

**Reporting of Complaints and Allegations of
Non-Compliance to the Collaborative
JBVAMC/NU/UIC IRB (UIC IRB#4) from
the JBVAMC and Northwestern University
Performance Sites**

310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

Version: 1.0
Date: 02/11/2009
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 152
AAHRPP Elements: NA

Concerns or complaints related to human subjects research reviewed and approved by the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) ("The Collaborative IRB"), may be conveyed through members of the HSPPs at JBVAMC, Northwestern University (NU) and UIC. Since research approved by the Collaborative IRB may be performed at JBVAMC, NU and UIC, procedures for handling complaints or allegations of non-compliance must address those originating from any of the three institutions. Complaints or allegations of non-compliance originating at UIC will be handled as described in the UIC HSPP policy, *Handling Complaints and Allegations of Potential Non-compliance with Human Subject Protection Regulations, Policy and Procedures*. This SOP describes how complaints or allegations of non-compliance at the JBVAMC and NU performance sites are communicated to the Collaborative IRB.

PROCEDURES:

I. Reporting Procedures

A. Transmission and Documentation of Reports.

1. An institution-specific phone number is provided as a contact number for subject complaints and concerns on the JBVAMC, NU, and UIC informed consent forms.
2. Complaints or allegations of non-compliance received at NU or the JBVAMC are initially evaluated by the NU OPRS or JBVAMC R&D Office prior to forwarding to the Assistant Director of the Collaborative IRB.
3. Complaints or allegations of non-compliance whether received via phone, email, letter or other communications are taken in and pertinent information collected by designated personnel from the HSPP at NU or JBVAMC. The information is transcribed to form *Subject Complaint/Unanticipated Problem Record - Transcription Form* and transmitted to the Assistant Director of the Collaborative IRB.
4. Anonymous callers:
 - a) The recipient of an anonymous allegation should inform the caller that the matter will be investigated to the extent possible given the information provided.

- b) The recipient of the call should ask the caller for any available evidence that the caller is willing to give that will facilitate an investigation into the matter.
 - c) The caller should not be required to provide a name or contact information.
- B. Investigation of the Complaint or Allegation of Non-Compliance.
 1. An initial assessment of the complaint or allegation is performed by the HSPS personnel.
 - a) If issue is minor and the local site is able to resolve the issue (e.g., isolated subject payment complaint), no further action is required and the completed *Subject Complaint/ Unanticipated Problem Record - Transcription Form* is forwarded to the Assistant Director of the Collaborative IRB for logging as described below.
 - b) If the initial evaluation shows that the complaint is substantive and/or the occurrence represents possible non-compliance, the complaint or allegation and *Subject Complaint/ Unanticipated Problem Record - Transcription Form* are forwarded to the Assistant Director of the Collaborative IRB for additional action. Assistance from the NU OPRS and JBVAMC R&D Office will be solicited as necessary.
 2. The Assistant Director presents the results of the initial evaluation to the Collaborative IRB Chair or designee.
 3. If issue is resolved by the Collaborative IRB Assistant Director and/or the IRB Chair determines that no further action is required, and the issue does not represent non-compliance, no further action is required.
 4. Complaints and allegations that are not non-compliance and/or minor subject complaints resolved by the Assistant Director are logged. A compilation of these complaints are provided to the Collaborative IRB and the EC annually to make them aware of issues and/or recurring concerns that may require new or revised policies and procedures.
 5. If the issues raised in the allegation cannot be completely resolved by the Assistant Director and/or the Collaborative IRB Chair or designee determines that non-compliance might be serious or continuing, the IRB Chair or designee proceeds as described in UIC HSPS policy *Handling Complaints and Allegations of Potential Non-compliance with Human Subject Protection Regulations, Policy and Procedures*.
 6. If referral of the complaint or allegation of non-compliance to the HSEIC occurs, the EC functions as the HSEIC for matters involving the Collaborative IRB.

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\(b\)\(5\)](#)
[OHRP Guidance on Reporting Incidents to OHRP](#)
[VHA Handbook 1200.05](#)