

<p>This document summarizes changes in <i>Policy 104 Managing Research-Related Complaints from Subjects</i> (referred to as Policy 104 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.</p> <p>The policy describes how the NIH Intramural Research Program’s (IRP’s) Human Research Protection Program (HRPP) manages research-related complaints received from a research subject, a subject’s legally authorized representative (LAR) and/or family, or others.</p> <p>NIH investigators are responsible for reviewing Policy 104 and complying with the requirements of the policy.</p> <p>Note: Text from the policy and other policy titles are italicized.</p>	
<p>Policy 104 Managing Research-Related Complaints from Subjects</p>	<p>SOP Superseded by Policy 104</p>
<p>Policy 104 Managing Research-Related Complaints from Subjects fully supersedes</p>	<p>SOP 22 – Research Subject Information and Services and Research-related Complaints from Research Subjects</p>
<p>Applicability of Policy 104 – This policy applies to:</p> <ul style="list-style-type: none"> • This policy applies to NIH investigators. • This policy applies to non-NIH investigators when the NIH Institutional Review Board (IRB) is the Reviewing IRB. 	
<p>POLICY Requirement</p>	<p>SOP Requirement</p>
<p>Section C.1. – <i>NIH Principal Investigators (PIs) will assure that that research subjects (or their LAR) receive contact information for individuals, both within and external to the research team, who can address or receive complaints regarding research participation. This information will be provided, via the informed consent form or verbally, and upon request.</i> (See also Section E.2.a.I.)</p> <p>These requirements remain unchanged, except that this policy is more specific that this is an NIH PI responsibility.</p> <p>The listing of the CC Patient Representative for NIH Clinical Center (CC) consents is already part of the required NIH language in the CC consent template.</p>	<p>Section 22.3.C. – <i>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 problem.</i></p>

<p>Section C.2. – <i>Complainants may bring complaints regarding research participation to the attention of NIH investigators or to the designated contacts as described in the research informed consent document. Complainants may also bring their complaints to OHSRP.</i></p> <p>Where subject complaints can be lodged have not changed from SOP 22, except that Policy 104 is more explicit that complainants may bring their complaints directly to OHSRP.</p>	<p>Section 22.4.2 – <i>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.</i></p>
<p>Section C.3. – <i>Any NIH investigator or OHSRP staff receiving a subject complaint regarding research participation, will inform the subject or delegate to another the responsibility to do so), when pertinent, that:</i></p> <ul style="list-style-type: none"> <i>a. The name of the complainant(s) will be kept confidential to the extent possible, and that complete confidentiality cannot be assured;</i> <i>b. The corresponding subject's identity may be revealed during the investigation;</i> <i>c. Anonymous complaints will be accepted. However, anonymity may hinder both the investigation of the complaint, as well as inhibit the ability to provide responses to the complainant;</i> <i>d. The issue will be considered by those receiving the complaint as soon as feasible, but it may be referred to other parties, as appropriate;</i> <i>e. Complaints that indicate possible non-compliance will be addressed according to Policy 802 Non-compliance in Human Subjects Research;</i> <i>f. Complaints that indicate possible unanticipated problems will be addressed according to Policy 801 Reporting Research Events; and</i> 	<p>Section 22.4.3 – <i>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).</i></p> <p><i>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.</i></p>

<p><i>g. Results of a subsequent inquiry or an investigation, if any, may be provided to the non-anonymous complainant, consistent with C.4. below.</i></p> <p>(See also Section E.1.a.I.)</p> <p>Policy 104 is far more explicit about the responsibilities for <u>all NIH investigators</u> when addressing a research-related complaint with a complainant.</p>	<p>Policy 104 is far more explicit regarding information that should be provided to complainants when lodging a complaint as to the expectations and limitations regarding investigation of, and internal communications about, a complaint.</p>
<p>Section C.4. – <i>Communications to complainants will be consistent with the Privacy Act of 1974, federal laws, regulations, and policy, including NIH policy.</i></p> <p><i>a. In some instances, for example, the complainant may be told that appropriate measures have been taken, or that the matter is being investigated and no further information will be forthcoming.</i></p> <p>Section E.1.a. – <i>When receiving or discussing complaints with complainants, NIH Investigators (or their designee) must:</i></p> <p><i>ii. Communicate respectfully with the complainant: The point of contact for the complainant should respond to inquiries from the complainant about the status or outcome of the investigation as consistent with privacy rules and other applicable federal law, regulation, or policy, including NIH policy. However, in some instances, the complainant may be told, for example, that appropriate measures have been taken, or that the matter is being investigated and no further information will be forthcoming.</i></p> <p>Policy 104 is more explicit regarding what may be shared with complainants in responses to inquiries during the investigation and following the outcome of an</p>	<p>Section 22.4.6. – <i>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.</i></p>

<p>investigation. This includes that “appropriate measures have been taken” without being explicit as to which measures are being taken.</p> <p>NIH Investigators should confer with OHSRP office of Compliance and Training before providing results of investigations to complainants, if there any questions about what may be shared.</p>	
<p>Section C.5. – <i>All those who receive research-related complaints, whether written or verbal, will document the complaint (e.g., in the research record, CRIS, the office tracking system) consistent with federal law, regulation, and policy, including NIH policy.</i></p> <p>Section E.1. a. III. – <i>Document complaints (e.g., in the research record, CRIS) consistent with federal law, regulation, and policy, including NIH policy</i></p> <p>This requirement remains unchanged from SOP 22 but is more explicit with regard to documentation in CRIS.</p>	<p>Section 22.4.3. – <i>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.</i></p>
<p>Section C.6. – <i>6. Receiving NIH investigators will report all complaints to the NIH PI, or IC leadership for response or referral of the matter, as appropriate. If OHSRP receives the complaint initially, it will inform the PI.</i></p> <p>Section E.1.a. – <i>When receiving or discussing complaints with complainants, NIH Investigators (or their designee) must:</i></p> <p><i>IV. Report all complaints to the NIH PI or IC leadership.</i></p> <p><i>i. When reporting subject complaints to the PI, staff should honor a subject’s request for anonymity to the extent possible.</i></p> <p>This is a change from SOP 22, the policy requires that the NIH investigators report all</p>	<p>Section 22.4.4.B. – <i>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.</i></p> <p>Section 22.4.3. – <i>If a complaint related to research participation is received initially by OHSRP, the</i></p>

<p>complaints to their NIH PI or IC leadership, as applicable, not just those complaints that cannot be resolved by the investigator.</p>	<p><i>appropriate IRB Chair and the PI of the relevant protocol will be notified, as appropriate.</i></p>
<p>Section C.7. – <i>When an NIH PI receives a research-related complaint, the PI will address the complaint as soon as feasible, and/or refer the matter to other NIH or IC offices, as appropriate.</i></p> <p>Policy 104 is explicit that the NIH PI will address the complaint as soon as feasible. Previously SOP 22 did not specify this as a responsibility of the NIH PI.</p> <p>Section E.1.a. – <i>When receiving or discussing complaints with complainants, NIH Investigators (or their designee) must:</i></p> <p><i>V. Address complaints to the extent possible within the investigator’s ability, scope, and authority, as soon as feasible. When necessary, the complaint must be referred to other NIH ICs or offices as appropriate (e.g., the IC Privacy Office, NIH Police, Clinical Center).</i></p> <p>AND</p> <p>Section E.2.a. – <i>In addition to NIH Investigator responsibilities at E.1.a. above, the NIH PI is responsible for:</i></p> <p><i>ii. Providing appropriate support, management, oversight, and assistance regarding complaints reported to study team members, upon PI awareness of the complaint.</i></p> <p>Policy 104 is explicit that NIH investigators (not just NIH PIs) have a role to play in addressing complaints but acknowledges that how complaints are addressed by NIH investigators should be commensurate with their ability, scope and authority. SOP 22 did</p>	<p>Section 22.4.4.A. – <i>Attempts are made to respond to complaints as soon as possible. The complainant is informed that the issue will be addressed further, appropriate, and that a response to him/her will be forthcoming as consistent with Section 22.4.6.</i></p>

<p>not specify this as a responsibility of NIH investigators.</p>	
<p>Section C.8. – <i>The NIH PI will report as follows:</i></p> <ul style="list-style-type: none"> a. <i>Complaints that indicate possible unanticipated problems according to Policy 801 Reporting Research Events.</i> b. <i>Complaints that indicate possible non-compliance according to Policy 802 Noncompliance in Human Subjects Research.</i> c. <i>Unresolved complaints at the time of Continuing Review, consistent with Policy 205</i> d. <i>Requirements for IRB Submissions, when the NIH IRB is the Reviewing IRB.</i> e. <i>Complaints consistent with the external IRB’s reporting requirements, and consistent</i> f. <i>with the terms of the reliance agreement, when a non-NIH IRB is the Reviewing IRB.</i> g. (See also Section E.2.a.IV.) <p>Section C.9. – <i>Regardless of whether the NIH IRB is the reviewing IRB, the PI will notify the OHSRP office of Compliance and Training of unresolved complaints. The OHSRP office of Compliance and Training is available to assist NIH PIs in handling and responding to complaints. (See also Section E.2.a.III.)</i></p> <p>Policy 104 provides more explicit instructions to the NIH PI for which office to report unresolved research-related complaints to within OHSRP.</p>	<p>Section 22.4.4.B. – <i>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.</i></p>
<p>Section C.10. – <i>NIH investigators will cooperate with investigations under this policy. (See also Section E.1.a.VI.)</i></p> <p>Policy 104 is explicit that NIH investigators will cooperate with investigations of subject complaints. SOP 22 did not specify this requirement.</p>	<p>NA</p>
<p>Section C.11. – <i>As necessary, the OHSRP, which includes the office of Compliance and</i></p>	<p>Section 22.4.4.C. – <i>The IRB Chair, IC Compliance Office and OHSRP work collaboratively, with others</i></p>

<p><i>Training, will work with appropriate parties and/or offices, consistent with the nature of the complaint.</i></p> <p><i>a. Matters outside the scope of the Human Research Protection Program (HRPP) will be referred to the appropriate NIH office or IC.</i></p> <p><i>b. Matters within the scope of the HRPP may also be handled by NIH offices other than OHSRP, when appropriate.</i></p> <p>Policy 104 is explicit that OHSRP, including the office of Compliance and Training, will refer to or work collaboratively with, other NIH offices, consistent with the nature of the complaint.</p>	<p><i>as appropriate (e.g., Patient Representative, CC Bioethics Department), to investigate the complaint(s) further.</i></p> <p>Section 22.4.4.D. – Results of an investigation: <i>At the conclusion of an investigation, the IRB Chair, OHSRP, and other involved parties as appropriate, will decide if further action is needed.</i></p>
<p>Section C.12. – Any IRB Chair (including the NIH IRB Executive Chair), the OHSRP Director, or the IRBO Director may immediately suspend the research and/or refer the issue to the IRB to determine whether additional actions are required.</p> <p>Policy 104 specifies that the immediate action may be taken by the IRB Chair or OHSRP leadership to protect the rights, safety and welfare of subjects, if warranted.</p>	<p>NA</p>
<p>Section C.13. – In response to a subject complaint, the IRB may take any or all of the following actions, including, but not limited to:</p> <p><i>a. Modify the research protocol and/or consent(s);</i></p> <p><i>b. Suspend or terminate IRB approval for some or all of the Principal Investigator’s (PI’s) studies;</i></p> <p><i>c. Require additional education for the investigator(s);</i></p> <p><i>d. Inform other IC or NIH Officials to consider additional actions, as appropriate.</i></p> <p>The actions that may be taken by an IRB in response to a research-related complaint are unchanged but are reordered for clarity.</p>	<p>Section 22.4.5. – 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: <i>(sic) Modifying the research protocol and/or consent document(s)</i></p> <p><i>A. Educational measures for the researcher or research team</i></p> <p><i>B. Suspending or terminating IRB approval for some/all of the PIs studies</i></p> <p><i>C. Informing other IC or NIH officials as appropriate.</i></p>