General and Structural Changes to the NIH Human Research Protection Program Policies

Why the Policy Structure was Changed

The NIH Intramural Research Program (IRP) had policy, regulatory and operational reasons for updating and changing the NIH Human Research Protection Program (HRPP) policies. Some of the major drivers for revisions to the HRPP policies include:

1. The implementation of the NIH Single IRB Policy, effective January 25, 2018, which requires a single Institutional Review Board (IRB) for multi-site research.
2. The implementation of the 21st Century Cures Act, which provides additional privacy protections by prohibiting disclosure of identifiable sensitive information collected from human subjects. This resulted in the changes for requirements for Certificates of Confidentiality issued by the NIH.
3. The implementation of the revised Common Rule (45 CFR 46), which became partially effective on January 19, 2019, and fully effective on January 20, 2020, with the implementation of the cooperative research provisions.
4. At the recommendation of the Advisory Committee to the DDIR, the consolidation of the NIH IC-based IRBs into a centrally operated single NIH Intramural IRB for review of NIH research and the Research Compliance Review Committee for review of serious or continuing non-compliance.
5. Lastly, the centralization and streamlining of IRB operations into the Office of IRB Operations (IRBO) and the expansion of the Office of Human Subjects Research Protections (OHSRP) required a major reorganization and new HRPP leadership.

How the HRPP Policies Changed Structurally

From HRPP SOP to HRPP Policy

The biggest structural change to the entire set HRPP policies is the transition from a Standard Operating Procedure (SOP) structure that includes both policy and procedural requirements, to a policy structure, that focuses on policy and only required roles or procedures. Because only required procedures are included in the policies, NIH Investigators should also review Guidelines that accompany certain policies to learn more about the NIH Institutional Review Board (IRB) procedures.

Policy Organization

The other major structural change is how the policies are ordered and numbered. The organization of the HRPP policies are grouped as follows:

a. 100 Series – Institutional Authorities and Requirements
b. 200 Series – IRB Authorities and Requirements
c. 300 Series – Investigator Responsibilities
d. 400 Series – Regulatory Protections for Vulnerable Populations
e. 500 Series – FDA Requirements for Human Subjects Research
f. 600 Series – Reserved
g. 700 Series – International Research Requirements

NIH Investigators should note the following points regarding the organization of the policies listed above. The majority of policies contain responsibilities for NIH investigators and the NIH

IRB. Therefore, investigators should review all policies and become familiar with the applicable requirements and responsibilities within.

Policy structure

Each policy contains the same sections, in the same order:

A. Purpose
B. Scope
C. Policy
D. Definitions (see more below)
E. Responsibilities
F. References
G. Appendices
H. Revision History
I. Supersedes

For example, it is important to pay attention to the new Scope section in each policy to see who the policy applies to (e.g., many policies now include non-NIH investigators in the Scope section). This addition shows the broad impact of single IRB requirements for multi-site research is on the HRPP policies.

There will be one further structural change to the policies due to the establishment of the OHSRP policy glossary. The OHSRP has established a central glossary to support the HRPP policies. This major effort is to standardize terms across policies to the greatest extent possible. This glossary is a living tool, permitting it to be updated over time without adversely impacting the policies. However, once the glossary is published, defined policy terms will link to this glossary, and the definition sections will be removed from the policy documents. This will shift the policy sections into their final order as follows:

A. Purpose
B. Scope
C. Policy
D. Responsibilities
E. References
F. Appendices
G. Revision History
H. Supersedes

Implementation of the HRPP Policies

Upon implementation, each HRPP policy will fully supersede the applicable HRPP SOP, policy requirement, or required procedures. The HRPP policies will be published and maintained by OMA in the NIH Policy Manual System. They will be readily available from the OHSRP website on the Policy and Accreditation webpages. As the SOPs are superseded, they will be placed in a policy archive and will be available for historical reference and maintained consistent with NIH records management requirements.