HRPP POLICY APPROVAL & IMPLEMENTATION

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Policy Number: 001

SOP Title: NIH Human Research Protection Program (HRPP) Policy Development

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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NIH Intramural Research Program		
Office of Human Subjects Research Protections	**Effective Date: 07/28/2020**	
NIH Human Research Protection Program (HRPP) Policy Development	**Policy 001**	**Version: 1.0**

POLICY

A. PURPOSE

1. The purpose of this policy is to establish the requirements for the development, maintenance, and accessioning of Intramural Research Program (IRP) policies for the conduct of human subjects research.

B. SCOPE

1. This policy applies to:
   a. The Deputy Director for Intramural Research (DDIR);
   b. The NIH Office of Human Subjects Research Protections (OHSRP) and its offices;
   c. The Office of Management Assessment (OMA); and
   d. All NIH Institutes and Centers (ICs) that conduct human subjects research under the IRP.

C. POLICY

1. NIH HRPP policy will:
   a. Be issued by the NIH Office of the Director (OD), Office of Intramural Research (OIR), OHSRP, which has the primary authority at NIH for writing and implementing NIH Human Research Protection Program (HRPP) policies.
   b. Be subject to oversight by the NIH Deputy Director for Intramural Research (DDIR).
   c. Be approved by the Deputy Director for Intramural Research (DDIR), as head of the NIH IRP.
   d. Be applied uniformly by OHSRP to all NIH ICs that operate under the NIH IRP.
   e. Be developed and revised by the OHSRP office of Policy and Accreditation, as appropriate and necessary, in accordance with the needs of the NIH HRPP, and consistent with federal law, regulation and policy, including NIH policy, and accreditation standards. Such policies will describe:
      I. The policy requirements for the NIH HRPP; and
      II. The required organizational and staff responsibilities.

f. Be submitted to the NIH Office of Management Assessment (OMA) by the OHSRP office of Policy and Accreditation, for publication in the NIH Policy Manual System. In order to be published and maintained by OMA in the NIH Policy Manual System, HRPP policies will be:

   I. Drafted in the format established between OMA and OHSRP;

   II. Prepared in accordance with NIH Policy Manual #1710 - Publishing and Maintaining Policies;

   III. Compliant with 29 U.S.C § 794 (d), Section 508 of the Rehabilitation Act of 1973, prior to posting on an NIH website, to a shared document directory or distributed in electronic format; and

   IV. Accessible from the NIH Policy Manual website (https://policymanual.nih.gov/chapter/browse/byfunctionalseries/8).

g. Be published and retained by the NIH Office of Management Assessment (OMA). The HRPP policies and the manual chapter will be developed by OHSRP in accordance with:

   I. The NIH Policy Manual #1710 - Publishing and Maintaining Policies;

   II. 29 U.S.C § 794 (d), Section 508 of the Rehabilitation Act of 1973; and

   III. The NIH Records Management Schedule.

h. Be communicated by the OHSRP to the NIH IRP community, upon implementation, and be available on the OHSRP Office of IRB Operations website (https://irbo.nih.gov/confluence/display/IRBO/OHSRP), both internally and externally to the NIH.

2. The authority for development of IRP HRPP policy: IRP HRPP policy may only be authorized by the DDIR through the OHSRP Director. No IC-level HRPP policies are authorized to apply to the broader IRP HRPP.

   a. As such, the NIH ICs do not have the authority to write, amend, or supersede NIH HRPP policy.

3. When there are any policy conflicts between HRPP policy and NIH policy, the OHSRP Director will inform the NIH DDIR of the policy conflict, the reason(s), and the proposed course of action.

   a. The DDIR must concur with the proposed course of action, prior to approving the final policy.

4. The organization of the HRPP policies will be 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 and Data and Safety Monitoring
   f. 600 Series – Reserved
   g. 700 Series – International Research Requirements
   h. 800 Series – Compliance and Research Event Reporting Requirements.
5. The HRPP policies will undergo formal review by the OHSRP office of Policy and Accreditation at a minimum of every three (3) years for compliance with law, regulation and policy, including NIH policy, accreditation standards and operational needs. The HRPP policies will be updated at that time, as applicable.
   a. However, these policies may be reviewed and revised more frequently at the discretion of the OHSRP Director.
6. Agency-wide policy documents are considered permanent records. Therefore, HRPP policies will be retained and disposed by of OMA and OHSRP under the authority of the NIH Records Management Schedule.
7. Access to HRPP records will be determined by the OHSRP Director. This determination will be based on documentation of a legitimate need and made in accordance with applicable federal law, regulation, and policy, including NIH policy. For more information, see *Policy 206 Maintenance of Records*.

D. DEFINITIONS

1. The NIH HRPP Glossary which contains definitions of all HRPP terms is located at [LINK HERE].

E. RESPONSIBILITIES

1. OHSRP Director responsibilities

a. The OHSRP Director is responsible for:

I. Acting as the primary authority at NIH for developing, and implementing NIH HRPP policies;

II. Ensuring that NIH HRPP policies comply and conform with federal law, regulation and policy, including NIH policy, and accreditation standards;

III. Ensuring that NIH HRPP policy drafts are disseminated for review and comment by HHS and NIH policy offices, as applicable;

IV. Ensuring that final approved NIH HRPP policy is disseminated to the appropriate IC communities upon implementation;

V. Determining when new NIH HRPP policies should be developed.

2. The OHSRP office of Policy and Accreditation Responsibilities

a. The OHSRP office of Policy and Accreditation is responsible for:

I. Ensuring that HRPP policies and the corresponding manual chapter are developed consistent with the agreed upon format established between the OHSRP and OMA. (NIH Policy Manual #1710 - Publishing and Maintaining Policies)

II. Ensuring that approved policies are processed through OMA for publication in the NIH Manual System. Such policies must meet the following criteria:

i. The policy is not targeted solely toward a restricted audience (e.g., only NIH federal employees);

ii. The policy does not contain sensitive information that should not be publicly accessible; and

iii. The policy is understandable by a majority of the general NIH population, e.g., not overly technical.

III. Consulting and vetting NIH HRPP policies with NIH policy offices (e.g. the NIH Senior Official for Privacy, the Office of Human Resources (OHR)), as appropriate.

IV. Advising the OHSRP Director of any conflicts which require adjudication by the DDIR.

V. Clearing HRPP policies with the HHS Office of General Counsel to ensure that they are legally sufficient.

VI. Informing the NIH IRP community when approved policies are implemented.

VII. Coordinating with the OHSRP office of Compliance and Training, for any educational materials or sessions needed to educate the NIH IRP community about new policy requirements.

VIII. Ensuring that all published policies are in compliance with HHS 508 requirements.

IX. Ensuring that all links to implemented HRPP policies on the IRBO website must directly link to the NIH Policy Manual System.

i. All policy versions developed for this series of policies (see *C.2.* above) must be archived by OMA and accessible according to *Policy 206 Maintenance of Records*.

ii. All HRPP Standard Operating Procedure (SOPs) previously developed by OHSRP must be maintained by OHSRP and made accessible according to *Policy 206 Maintenance of Records*.

X. Reviewing internal controls relative to this policy.

XI. Conducting a formal review of HRPP policies not less than once every three (3) years. Such a review must identify needed policy revisions, if any. This does not preclude an earlier review and revision of HRPP policies as needed, and when directed by the OHSRP Director.

3. Deputy Director for Intramural Research Responsibilities

a. The DDIR must:

I. Provide oversight and approve NIH HRPP policies; and

II. Adjudicate disagreements on access to NIH HRPP policy records.

b. When there is an identified policy conflict, the DDIR must concur with the proposed course of action, prior to approving the final policy.

4. Institute and Center Responsibilities

a. Institutes and Centers must comply with NIH HRPP policy in the conduct of human subjects research.

b. Institutes and Centers may not write, amend or supersede NIH HRPP policy.

5. **Office of Management Assessment Responsibilities**

   a. The NIH Office of Management Assessment (OMA) must publish and retain HRPP policies and the manual chapter developed by OHSRP in accordance with:

      I. The NIH Policy Manual #1710 - Publishing and Maintaining Policies;

      II. 29 U.S.C § 794 (d), Section 508 of the Rehabilitation Act of 1973; and

      III. The NIH Records Management Schedule.

   b. OMA must make implemented policies available internally and externally to the NIH.

      I. OMA must provide for determination by the OHSRP Director, any request to access draft NIH HRPP policies.

   c. The formal review of NIH HRPP policies by the OHSRP office of Policy and Accreditation must be monitored and tracked by the OMA (see *E.2.a.XI.* above).

F. REFERENCES

1. **Federal Laws and Regulation:**

   29 U.S.C § 794 (d), Section 508 of the Rehabilitation Act of 1973, as amended

2. **NIH Policy:**
   NIH Manual Chapters
   NIH Policy Manual #1710 - Publishing and Maintaining Policies
   NIH Human Research Protection Program (HRPP) Policies NIH Records Management Schedule
   Policy 206 Maintenance of Records

3. **Guidance:** NA

G. APPENDICES: NA

H. REVISION HISTORY: NA

I. SUPERSEDES DATE: 07/28/2020

Introduction to the NIH Human Research Protection Program