

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

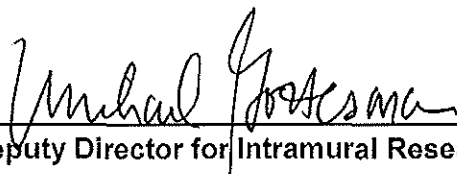
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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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Deputy Director for Intramural Research

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

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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).

The handbook includes a description of the role and availability of the CC Patient Representative and informs subjects' of their responsibility to communicate any problems or concerns related to their care and/or treatment at the CC. It is also available on the CC web site under "Patient Information."

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 or the Office of Human Subjects Research Protections (OHSRP).

B. Information provided at non-CC NIH sites (e.g., NIA, NIDA, and NIDDK/Arizona) is determined by Institute or Center (IC) officials and the applicable IC Institutional Review Board (IRB). For NIEHS, it is determined by the NIEHS IRB and NIEHS Compliance Office.

- C. Information specific to individual NIH research protocols: Consistent with the requirements at 45 CFR 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 action.

22.4.2 LODGING COMPLAINTS

- A. Research subjects may bring their problems or complaints *regarding their participation in research* to the attention of Principal and/or Associate Investigators (PIs or AIs) or other health care/research staff (e.g., nurses, social workers); OHSRP staff; the NIH IRB Chair and/or IC or other NIH officials. In addition, at the CC, 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 an IC Compliance Office.
- B. Issues or complaints related to the quality of clinical care and/or patient safety related concerns at the CC 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 PI 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, **CC**. 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 **Standard Operating Procedures**), the IRB Chair and OHSRP will also be informed.
- C. 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.
- D. 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 **Section 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:

Modifying the research protocol and/or consent document(s)

- A. Educational measures for the researcher or research team
- B. Suspending or terminating IRB approval for some/all of the PIs studies
- C. 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 CC, the Director of OHSRP, the CC Patient Representative and the Director of 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://cc.nih.gov/participate/patientinfo/services.shtml>

****MEMORANDUM****

December 20, 2013

TO: Addressees

FROM: Deputy Director for Intramural Research

SUBJECT: Reporting Concerns, Research-related Complaints and Non-Compliance Regarding Human Subjects Research Occurring within the NIH Human Research Protection Program (HRPP)

This memorandum reaffirms my commitment to maintain full and open communications regarding human subjects research within the NIH Human Research Protection Program (HRPP). Anyone at the NIH, including research participants, NIH employees and contractors, should immediately report any concern or complaint to me or the Director, Office of Human Subjects Research Protections (OHSRP). Complaints may be made anonymously. All Principal Investigators (PIs), research nurses, clinical coordinators, protocol monitors and other members of the research team are responsible for ensuring compliance with federal regulations and HRPP Standard Operating Procedures (SOPs).¹

Generally, initial concerns related to the performance of a specific study should be directed to the research team. Concerns about specific human research protocols, performed in either inpatient or outpatient settings, and reportable incidents, described below, will be fielded by the Chairs of the Institutional Review Boards (IRBs) and directed to the full IRB as needed. Concerns not directly related to a particular study should be addressed to me as the NIH Institutional Official for the Federalwide Assurance or the Director, OHSRP, who assists me in assessing all allegations of non-compliance in accordance with the policies described in SOP 16A "Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP)." Any of the following incidents must be reported to the responsible NIH IRB or OHSRP as quickly as possible after identification and within specified timelines. Examples of reportable incidents include *but are not limited to*:

- Complaints made by participants about the research that cannot be resolved by the research team
- Instances of failure to adhere to the protocol discovered through internal or external monitoring programs
- Allegations of non-compliance with protocol requirements and federal policies
- Unreported unanticipated problems or adverse events
- Initiating research without proper consent
- Changes to the protocol without IRB approval
- Failure to obtain continuing IRB review and approval

Research subjects may bring problems or complaints regarding their participation in research at any NIH site to the attention of the Principal Investigator or research team, OHSRP staff, the NIH IRB Chair, the CC Patient Representative and/or Institute or other NIH officials, as described in SOP 22 "Research Subject Information and Services and Research-related Complaints from Research Subjects."

If you are uncertain about whether an incident or activity should be reported, please report it.

I stress that NIH will not tolerate any reprisal against any individual who has come forward with concerns involving participants in clinical research protocols. Reprisals are prohibited by law and perpetrators are subject to sanctions. Individuals who feel that a personnel action has been taken against them because they reported complaints or apparent non-compliance with a clinical research protocol may present their case to their supervisor, IC Director, the NIH Director, the Office of the Inspector General or the Office of Special Counsel. If individuals believe they are the subject of any form of discrimination, they should file a complaint with the Office of Equal Opportunity and Diversity Management.

Please direct questions or comments regarding this memorandum to me or to the Director, OHSRP; tel. 301-402-3444; email: ohsr_nih_ddir@od.nih.gov; mailing address: Bldg. 10, Room 2C-146.

Michael M. Gottesman, M.D.

Addressees:
IC Directors, Scientific Directors and Clinical Directors
IRB Chairs
IPAC
NIH IRP Principal Investigators

¹ DHHS regulations for protecting human subjects, 45 CFR 46; the FDA regulations, 21 CFR parts 50, 56, 312, and 812, and NIH HRPP Standard Operating Procedures (SOPs) are listed on the Office of Human Subjects Research Protections (OHSRP) website at <http://ohsr.od.nih.gov/>