



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

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**SOP: COMPLAINTS AND/OR  
ALLEGATIONS OF  
NONCOMPLIANCE IN HUMAN  
RESEARCH STUDIES POLICY &  
PROCEDURES**

*Please note that this is not the SOP for the Audit Subcommittee.*

**PURPOSE**

The purpose of this Standard Operating Procedure is to establish procedures for resolving complaints and /or allegations in human research studies presented to the Research & Development Office at the Jesse Brown VA Medical Center.

**POLICY**

If the R&D Office is made aware of a complaint and/or allegation of noncompliance, the Associate Chief of Staff or the Administrative Office will immediately notify the appropriate oversight committee, namely the IRB for human subjects protocols, the IACUC for animal protocols and the Research Safety Officer/Subcommittee for Research Safety for safety related issues. Care is taken to maintain confidentiality when corresponding with/leaving messages for all involved parties. Records will be maintained by the Research and Development office to ensure that each complaint and/or allegation receives a response. All allegations **concerning human subjects** will be referred to the IRB for determination. Remedial action for and consequences of findings of noncompliance will be established by the appropriate subcommittee (IRB for human subjects research, IACUC for animal research, SRS for safety related issues) for each incident. These include but are not limited to compliance audits, letters of reprimand, suspension and/or termination of research protocol, and restrictions on serving as an investigator on human subjects protocols. Findings will be reported to the Jesse Brown VA Medical Center Director and all other appropriate parties and authorities.

## **INTRODUCTION**

The R&D office has and follows written policies and procedures that establish a safe, confidential and reliable channel for current, prospective, or past research subjects 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 subjects to contact the Principal Investigator. Additionally, there is information in the informed consent document for the research subject to contact Patient Advocates at 312-569-6146; or R&D Offices at 312-569-6166; 312-569-7441 during normal office hours (Monday through Friday). Subject complaints and follow-up actions are documented in writing and maintained in a secure location in the R&D Office.

## **SCOPE**

The R&D Committee recognizes that it must be responsive to the concerns of research subjects. It is generally felt that guidance provided in 38 CFR 16.116(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 to file a complaint.

## **RESPONSIBILITIES**

### **Principal Investigator**

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 312-569-6166, or the Research Medical Administration Specialist at VA (312-569-7441 or 312-569-6166), or to the UIC-IRB #4 at the University of Illinois at Chicago 312-996-1711/ Northwestern University Institutional Review Boards (IRBs) at 312- 503-9338. Any serious or continuing non-compliance must be reported to the IRB and the Facility Director. The ACOS may be the Director's designee for receiving these reports, but they must be made and conveyed to the IRB and Director in a timely way. Any member of the research community must report any serious or continuing non compliance regarding human subjects protocols to the IRB and to the Facility Director within 5 business days of becoming aware of the concern.

## **PROCEDURES**

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.

Subjects enrolled at the JBVAMC may contact the Patient Advocate or the R&D Office by phone as above.

When a subject complaint is recorded a 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 PI's 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**

If a subject becomes incarcerated, the IRB must be notified and action must be taken since the research study most likely did not originally involve prisoners.

For research involving prisoners as subjects, the IRB follows federal regulations at 45 CFR 46 Subpart C per IRB SOP entitled Research Involving Prisoners, Version 1, 2/16/09.

**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 form and forward it to ACOS (Associate Chief of Staff for Research and Development) for further action.

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 complaint is minor and can be resolved by contacting the Principal Investigator or Study Coordinator, the ACOS will contact the appropriate study personnel and document in writing the resolution of the complaint. The ACOS may follow-up with the subject who lodged the complaint to ensure that appropriate actions were taken.

If the complaint is judged to be serious, it will be forwarded to the IRB. Appropriate corrective actions will be determined by the IRB, acted upon, and reports will be filed appropriately.

Research subject complaint records will be maintained in the strictest confidence and will not be discussed with anyone other than those directly involved in the complaint or as needed to resolve the complaint.

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.

## **REFERENCES**

General requirements for informed consent:

38 CFR 16.116(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 CFR16. 103(b)(5); 38 CFR16.116 (a) (7); 45 CFR 46.103 (b) (5); and 21 CFR 50.25 (a) (7)

**45 CFR 46, Subpart C**

**UIC SOP Research Involving Prisoners, Version 1, 2/16/09**

## **Appendix A**

Research Subject Complaint / Unanticipated Problem Record Form.

### **REVISION LOG:**

#### **SOP: COMPLAINTS AND/OR ALLEGATIONS OF NONCOMPLIANCE IN HUMAN RESEARCH STUDIES POLICY & PROCEDURES**

| <b>Version (#, date)</b> | <b>Replaces (#, date)</b> | <b>Summary of changes</b> |
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| 3.4; April 5, 2011       | 3.4; November 25, 2009    |                           |
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