

NIH HRPP SOP 22 v1

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &  
IMPLEMENTATION**

**OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS**

**SOP Number: 22**

**SOP Title: RESEARCH SUBJECT INFORMATION AND SERVICES AND  
RESEARCH-RELATED COMPLAINTS FROM RESEARCH SUBJECTS**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB  
Chairs, IRB Administrators, Protocol Navigators**

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**SOP 22 RESEARCH SUBJECT INFORMATION AND SERVICES AND  
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## **SOP 22 RESEARCH SUBJECT INFORMATION AND SERVICES AND RESEARCH-RELATED COMPLAINTS FROM RESEARCH SUBJECTS**

### **22.1 PURPOSE**

The purpose of this policy is to describe (a) how NIH communicates with research subjects and provides services to them, and (b) to explain how the NIH handles research-related complaints from research subjects.

### **22.2 POLICY**

The NIH's human research protection program (HRPP) has procedures in place to provide information and services to research subjects. The HRPP also ensures that complaints about participation in research are given serious consideration and that efforts are made to identify and resolve such complaints.

### **22.3 INFORMATION AND SERVICES PROVIDED TO RESEARCH SUBJECTS**

A. Information provided to subjects seen at the NIH's Clinical Center (CC):

1. At the time of their registration, the NIH CC gives research subjects the "NIH Clinical Center Patient Handbook" which provides information about their rights and responsibilities (see References below).  
This includes a discussion of the role and availability of the CC Patient Representative and subjects' responsibilities to communicate any problems or concerns related to their care and/or treatment at the CC. This handbook is available on the CC web site under "Patient Services."
2. Clinical Center Web Site: This publicly-available web site devotes a section to "Patient Services" which includes information about the Patient Representative (see References below).
3. In designated areas throughout the CC, notices are posted with information about the role of and how to contact the CC Patient Representative.

- B. Information provided at non-CC NIH sites (NIA, NIDA, NIEHS, NIDDK/Arizona) will be determined by IC officials and the applicable IC IRB. For NIEHS, it will be determined by the NIEHS IRB and NIEHS Compliance Office.
- C. Information specific to individual NIH research protocols: Consistent with the requirements at 45 CF 46.116(a)(7), all NIH IRB-approved research consent documents list the names and phone numbers of investigators specific to each protocol who can answer questions and address subjects' concerns. For research conducted in the NIH CC, each consent document also lists the CC Patient Representative as a person who can assist subjects in addressing any concerns or problems.

## 22.4 RESEARCH-RELATED COMPLAINTS

### 22.4.1 DEFINITIONS

- A. **Complaint:** An expression of concern, dissatisfaction or grievance by any individual or organization related to any aspect of an NIH research protocol or research activity involving human subjects. Complaints may be lodged by research subjects, their family members or friends, and by NIH health care staff or others.

Complaints that uncover the possibility of non-compliance are addressed according to SOP 16A "Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP)".

- B. **Investigation:** A fact-finding activity for the purpose of creating a factual record and the examination of that record to decide whether the complaint requires further follow-up and/or remediation. An investigation may result in a recommendation(s) for further actions.

### 22.4.2 LODGING COMPLAINTS

- A. Research subjects may bring their problems or complaints *regarding their participation in research* at any site to the attention of Principal and/or Associate Investigators or other health care/research staff (e.g., nurses, social workers); OHSRP staff; the NIH IRB Chair and/or Institute or other

NIH officials. In addition, at the Clinical Center, subjects may contact the Department of Bioethics and/or the CC Ethics Committee, and the CC Patient Representative. At non-CC sites, complaints also may be referred to the IC Compliance Office.

- B. Issues or complaints related to the quality of clinical care and/or patient safety related concerns at the Clinical Center should be directed to the Office of the Deputy Director for Clinical Care (DDCC) or to comparable persons/entities for research conducted at non-CC NIH sites.
- C. Complaints that deal with concerns unrelated to research or patient safety/clinical quality, e.g., quality of food, parking problems, etc., are referred to appropriate entities such as the CC Office of the Chief Operating Officer, the CC Department of Social Work and/or the CC Patient Representative or to comparable persons/entities for research conducted at non-CC NIH sites.

### **22.4.3 DOCUMENTING COMPLAINTS**

Complaints, written or verbal (including telephone complaints) will be documented and kept on file by the recipient (e.g., the PI, the Patient Representative) and in the relevant receiving office (e.g., the IRB administrative office, the OHSRP, the Office of the DDCC, the IC Compliance Office) consistent with applicable laws for privacy. If a complaint related to research participation is received initially by OHSRP, the appropriate IRB Chair and the Principal Investigator of the relevant protocol will be notified, as appropriate.

- A. Generally, the following information will be documented as applicable:
  - 1. Subject's (or complainant's) name, address, and phone number, if provided;
  - 2. Protocol title/number and the name of the PI;
  - 3. Date(s) of the incident if known, and;
  - 4. An explanation of the concern, complaint, or question.
- B. Anonymous reports are accepted. However, the person receiving the complaint may need to advise the complainant that the inability to follow-up to gather more information may hinder an investigation and that the

results of an investigation and/or the provision of follow-up information may not be possible (see section 22.4.6).

- C. The name of the complainant(s) will be kept confidential to the extent possible. Complainants may be advised that complete confidentiality cannot always be maintained during an investigation.

#### **22.4.4 INVESTIGATING COMPLAINTS**

The following procedures apply to investigating complaints lodged by subjects or others.

- A. Attempts are made to respond to complaints as soon as possible. The complainant is informed that the issue will be addressed further, as appropriate, and that a response to him/her will be forthcoming as consistent with section 22.4.6.
- B. Complaints from research subjects that cannot be resolved by the research team or Patient Representative will be referred to the appropriate IC Clinical Director or the Director of the Clinical Center. When appropriate, such as when the complaint may relate to allegations or incidents of non-compliance or to other human subject protection issues (e.g., informed consent, confidentiality, or other topics covered by the NIH HRRP SOPs), the IRB Chair and OHSRP will be informed also.

The IRB Chair, IC Compliance Office and OHSRP work collaboratively, with others as appropriate (e.g., Patient Representative, CC Bioethics Department), to investigate the complaint(s) further.

- C. Results of an investigation: At the conclusion of an investigation, the IRB Chair, OHSRP, and other involved parties as appropriate, will decide if further action is needed.
  - 1. The complaint requires no further action.
  - 2. The complaint is not research-related and is more appropriately handled through non-IRB channels. It will be referred to the appropriate entity (such as the CC Social Work Department).

3. The complaint is research-related and will be forwarded to the appropriate IRB for review.

#### **22.4.5 IRB REVIEW OF FINDINGS RELATED TO COMPLAINTS**

The convened IRB will review issues which meet the criterion under **22.4.4.C.3**, above. It will take appropriate action to ensure the safety and welfare of human research subjects. These actions may involve but are not limited to:

- A. Modifying the research protocol and/or consent document(s);
- B. Educational measures for the researcher or research team;
- C. Suspending or terminating IRB approval for some/all of the PI's studies;
- D. Informing other IC or NIH officials as appropriate.

#### **22.4.6 COMMUNICATION OF THE RESULTS OF AN INVESTIGATION TO THE COMPLAINANT**

Unless the complaint is anonymous, complainants will be notified, when appropriate, by OHSRP or the IRB Chair of the outcome of the investigation conducted by OHSRP and/or the IRB Chair/IC Compliance Office. This communication will be consistent with the Privacy Act and other applicable laws and policy. In some instances, the complainant may simply be told that the matter is being investigated and no further information will be forthcoming.

#### **22.5 COMMUNICATION ABOUT RESEARCH SUBJECT COMPLAINTS WITHIN THE NIH'S HRPP**

In order to promote open communication about research subject complaints in the Clinical Center, the Director, OHSRP, the CC Patient Representative and the Director, CC Department of Bioethics, shall meet as needed to review issues related to subject complaints. Non-CC sites may also arrange for meetings with the IRB Chair, OHSRP, and IC Compliance Office to review issues related to subject complaints.

## REFERENCES

- A. NIH Clinical Center Patient Handbook:  
<http://clinicalcenter.nih.gov/participate/pdf/pthandbook.pdf>
  
- B. NIH Clinical Center webpage “Patient Services” and CC Patient Representative:  
<http://clinicalcenter.nih.gov/participate/patientinfo/services.shtml#rep>