NIH Policy Manual

3014-100 - NIH Intramural Research Program's Human Research Protection Program

Issuing Office: OD/OIR/OHSRP **Phone:** (301) 402-3713

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Transmittal Notice

1. **Explanation of Material Transmitted:** This Manual Chapter describes the NIH Human Research Protection Program (HRPP) of the NIH Intramural Research Program (IRP). The Office of Human Subjects Research Protections(OHSRP) is the lead office for the NIH HRPP. This manual chapter describes the structure and components of the NIH HRPP and the OHSRP. This chapter has been revised to include coverage of Visiting Fellows (VFs) under the NIH FWA without a separate Agreement, and to include VFs in the definition of "NIH Investigator." This manual chapter taken together with the HRPP Policies, will fully supersede Manual Chapter 3014 and the Introduction to the NIH Human Research Protection Program. Effective December 2019, the NIH HRPP completed a reorganization and consolidation resulting in the centralization of IRB operations and transition to a centralized and flexible IRB system. **Partial Revision 8/10/2021**: This revision adds overarching statements regarding NIH inclusion policies for research involving human subjects, and for equity, diversity and inclusion. **Partial Revision 11/7/2022**: This revision distinguishes coverage under the NIH Federalwide Assurance (FWA) between Intergovernmental Personnel Act (IPA) appointees and detailees. This revision also specifies the requirement for a continuity plan in case of an emergency that impacts the NIH IRP HRPP and the rights, safety or welfare of its research subjects, for the OHSRP and the NIH IRB.

2. **Filing Instructions:**

- **Insert:** NIH Manual Chapter 3014-100, dated 11/19/2020, **Partial Revision Date:** 11/07/2022
- **Implementation Date:** 11/24/2020

3. **PLEASE NOTE:**

- The current policies can also be found at: https://irbo.nih.gov/confluence/display/ohsrp/Policy.
- For information on content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Compliance Management, OMA, on (301) 496-4606, policymanual@nih.gov or enter this URL:

https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx

A. Purpose

1. Describes the Human Research Protection Program (HRPP) of the NIH Intramural Research Program (IRP), including its components and their functions. The purpose of the NIH HRPP is to help investigators conducting human subjects research to understand their obligations and to protect the rights, safety, and welfare of human subjects.
2. Describes select laws, regulations and policies applicable to human subjects research activities conducted by the NIH IRP.
3. Describes coverage of investigators under the NIH Federalwide Assurance (FWA).
4. Describes the delegated authorities for the management of the NIH HRPP.

B. Scope

1. This policy applies to;

    a. NIH investigators;
    b. Non-NIH investigators when the NIH IRB is the Reviewing IRB;
    c. The NIH IRB;
    d. The NIH Institutional Official (IO), who is also the Deputy Director for Intramural Research (DDIR);
    e. Institute/Center (IC) Directors, Scientific Directors (SD) and Clinical Directors (CD); and
    f. The Office of Human Subjects Research Protections (OHSRP), including its offices and staff.

C. Policy

1. The policies of the NIH HRPP are grounded in the foundational ethical principles embodied in the Nuremberg Code of 1947 and in particular, the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report) issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The Belmont Report principles of *respect for persons, beneficence* and *justice* are the basis for the ethical conduct of human subjects research, and are the foundation for the federal regulations for the Protection of Human Subjects (45 CFR 46, HHS Common Rule).
2. The OHSRP is responsible for the development, maintenance and publication of NIH HRPP policies. These policies are intended to aid NIH investigators, the NIH IRB, and others to comply with these ethical principles for the conduct of human subjects research on behalf of the NIH IRP.
3. Only the NIH Institutional Official (IO), or designee, has the authority to determine which investigators are covered by the NIH FWA with no written agreement, and which investigators will be covered under the NIH FWA with a written agreement.

a. The OHSRP Director has the authority to determine when an authorization agreement (reliance agreement) is required, if coverage under the NIH FWA is not appropriate.
b. Only the IO, or designee, may execute a reliance agreement, or an FWA coverage agreement on behalf of the NIH.

4. When conducting human subjects research, NIH investigators are expected to adhere to the highest ethical standards, and to comply with federal law, regulation and policy, including NIH policy.
5. When reviewing human subjects research, the NIH IRB is expected to apply federal law, regulation and policy, including NIH policy, as applicable.

D. Definitions

OHSRP has developed a comprehensive glossary of definitions that describe the terms listed below. The glossary can be found at the following link: NIH IRP HRPP Policy Glossary

Note: There *may be more than one definition per term*, so please review terms carefully to make sure they match the terms listed below. Qualified terms are indicated with a parenthetical qualification. When reviewing a definition, be sure that you are reviewing the appropriate definition that links to this policy. To further assist the reader, each term in the glossary cites the relevant policy number(s) indicating where the term is utilized.

Definitions demarcated with (Pre-2018 Common Rule definition) apply to research approved by an IRB (or deemed to be exempt, or for which no IRB review was required under the regulations) prior to the effective date of the 2018 Common Rule (January 21, 2019).

Definitions demarcated with (2018 Common Rule definition) apply to all research approved by an IRB (or deemed to be exempt, or for which no IRB review was required under the regulations) on or after January 21, 2019, and to research transitioned to the 2018 requirements in accordance with HRPP policy.

1. Federal Employee (For the purposes of Human Research Protection Program Policies)
2. Human Subject (2018 Common Rule definition)
3. Human Subject (Pre-2018 Common Rule definition)
4. NIH Human Research Protection Program (HRPP)
5. NIH Intramural Research Program (IRP)
6. NIH Investigator
7. Research (2018 Definition)
8. Research (Pre-2018 definition)

E. Responsibilities and Requirements

1. **Compliance with Law, Regulation and Policy:**

a. All human subjects research conducted by NIH investigators, or by non-NIH investigators under the NIH FWA, or when the NIH IRB is the Reviewing IRB, will be performed in accordance with applicable federal law, regulation and policy, including NIH policy. These include, but are not limited to, the following:

   I. All NIH IRP research subject to the Department of Health and Human Services (HHS) Common Rule published at 45 CFR 46 Subpart A and all other subparts of 45 CFR 46, and its revisions:

      i. Research subject to the pre-2018 Common Rule requirements: Research that was, prior to January 21, 2019, initially approved by an IRB, or for which IRB review was waived, or was determined to be exempt, will follow the requirements of the pre-2018 Common Rule, unless the IRB has documented that the research will be transitioned to the 2018 Common Rule requirements.
      ii. Research subject to the 2018 Common Rule requirements: Research approved by an IRB, or for which IRB review was waived, or determined to be exempt on or after January 21, 2019, will comply with the 2018 Common Rule requirements.

   II. When applicable, NIH IRP research is also subject to the Food and Drug Administration (FDA) regulations such as those published at 21 CFR parts 50, 56, 312, 600, 812 and 814. (See also Policy *3014-500 Research Involving Drugs, Biological, and Nutritional Products*, Policy *3014-501 Research Involving FDA Regulated Devices* and Policy *3014-502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices (Test Articles)*);
   III. In its human subjects research and related record-keeping activities, NIH follows the applicable requirements of the Privacy Act of 1974, 5 USC 552a (Privacy Act), the HHS Privacy Regulations, 45 CFR 5b, and HHS and NIH policy. (See *Policy 3014-107 Privacy and Confidentiality* *and* *Policy 3014-206 Maintenance of Records*);
   IV. To further protect the privacy of research participants enrolled in research conducted by NIH investigators, or in collaboration with NIH investigators, the NIH IRP has been issued a Certificate of Confidentiality for applicable research pursuant to Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)). (See the NIH Policy for Issuing Certificates of Confidentiality, and also *Policy 3014-107 Privacy and Confidentiality*.)

      i. In addition, under Section 301(f) of the Public Health Service Act (42 U.S.C. 241(f)), the Secretary may exempt from disclosure under the Freedom of Information Act (FOIA) biomedical information about a research participant that is gathered or used during the course of biomedical research if, A) the participant is identified; or B) there

is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of a participant. (See *Policy 3014-107 Privacy and Confidentiality*).

V. For its conflict of interest requirements, the NIH is guided by applicable criminal statutes (18 USC §§ 203, 205, and 207-209), government-wide ethical conduct regulations (5 CFR Parts 2634-2641, and, as applicable 5 CFR §5501.110) , the Supplemental Standards of Ethical Conduct for Employees of the DHHS (5 CFR Parts 5501-5502), Federal Technology Transfer Act of 1986, 15 USC §1501-1634, the Bayh-Dole Act (35 USC §200 et al), and Sections 231, 405(b)(1)(H), and 497 of the Public Health Service (PHS) Act, as amended (42 U.S.C. §§238, 284(b)(1)(H), and 289f). (See also *Policy 3014-102 Institutional and Investigator Conflict of Interest*.);

VI. NIH inclusion policies for research involving human subjects require that IRP clinical research not exclude individuals of any particular sex/gender, race, ethnicity, or age, unless there is a sound scientific rationale. (For more information see Inclusion Policies for Research Involving Humans Subjects.);

VII. The policies of the NIH Human Research Protection Program (HRPP);

VIII. The NIH Policy Manual;

IX. The Guidelines for the Conduct of Research in the IRP at the NIH;

X. The Guide to Training and Mentoring in the Intramural Research Program;

XI. The Clinical Center (CC) Medical Administrative Series Policies, as applicable;

XII. In addition to protecting the rights, safety and welfare of human subjects participating in research conducted by NIH investigators, the IRP promotes the precepts of equity, diversity and inclusion by all members of the Human Research Protection Program consistent with federal requirements and NIH policy (e.g., it is expected that NIH staff will not discriminate on the basis of race, color, religion, sex, sexual orientation, or gender identity, national origin, age (40 or older), disability or genetic information). (For more information see the Office of Equity, Diversity and Inclusion.); and

XIII. The NIH IRP HRPP complies with the established Continuity of Operations Plans (COOPs) of the NIH Office of Intramural Research (OIR). OHSRP maintains the HRPP COOP consistent with law, regulation and policy to ensure the continuity of operations of the NIH IRB and critical functions of the OHSRP to protect the rights, safety and welfare of human subjects participating in NIH IRP research during and following an emergency. As such the OHSRP and IRB operations have been deemed a Mission Essential Function (MEF) of the NIH OIR. (For more information, see Manual Chapters 3014-101, 1428, 1429 and 1430.)

2. **Federalwide Assurance**

a. The NIH maintains a Federalwide Assurance (FWA), FWA00005897, that certifies the NIH will comply with the HHS regulations for the protection of human research subjects (45 CFR 46) for all research conducted or supported by the NIH IRP. The NIH is considered to be "engaged" in human subjects research (*Policy 3014-200 NIH IRB Scope and Authority*) as determined by OHSRP, taking into consideration 45 CFR 46 and applicable HHS Office for Human Research Protections (OHRP) guidance.
b. The FWA also defines other responsibilities of the institution including: the provision of sufficient institutional support for the HRPP; the authority of NIH's IRB to approve, require modification in, or disapprove human subjects research; the existence of written procedures describing the NIH IRB's process for the review of research; and the reporting to OHRP of certain events (*Policy 3014-801 Reporting Research Events* and *Policy 3014-802 Non-Compliance in Human Subjects Research*).
c. The NIH Institutional Official, or designee, has the authority to determine which investigators are covered by the NIH FWA. Coverage under the NIH FWA is as follows:

I. NIH investigators are covered with no additional agreement. This includes NIH federal employees (intramural or extramural), Intergovernmental Personnel Act (IPA) appointees,Special Volunteers (SVs), Visiting Fellows (VFs), Intramural Research Training Awardess (IRTAs) and Cancer Research Training Awardees (CRTAs). (Note that for some NIH investigators other NIH policies also apply, for more information see 2300-308-1 -Guest Researcher/Special Volunteer Programs, 2300-320-7 Intramural Research Training Award (IRTA) Program Automated Fellowship Payment System, , 2300-308-4 - NIH On-Site Research Collaborator Policy and 2300-320-3 NIH Intramural Visiting Fellows Program (VFP) Policies.)

II. Unless otherwise specified by the terms of the contract, NIH contractors are only covered by the NIH FWA without an additional written agreement, if:

i. The contractor is working at an NIH site with an NIH employee; or
ii. It has been determined by the OHSRP Director or designee, in writing, that the contractor's activities are covered by the NIH FWA.

III. All other investigators (e.g., external collaborators, guest researchers, including IPA detailees, rotating fellows and rotating students) conducting human subjects research, who are not described in Section *E.2.c.I.* above, are not covered under the NIH FWA unless through a written agreement. (For more information see *Policies 3014-105 IRB Reliance* and *3014-109 Coverage Under the NIH Federalwide Assurance*, 2300-308-1 - Guest Researcher/Special Volunteer Programs, and 2300-320-3 NIH Intramural

Visiting Fellows Program (VFP) Policies.)

3. **Intra-Institutional Relationships within NIH IRP**

The NIH HRPP is made up of the NIH IC intramural programs (NIH IRP), this includes, NIH officials, the OHSRP and its offices, the NIH IRB, NIH investigators, and NIH staff who support human subjects research activities.

a. Deputy Director for Intramural Research (DDIR) and Deputy Director for Intramural Clinical Research (DDICR) – The NIH HRPP is overseen by the DDIR located in the Office of the Director (OD). The DDIR is assisted by the DDICR. Together, they share overall responsibility for the NIH HRPP. Their roles and responsibilities are described below:

    I. The DDIR – The DDIR through written delegated authority from the NIH Director:

        i. Is responsible for oversight of human subjects research at the NIH.
        ii. Is the Signatory Official for all policies that apply to the NIH HRPP.
        iii. Has the authority for day-to-day oversight of the NIH HRPP. This authority has been further delegated by the DDIR to the OHSRP Director. The OHSRP Director is the designated Human Protections Administrator (HPA) for the NIH FWA.

    II. In addition, the DDIR is the Institutional Official (IO), and is the signatory official for the FWA which is filed with the HHS OHRP. The DDIR is the overall official responsible for the NIH HRPP.
    III. The DDICR – The DDICR assists the DDIR to oversee the IRP clinical research program and advises the DDIR.

b. Institute/Center (IC) Leadership – Each IC that performs IRP clinical research is administered by the Institute Director, Scientific Director (SD), and Clinical Director (CD):

    I. The IC Directors have overall responsibility for their IC's intramural activities, but generally delegate authority to their IC's SDs and CDs.
    II. The IC SD reports to the IC Director, and is responsible for the overall direction of, and allocation of, resources for the laboratory and clinical research programs carried out within their IC's intramural laboratories and branches, and in the CC research complex.
    III. The IC CD reports to the IC Director or IC SD and is responsible specifically for oversight and conduct of the clinical research program carried out in the IC's intramural clinical branches, and the CC research complex.

c. Office of Human Subjects Research Protections – The OHSRP is an office within the IRP, located in the OD, and reports to the DDIR. The OHSRP performs human subjects

research oversight for the NIH HRPP. OHSRP and its offices carry out the day-to-day operations, and compliance support for NIH IRP human subjects research activities and the NIH IRB. OHSRP is responsible for the development and maintenance of NIH HRPP policies. OHSRP also maintains accreditation of the NIH HRPP. OHSRP maintains the NIH OIR HRPP continuity of operations plan (COOP) and Mission Essential Function (MEF). OHSRP provides NIH investigators, the NIH IRB, and non-NIH investigators (when the NIH IRB is the Reviewing IRB) with information to enable them to understand and comply with the ethical principles, regulatory requirements and policies for conducting human subjects research. OHSRP is comprised of the following components:

I. Office of Compliance and Training
II. Office of IRB Operations (IRBO)
III. Office of Policy
IV. IRB Executive Chair

Note: For a description of the functions of OHSRP roles and offices, see *Policy 3014-101 – Organizational Structure of the OHSRP.*

d. NIH Institutional Review Board (IRB) – The NIH IRB reviews and approves exempt and non-exempt human subjects research conducted by the IRP, in accordance with the regulatory mandates to protect the rights, safety and welfare of human subjects.
e. Office of Research Support and Compliance (ORSC) – The ORSC is located within the NIH Clinical Center (CC) and reports to the CEO of the NIH CC. ORSC ensures the quality and integrity of clinical research and product manufacturing/compounding conducted at the NIH, by providing regulatory and compliance support and guidance for all NIH investigators in the areas of protocol navigation and coordination, quality assurance, auditing and monitoring, support for FDA regulated studies, and centralized facility oversight.
f. The OHSRP also works in a coordinated effort with other offices within the NIH:

I. The HHS Office of the General Counsel, Public Health Division, NIH Branch (OGC) - OGC provides legal consultation and counsel on policy development as well as on the laws, regulations, and policies associated with research activities conducted by the NIH Intramural Research Program.
II. The NIH Privacy Program – The NIH is subject to the Privacy Act of 1974 (5 USC 552a). The NIH Privacy Program establishes policies for ensuring that information collected, and records stored by the NIH, comply with Privacy Act requirements. In addition, the NIH Privacy Program is responsible for managing and mitigating privacy breaches within the NIH. It coordinates with IC Privacy Officers across the NIH to prevent and manage situations where persons other than authorized users have access, or potential access, to personally identifiable information (PII).

i. The NIH Privacy Program and the IC Privacy Coordinators are responsible for institutional compliance with the Privacy Act of 1974. When a non-

routine Privacy Act issue arises, NIH IRB staff may consult with the IC Privacy Officer regarding appropriate procedures.

III. The NIH Ethics Program – The NIH Ethics Program assists NIH staff to meet the requirements of the statutes and regulations governing behavior of employees of the Federal Government. The Program consists of a central NIH Ethics Office (NEO) located organizationally within the NIH Office of the Director (OD) and an ethics office in each IC, managed by a Deputy Ethics Counselor and staffed with one or more Ethics Coordinators/Specialists.

IV. The Office of Technology Transfer (OTT) – This office is located in the Office of the Director (OD). OTT evaluates, protects, markets, licenses, monitors, and manages the wide range of NIH discoveries, inventions, and other intellectual property as mandated by the Federal Technology Transfer Act and related legislation. Each IC maintains a Technology Transfer Office staffed by Technology Development Coordinators who provide advice and guidance to investigators and establish agreements as applicable.

V. Division of Emergency Management (DEM) – This office is the principal emergency planning resource for the NIH and is responsible for coordinating all NIH resources essential to emergency planning and preparedness functions. This includes serving as the NIH Emergency Coordinator with Montgomery County emergency preparedness organizations, state offices, and national emergency response organizations under the leadership of the Department of Health and Human Services (DHHS) and the Federal Emergency Management Agency (FEMA). OHSRP coordinates its continuity of operations plan (COOP) with DEM.

4. **Other Institutional Resources:**

a. NIH Clinical Center (CC) - The NIH Clinical Center (CC), consisting of the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Clinical Research Center, provides inpatient and outpatient hospital facilities for the IRP's biomedical and behavioral research. The CC contributes to the operations of the HRPP and is where the NIH IRP performs most of its research involving human participants. Within the CC, each IC with an intramural clinical research program participates in the usage and cost-sharing of the CC. Each IC provides certain infrastructure (e.g., laboratories, physical plant, space and personnel such as physicians, nurses, and support staff)) to sustain its clinical research program or facilitate other ICs' programs. Some CC leadership, staff, departments, and committees that contribute to the NIH HRPP include, but are not limited to:

I. Chief Executive Officer (CEO) – Oversees the day-to-day operations and management of the research hospital on NIH's Bethesda campus. The CEO guides the overall performance of the Clinical Center, focusing on setting a high bar for patient safety and quality of care, including the development of hospital operations policies.

II. The Deputy Director for Clinical Care – Is responsible for clinical quality and clinical performance improvement.
III. NIH Associate Director for Clinical Research and Chief Scientific Officer – Establishes scientific review policy in the IRP.
IV. The Office of Protocol Services (OPS) – Maintains the protocol data repository for the IRP and provides data in order to update systems such as Clinicaltrials.gov and internal CC systems.
V. ORSC – see Section E.3.e. above for description of this office.
VI. Department of Bioethics – This department conducts research in bioethics and organizes Ethics Grand Rounds. It also provides consult services to help research subjects, their families, investigators and other CC staff in the resolution of clinical ethical issues. It provides advice, upon request, to investigators in the development of protocols and informed consent documents. Assessment of cognitive impairment of subjects may be conducted by the Ability to Consent Assessment Team (ACAT), which is comprised of members of the Department of Bioethics as well as the NIMH Human Subjects Protection Unit (HSPU).
VII. CC Patient Representative – The Patient Representative serves as a link between the patient and the hospital. The Patient Representative makes every effort to assure that patients are informed of their rights and responsibilities and that they understand what the Clinical Center is, what it can offer, and how it operates. The Patient Representative also assists in resolving patient complaints and concerns, in conjunction with OHSRP, as applicable.
VIII. Office of Patient Recruitment (OPR) – OPR provides information to the public about research being conducted at the NIH CC. OPR also provides information to potential subjects about eligibility for participation on NIH protocols and provides information about potentially eligible subjects to NIH investigators.

i. Clinical Research Volunteer Program – This office is located in OPR. This office provides information to interested persons about protocols that enroll healthy volunteers.

5. **Advisory Committees – The following committees serve in an advisory capacity to the DDIR:**

a. The Board of Scientific Directors (BSD) – The BSD is chaired by the DDIR and is constituted of the NIH ICs' Scientific Directors. The BSD develops, reviews, and recommends policies affecting the intramural research programs of the NIH ICs to the DDIR. Recommendations may require further approvals by higher-level authorities, such as the NIH IC Directors, or the NIH Director. The SDs are usually joined once a month by the CDs in a regular meeting.

b. Medical Executive Committee (MEC) – The MEC is advisory to the CEO of the CC, and develops and approves policies governing standards of medical care in the CC. It is mainly comprised of the CDs whose ICs conduct human subjects research at the CC, and senior members of certain CC medical departments, services and branches. When necessary, the MEC also advises the DDIR on policy and matters pertaining to clinical research conducted in the CC.

6. **Other committees and groups at the NIH:**

a. CC Patient Advisory Group – This group consists of research participant representatives from the ICs that admit research subjects to the CC. Members of this group serve as informal advisors to the CC CEO and CC leadership regarding issues of concerns to patients. This group is open to membership by any patients or family members of patients at the NIH CC. This group meets twice a year.
b. Trans-NIH Bioethics Advisory Committee (TNBC) – The TNBC coordinates policy development among the Institutes and the Office of the Director (OD), NIH, in the areas of ethical, legal and social implications of NIH-funded research, including the research of the IRP. The TNBC meets monthly, or as needed, and is chaired by the Associate Director for Science Policy, OD. It is composed of senior staff members designated by the IC Directors. Relevant OD offices, including OHSRP, are also represented.

7. **Ancillary Review Committees:**

a. In addition to the NIH IRB, other institutional committees also provide oversight over NIH IRP human subjects research, as applicable. (See *Policy 3014-106 Ancillary Reviews* for more information.) These committees include, but are not limited to:

I. IC Scientific Review Committees;
II. Deputy Ethic Counselors (DEC);
III. Radiation Safety Committee (RSC);
IV. Radioactive Drug Research Committee (RDRC);
V. Recombinant DNA Advisory Committee (RAC);
VI. Institutional Biosafety Committee (IBC); and
VII. CRADA Review Subcommittee

F. References

1.Federal Regulations and Resources

FDA 21 CFR parts 50, 56, 312, 600, 812, 814 and 361.1

HHS 45 CFR 46

The Belmont Report

Nuremberg Code of 1947

Privacy Act of 1974 (5 USC 552a)

2.NIH Policies

NIH Ethics Policies

NIH Policy Manual

Medical Administrative Series Policies

Guidelines for the Conduct of Research in the IRP at the NIH

Guide to Training and Mentoring in the Intramural Research Program

Inclusion Policies for Research Involving Humans Subjects

The policies of the NIH Human Research Protection Program (HRPP)

NIH Policy for Issuing Certificates of Confidentiality

Policy for Scientific Review of Clinical Protocols Utilizing the NIH Intramural Program's Clinical Center

Policy 3014-101 Organizational Structure of OHSRP

Policy 3014-102 Institutional and Investigator Conflict of Interest

Policy 3014-105 IRB Reliance

Policy 3014-106 Ancillary Reviews

Policy 3014-107 Privacy and Confidentiality

Policy 3014-109 Coverage Under the NIH Federalwide Assurance

Policy 3014-200 NIH IRB Scope and Authority

Policy 3014-206 Maintenance of Records

Policy 3014-500 Research Involving Drugs, Biological, and Nutritional Products

Policy 3014-501 Research Involving FDA Regulated Devices

Policy 3014-502 Expanded Access, Including Emergency Use of Investigational Drugs, Biologics, and Medical Devices (Test Articles)

Policy 3014-801 Reporting Research Events

Policy 3014-802 Non-Compliance in Human Subjects Research

3.Guidance: NA