

NIH Policy Manual

3014 - NIH Intramural Human Research Protection Program

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Transmittal Notice

1. **Explanation of Material Transmitted:** Chapters and Appendices within NIH Policy Manual 3014, NIH Human Research Protection Program (HRPP), establish responsibilities and requirements for protecting the rights and safeguarding the welfare of human subjects who participate in research conducted or supported by the Intramural Research Program (IRP) of the National Institutes of Health (NIH). The Office of Human Subjects Research Protections (OHSRP) is the lead office for the NIH HRPP. The OHSRP has updated all applicable policies to adhere to the revised DHHS Common Rule (45 CFR 46). Effective December 2019, the NIH HRPP completed a reorganization and consolidation resulting in the centralization of Institutional Review Board (IRB) operations and transition to a centralized and flexible IRB system. HRPP Policies have been revised to reflect recent regulatory changes, as well as the reorganization and consolidation described above.

NOTE: Please see NIH Policy Manual 3014-100 which describes the structure and components of the NIH HRPP and OHSRP. Taken together with the HRPP Policies, Policy Manual 3014-100 will fully supersede Manual Chapter 3014, dated 5/17/2005. Until the revised policies are fully implemented, the remaining HRPP Standard Operating Procedures (SOPs) remain in effect until superseded. The current policies, SOPs, and supplemental information can be found at:

<https://irbo.nih.gov/confluence/display/ohsrp/Policy>. This policy establishes responsibilities and procedures for protecting the rights and safeguarding the welfare of human subjects who participate in research conducted or supported by the Intramural Research Program (IRP) of the National Institutes of Health (NIH).

2. **Filing Instructions:**

- Remove: NIH Manual Chapter 3014, dated 5/17/2005.
- Insert: NIH Manual Chapter 3014, dated 10/08/2020.

3. PLEASE NOTE:

- For information about this chapter, and its subcomponents please contact the issuing office above.
- For information regarding the NIH Policy Manual, go to <https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx>

HRPP Policy Development Requirements

- [3014-001 – NIH Human Research Protection Program \(HRPP\) Policy Development](#)

3014-100 Series – Institutional Authorities and Requirements

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3014-700 Series – International Research Requirements

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3014-800 Series – Compliance and Research Event Reporting Requirements

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- [3014-802 – Non-Compliance in Human Subjects Research](#)