to re-open the case to reconsider the matter in its entirety.
 - (2) The Appeals Committee may recommend that the IO appoint a new HSIC to reconsider the matter.

The determination of the IO, based on the recommendation of the Appeals Committee, or referred decisions from the HSEIC or the HSIC, will be presented in writing to the respondent within 10 working days of its decision and shall be final immediately. This decision will also be shared with the IRB, which may choose to take additional independent action.

VIII. Roles of the IO and the IRB.

- A. No other entity within the UIC may override a decision by the IO (through the HSEIC or HSIC or the Appeals Committee) that limits, imposes conditions or in any way restricts an investigator's privileges, or imposes conditions or restrictions upon an investigator or their research.
- B. Likewise, no other entity, including the IO, may override determinations or corrective actions related to the investigator's human subject research protocols imposed by the IRB that limits, imposes conditions or in any way restricts an investigator's privileges, or imposes conditions or restrictions upon an investigator's research protocols.

IX. An appeal of the IRB's determination(s) should follow the UIC HSPP policy *IRB Determination Appeal Process*.

X. Confidentiality and retaliation.

- A. The prompt review of complaints and allegations of non-compliance is critical for maintaining the integrity of UIC's HSPP and the IRB's ability to protect the human research subjects. A climate free from fear of sanction is required to foster reporting and ensure a fair review of complaints and allegations. Retaliation against any person who in good faith reports potential non-compliance (i.e., "whistleblower") is prohibited. Whistleblowers who report human subject protection concerns also have access to other mechanisms at UIC for protection from retaliation under The State Officials and Employees Ethics Act (Ethics Act) 5 ILCS 430/15-5. See the University of Illinois Office of

Business and Financial Services Policies and Procedures, section 9.6, at http://www.obfs.uillinois.edu/manual/central_p/sec9-6.html#bb.

- B. Allegations of non-compliance should remain confidential to the extent possible. Generally, complainants decide if they wish to remain unidentified or have their identity known. However, in order for a respondent involved in an allegation of non-compliance to have a meaningful opportunity to be heard, it may be necessary to identify the complainant. If the complainant is a subordinate of the respondent, the Committee will, to the best of its ability, protect the identity of the complainant while conveying the substance of the allegations and information gained to the respondent. The Committee cannot guarantee the anonymity of the complainant.

REFERENCES:

[21 CFR 50.25\(b\)\(5\)](#), [21 CFR 56.108\(b\)\(2\)](#)
[38 CFR 16.103\(b\)\(5\)\(i\)](#), [38 CFR 16.116\(b\)\(5\)](#)
[45 CFR 46.103\(b\)\(5\)\(i\)](#), [45 CFR 46.116\(b\)\(5\)](#)
[VHA Handbook 1200.5 paragraph 7, IRB Responsibilities and Authority](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
6.0, 10/01/08	5.0, 04/17/07	Describe the procedures for IRB evaluation, handling and making a determination of allegations of noncompliance; describing the process for coordinating activities between the IO and IRB.
6.1, 04/03/09	6.0, 10/01/08	Revised Procedure Section II.D. to include the OVCR Associate Director of Research Compliance. Added procedure steps for notifying the HSEIC that action is needed.
6.2, 06/18/09	6.1, 04/03/09	Added Assistant Director of Quality Assurance/ Quality Improvement title.
6.3, 01/25/11	6.2, 06/18/09	Updated to bring into compliance with VHA Handbook 1058.01, dated 5/21/10.

ADDENDUM

Examples of Apparent Serious Noncompliance (VHA Handbook 1058.01, 5/21/10)

- (1) Any finding of noncompliance with human research requirements by any VA office (other than ORO) or any other Federal or state entity (e.g., FDA). Subsequent reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.
- (2) Initiation of VA human subject research, regardless of level of risk or number of subjects, without written notification from the ACOS for Research that the project may begin.
- (3) Initiation of VA human subject research, regardless of level of risk or number of subjects, without approval by the IRB.
- (4) Initiation of research interactions or interventions with one or more subjects prior to obtaining required informed consent.
- (5) Lack of a required, signed informed consent document or lack of a required, signed Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorization for one or more subjects.
- (6) Use of an informed consent document, for one or more subjects, whose content was not approved by the IRB.
- (7) Failure to report one or more unanticipated SAEs or unanticipated serious problems involving risks to subjects or others as required by this Handbook.
- (8) Participation by one or more members of the research team in the conduct of an active protocol without the required credentialing, privileging, or scope of practice, or engaging in activities outside the approved scope of practice.
- (9) Continuation of interactions or interventions with human subjects beyond the specified IRB approval period.
- (10) Implementation of substantive protocol changes without IRB approval, except where necessary to prevent immediate hazard to a subject.
- (11) Involvement of prisoners or children in VA research, or conduct of international VA research, without the required approval by the VHA Chief Research and Development Officer (CRADO).
- (12) Any noncompliance involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others;
- (13) Any noncompliance that substantively compromises the effectiveness of the facility's human research protection or human research oversight programs.
- (14) Serious programmatic noncompliance. Examples include, but are not limited to:
 - (a) Conduct of IRB business by an improperly constituted committee or with less than a quorum of voting members present.
 - (b) Improper designation of research as exempt under 38 CFR 16.101(b).
 - (c) IRB approval of a waiver of informed consent, a waiver of documentation of informed consent, or a waiver of HIPAA Privacy Rule Authorization when the respective approval criteria at 38 CFR 16.116(c) or 16.116(d), 38 CFR 16.117(c), or 45 CFR 164.512(i)(1)(i) are not met or are not documented.

- (d) Programmatic failure to provide for and document Privacy Officer (PO) and Information Security Officer (ISO) review of proposed human subject research.
- (e) Any programmatic noncompliance involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others;
- (f) Any programmatic noncompliance that substantively compromises the effectiveness of the facility's human research protection or human research

Examples of Apparent Continuing Noncompliance (VHA Handbook 1058.01, 5/21/10)

- (1) Failure to implement IRB-required changes to an on-going protocol within the time period specified by the IRB.
- (2) Deficiencies in informed consent or HIPAA authorization procedures or documentation for ten or more subjects (e.g., outdated informed consent or HIPAA content; lack of required informed consent elements; lack of information required by VA; lack of signature of individual obtaining consent).
- (3) Failure to maintain documentation required by the IRB or by the IRB-approved protocol for ten or more subjects (e.g., inadequate medical record documentation where required; inadequate case report forms where required).
- (4) Failure to implement remedial actions within the periods specified at subparagraphs 5d(1) or 5d(2) in the absence of the justification described at subparagraph 5d(3).