

COMPLAINTS OR ALLEGATIONS OF NONCOMPLIANCE IN HUMAN RESEARCH STUDIES POLICY & PROCEDURES AT THE JESSE BROWN VA MEDICAL CENTER

1. The **purpose** of this memorandum is to notify all staff of the policy and procedures regarding complaints or allegations of noncompliance in human research conducted at the Jesse Brown VA Medical Center.
2. The principal investigator of the research study bears the ultimate responsibility for the conduct of the research project in compliance with all national, local, and institutional policies and procedures. Complaints and/or allegations of noncompliance may be brought to the attention of the ACOS for Research at 312-569-6683, or the Human Subject Research Specialist at VA (312-569-7441 or 312-569-6166), or to the appropriate IRBs at the University of Illinois at Chicago 312-996-1711/ Northwestern University Institutional Review Boards (IRBs) at 312- 503-9338.
3. The following points describe procedures to be followed for resolving complaints and/or allegations of noncompliance presented to the VA Research Office:
 - a. When made aware of a complaint or allegation of noncompliance, the Human Subject Specialist under the direction of the ACOS follows the procedure described in the UIC HSPP policy and procedure, *Reporting of Complaints and Allegations of Non-Compliance to the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) from the JBVAMC and NU Performance Sites*.
 - b. Care is taken to maintain confidentiality when corresponding with and leaving messages for all involved parties.
 - c. Records will be maintained by Research and Development office and Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) to ensure that each complaint and/or allegation receives a response.
 - d. When the Collaborative IRB conducts an investigation of the complaint or allegation, the UIC HSPP policy and procedure, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection*

Regulations. The findings (i.e., serious or continuing noncompliance) and recommended corrective actions of the Collaborative IRB will be communicated to the R&D committee for review and implementation.

- e. Findings will be reported to the VA Medical Center Director and all other appropriate parties and authorities as described in the UIC HSPP policies and procedures, *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance* and *Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)*.
4. If you have any questions regarding these policies, contact ACOS for Research and Development at 312-569-6683.

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I. Objective

The Research and Development Office recognizes the need for a mechanism that will allow research subjects to register complaints or concerns regarding their participation in a research project through an alternative source to the Principal Investigator and his/her staff.

The following process describes how a research subject's complaint or concern should be recorded. The processes also describe the steps that may be taken to address the subject's issues.

II. Introduction

The R&D has and follows written policies and procedures that establish a safe, confidential and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who may be unaffiliated with the specific research protocol.

Informed consent documents contain a current telephone number and other relevant information for research participants to contact the Principal Investigator. Additionally, there is information in the informed consent document for the research subject to contact Patient Advocate Office at 312-569-6146, Medical Administrative Specialist at the JBVAMC Research and Development Office at (312) 569-6616 or (312) 569-7426, or the UIC OPRS at (312) 996-1711 or 1-866-789-6215 (toll free) or e-mail at uicirb@uic.edu.

Subject complaints and follow-up actions are documented in writing and maintained in a secure location in the R&D Office and forwarded to the Assistant Director of UIC IRB#4.

III. Regulatory Requirements

The R&D Committee recognizes that it must be responsive to the concerns of research participants. It is generally felt that guidance provided in 45 CFR 46.116(a)

(7) under the “General requirements for informed consent” are meant to include a provision that will allow the research subject a means to contact a source at the JBVAMC and the Collaborative IRB to file a complaint.

IV. Standard Operating Procedures

Subjects enrolled at the JBVAMC may contact the Patient Advocate, the R&D Office or UIC OPRS by phone as listed in Section 2 above.

When a subject complaint is received, the *Research Subject Complaint/Unanticipated Problem Record* form should be completed. The following guidance is suggested when responding to the subject’s complaint:

What is your name? The subject can remain anonymous if they wish. Please explain that we will not release the subject’s name to anyone involved in the research study unless they are requesting to be contacted by study personnel. We will only provide their name when necessary to obtain additional information needed to resolve their complaint (i.e., billing issues.) We would like to have the subject’s name and contact information so that we can provide them with follow-up information regarding their complaint.

Is there a telephone number where you can be contacted? (Let the subject know that you want to be able to contact them should you get disconnected and so that someone will be able to contact them to provide them with a response (if needed) when resolving their complaint. The subject can provide an alternate form of contact if they wish (e-mail, mailing address, cell phone, etc.)

Make sure that telephone number is one where the subject can be contacted during normal business hours. Ask the subject if it is okay for someone to call them at that number.

What is the nature of your complaint? Try to get the subject to briefly summarize their complaint. Explain that someone will follow-up with them later if more information is needed.

Are you currently participating in a research study? If no, ask the subject when they participated in the research study they are calling about. If the subject states they have not agreed to participate in any research, but were contacted or enrolled inappropriately in a research study (or if their information was used), ask if they know who contacted them or what the research study was about.

Do you know the name of the researcher or the name of the study you are participating in / you previously participated in?

Do you have a copy of the consent document or information sheet you were given when you agreed to participate in the research?

On the consent document/info sheet is there the name of a person to contact and a telephone number other than the one you just called?

If yes, what is that name and number?

Have you tried to call that number? Did you talk with someone at that number? Do you remember whom? What did they tell you to do?

Can the issue be resolved by contacting the Principal Investigator or their staff? If the subject has not contacted the PI and the issue can be resolved by putting the subject in contact with the PI or the PI's staff (i.e., subject wants to withdraw from participation; subject has not been paid), let the subject know that you are going to transfer them to someone in the PI's office. Stay on the line until the transfer is complete.

If no one answers at the PIs contact number, return to the subject on the line and get their name and telephone number. Inform the subject that someone in OPRS will personally contact the investigator and give the investigator, or his/her staff, the subject's information. Inform the subject that someone from the investigator's office will be contacting him/her.

If the subject is incarcerated and cannot receive return telephone calls, give the subject a date and time to call our office for follow-up (allow about one week.) This will allow OPRS time to follow-up with the PI's office or work towards resolving the subject's complaint.

Closing the Complaint Report

Inform the subject that if they do not hear from someone regarding their complaint within one week, they should re-contact our office at the number they called today. Let the subject know that you will be forwarding their information on to the Research Subject Advocate who may contact them for follow-up.

If the subject asks your name, please give the subject your first name ONLY (for your protection). This will also allow the subject to speak with the same person again if they need to re-contact our office.

Complete and sign a *Research Subject Complaint/Unanticipated Problem Record* form and forward it to ACOS (Associate Chief of Staff for Research and Development) for further action.

An initial assessment of the complaint or allegation is performed by the HSPP personnel.

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 *Research Subject Complaint/Unanticipated Problem Record* form is forwarded to the Assistant Director of UIC IRB#4 for logging as described below.

If the initial evaluation shows that the complaint is substantive and/or the occurrence represents possible non-compliance, the complaint or allegation and *Research Subject Complaint/Unanticipated Problem Record* form are forwarded to the Assistant Director of UIC IRB#4 for additional action. Assistance from the NU OPRS and JBVAMC R&D Office will be solicited as necessary.

Following the receipt of a subject complaint, the ACOS will review the appropriate research protocol file and assess the complaint in relation to the research. If the issue is minor and the ACOS or R&D staff is able to resolve the issue (e.g., isolated subject payment complaint), no further action is required and the completed *Research Subject Complaint/Unanticipated Problem Record* form is forwarded to the Assistant Director of UIC IRB#4 for logging.

If the initial evaluation shows that the complaint is substantive and/or the occurrence represents possible non-compliance, the complaint or allegation and *Research Subject Complaint/Unanticipated Problem Record* form are forwarded to the Assistant Director of UIC IRB#4 for additional action. Assistance from the JBVAMC R&D Office and ACOS will be solicited as necessary. The allegation of noncompliance will subsequently be handled following the UIC HSPP policy and procedure, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*.

Subject complaint records will be maintained in a binder located in a secured, locked filing cabinet within the R&D Office. Subject complaint records will not be placed in the investigator protocol file.

V. References

General requirements for informed consent:

45 CFR 46.116(a)(7) “an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and who to contact in the event of a research-related injury to the subject”

38 CFR 16.103(b)(5); 38 CFR 16.116 (a) (7); M-3, Part I, Chapter 9, Appendix 9C; 45 CFR 46.103 (b) (5); and 21 CFR 50.25 (a) (7)

VI. Attachments

Research Subject Complaint / Unanticipated Problem Record Form