This document summarizes changes in *Policy 101 Organizational Structure of the OHSRP* (referred to as Policy 101 in this document) that NIH investigators should be aware of, from the SOP(s) mentioned below.

The policy describes the organizational structure and responsibilities of the Office of Human Subjects Protections (OHSRP) within the NIH Intramural Research Program's (IRP) Human Research Protection Program (HRPP).

NIH investigators are responsible for reviewing Policy 101 and complying with the requirements of the policy.

Note: Text from the policy and other policy titles are italicized.

Policy 101 Organizational Structure of the OHSRP partially supersedes:	**Introduction to the NIH Human Research Protection Program**

Applicability of Policy 101 – This policy applies to the:
• **NIH Institutional Official (IO)**
• **NIH Institutional Review Board (IRB) Executive Chair**
• **Staff of the Office of Human Subjects Research Protections (OHSRP) and its offices:**
  ○ **The Office of IRB Operations (IRBO)**
  ○ **The office of Compliance and Training (oC&T)**
  ○ **The office of Policy and Accreditation (oP&A)**	

Policy Requirement	**SOP Requirement**
Section C.1. – *OHSRP promotes the rights, safety and welfare of human subjects and promotes the NIH's research mandate by supporting the IRP. The functions of OHSRP include:* *a. Review exempt and non-exempt human subjects research activities;* *b. Develop NIH policies and procedures consistent with federal regulations and policy;* *c. Organize and conduct educational activities for NIH investigators and the NIH Institutional Review Board (IRB); and* *d. Conduct quality assurance and quality improvement activities to ensure NIH IRB compliance with federal regulations and policies.* OHSRP and its offices still perform many of the functions listed in the Introduction to the NIH HRPP. The Standard Operating Procedure (SOP) went into greater operational detail than Policy 101, which focuses on high-level policy and requirements of OHSRP and its components, taking into consideration the recent	**Section 4.C.1. –** *The NIH OHSRP: Reports directly to the DDIR. It helps IRP investigators, research staff, IRBs and others to understand and comply with the ethical guidelines, regulatory requirements, NIH policies and procedures for research involving human subjects.* **Section 4.C.1.** described the additional functions of OHSRP in more detail.

consolidation of IRB operations and the centralization of the previous 13 NIH IRP IRBs into two IRBs (NIH Intramural IRB and the Research Compliance Review Committee).	
Section E.1.a – *The Institutional Official (IO) is responsible for, ensuring the HRPP, under the auspices of OHSRP, functions effectively and that the NIH IRP provides the resources and support necessary to comply with all requirements to safely and effectively conduct research involving human subjects.* See **Section E.1.a.** for more details about how the NIH IO accomplishes these responsibilities.	**Section 4.A.2. –** *The DDIR is the NIH Institutional Official responsible overall for the NIH HRPP. The DDIR, through written delegated authority from the Director, NIH, is the signatory official for the FWA, filed with the DHHS, OHRP, and is responsible for oversight of human subjects research at NIH.* The roles, authorities and responsibilities of the NIH IO have not changed from the *Introduction to the NIH HRPP*.
Section E.2. – *The Director of OHSRP will work closely with the IO to ensure that resources are adequate to maintain the proper functioning of the NIH HRPP and the functional offices of OHSRP.*	These responsibilities are unchanged from the Introduction to the NIH HRPP.
Section E.3. – *OHSRP's office of Compliance and Training is responsible for:* *a. The ongoing evaluation of the effectiveness of the NIH IRB and the IRBO. It promotes and ensures IRB compliance with human subjects protection regulations and policy. This office helps NIH Investigators and the NIH IRB understand and comply with the ethical guidelines, regulatory requirements, and NIH policies and procedures for research involving human subjects.* *b. Conducting QA/QI reviews of the NIH IRB* *c. Conducting investigations of alleged noncompliance with federal regulations and NIH policy related to protection of human subjects that are/were under the jurisdiction of an NIH IRB or that may involve additional alleged noncompliance within the NIH HRPP.* *d. Assessment, triage, and management of problem reports submitted to OHSRP as well as reporting unanticipated problems, serious and/or continuing noncompliance and IRB suspension or termination of research to federal agencies as required. (See Policies 801 Reporting Research Events and 802 Non-Compliance in Human Subjects Research, respectively.*	The OHSRP oC&T did not previously exist at the NIH. However, these were responsibilities of the OHSRP previously.

e. *Providing NIH investigators and the NIH IRB with programs and educational resources in research ethics and human subject safety, with an emphasis on the proper conduct of research (Policy 103 Education Program). The NIH CC ORSC may also assist with targeted training as needed.*	
Section E.4. – *The OHSRP office of Policy and Accreditation is responsible for:* *a. Writing and maintaining HRPP policy as needed. This office may make other policy decisions and/or hear requests for policy exceptions.* *b. Managing and ensuring the continued accreditation of the NIH HRPP, including all required reporting and preparation for site visits and site visit responses.*	The OHSRP oP&A did not exist previously. However, these were responsibilities of the OHSRP previously.
Section E.5. – *Unless otherwise determined by written agreement, the NIH IRB(s) are responsible for the review and approval of all non-exempt human subjects research conducted by NIH investigators. The NIH IRB ensures the rights, safety and welfare of human subjects are adequately protected and its review of research is conducted in accordance with applicable federal regulations and NIH policies. (See Policy 200 IRB Scope and Authority.)*	These responsibilities were formerly conducted by the NIH IC IRBs.
Section E.6. – *The Office of IRB Operations (IRBO) is responsible for:* *a. Managing and supporting the efficient and effective regulatory oversight of the NIH IRB. (See Policy 203 Support of the IRB Operations, for specific responsibilities, roles and activities of the IRBO.)* *b. Interfacing, as necessary, with other divisions of the NIH IRP that are responsible for the review and approval of research (Policy 100 Human Research Protection Program and Policy 106 Ancillary Reviews).* *c. Maintaining documentation of IRB minutes and making these available upon request to the Director of OHSRP and the IO. (See Policy 206 Maintenance of Records.)* *d. Preparing the minutes of the NIH IRB. When clarifications of the minutes are requested by the IO or the Director of OHSRP, or their designees, these requests will be provided to*	NA. The IRBO did not exist previously. These were responsibilities of the previous NIH IC IRBs. The OHSRP was previously responsible for exemption determinations and reliance agreements.

the IRBO Director and then forwarded to the IRB for additional review and action, as required. *e. Executing cooperative research agreements such as reliance (authorization) agreements and Individual Investigator Agreements (IIA) between the NIH and non-NIH institutions or independent IRBs.*	
Section E.7. – describes the role of the NIH IRB Executive Chair.	NA. This role did not exist previously at the NIH.
Section E.8. – *The CC ORSC, overseen by the Clinical Center CEO, assists the NIH IRP by providing:* *a. Regulatory and compliance support including post-approval monitoring to ensure investigator compliance with the protocol and federal regulations as well as NIH policies.* *b. Guidance to NIH researchers in the areas of protocol navigation and coordination, quality assurance, auditing and monitoring, support for FDA regulated studies, and centralized facility oversight.* *c. QA/QI of the NIH RCRC (see C.1.d. above.)*	NA. This role did not exist previously at the NIH.