

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

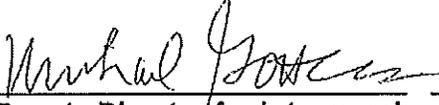
OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: INTRODUCTION

SOP Title: INTRODUCTION TO THE NIH HUMAN RESEARCH PROTECTION
PROGRAM (HRPP)

Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators

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INTRODUCTION TO THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

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INTRODUCTION TO THE NIH HUMAN RESEARCH PROTECTION PROGRAM

1. THE NIH MISSION

The mission of the National Institutes of Health (NIH) is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life and **reduce illness** and disability.

The NIH's Intramural Research Program (IRP) established the Human Research Protection Program (HRPP) to protect the rights and safeguard the welfare of human subjects who participate in its research studies. The NIH HRPP endorses the following goals:

- A. NIH performs clinical research according to the highest scientific and ethical standards and in a manner that promotes and respects the rights and welfare of all human subjects, consistent with applicable laws, regulations and policies including but not limited to The Belmont Report and, when applicable, the Food and Drug Administration's (FDA) Guidance for Industry: E6 Good Clinical Practice: Consolidated Guidance (1996) (see **References** below for links to these resources).
- B. NIH ensures that the performance of all research involving human subjects conducted in the IRP complies with applicable federal laws, Department of Human and Health Services (DHHS) (e.g. The Common Rule, 45 CFR 46) and FDA regulations (e.g. 21 CFR parts 50, 56, 312 and 812); the Standard Operating Procedures (SOPs) of the NIH HRPP; NIH Manual Chapters; , Guidelines for the Conduct of Research in the Intramural Research Program at NIH, and the Guide to Training and Mentoring in the Intramural Research Program at NIH (see **References** below for links to these resources).
- C. NIH complies with the **requirements** of the NIH Policy Manual 3014 - NIH HRPP, which provides a detailed description of the clinical research infrastructure and resources each Institute and Center is expected to provide in the areas of clinical informatics, data management, protocol tracking, biostatistics, quality assurance and quality control, protocol review, human resources, physical plant, training and education (see **4.D** below).
- D. NIH requires its investigators to understand the regulatory definition of research with human subjects, to know when they are conducting research

with human subjects, and it provides appropriate training for investigators and Institutional Review Boards (IRBs) (see SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)).

- E. NIH establishes and maintains IRBs. These IRBs are responsible for the prospective and continuing review and approval of research activities involving human subjects. Their primary mandate is to protect the rights and safeguard the welfare of human research subjects (see SOP 1- HSR and the NIH IRB System and SOP 3 - Management and Administrative Operations of the IRB).
- F. The composition and operation of each NIH IRB conforms to the terms and conditions of federal regulations (see SOP 2 - IRB Membership and Structure).
- G. NIH IRBs review research protocols only after they have been reviewed by the applicable Institutes and Centers (ICs) and found to be scientifically meritorious (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)).
- H. NIH ensures that the IRBs exercise independent authority and decision-making with respect to the review and approval of research with human subjects (see SOP 1- HSR and the NIH IRB System.)

2. THE NIH FEDERALWIDE ASSURANCE (FWA)

The NIH has a FWA (#00005897) on file with the DHHS Office for Human Research Protections (OHRP). Through this document NIH commits to DHHS that it will comply with the requirements set forth in the regulations for the protection of human subjects at 45 CFR 46.

3. THE NIH INTRAMURAL RESEARCH PROGRAM (IRP)

- A. The IRP consists of separately funded programs within the ICs of the NIH:
 - 1. National Institute on Alcohol Abuse and Alcoholism (NIAAA)
 - 2. National Institute of Allergy and Infectious Diseases (NIAID), including the Vaccine Research Center and the Rocky Mountain Laboratory, Hamilton, Montana

3. National Institute on Aging (NIA)
4. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
5. National Institute of Biomedical Imaging and Bioengineering (NIBIB)
6. National Cancer Institute (NCI), including the Frederick Cancer Research and Development Center, Frederick, Maryland
7. Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), including the Perinatology Research Branch, Wayne State University, Hutzel Hospital, Detroit, Michigan
8. National Institute of Deafness and other Communication Disorders (NIDCD)
9. National Institute of Dental and Craniofacial Research (NIDCR)
10. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), including the Phoenix Epidemiology and Clinical Research Branch, Phoenix, Arizona.
11. National Institute on Drug Abuse (NIDA), Baltimore, Maryland
12. National Institute of Environmental Health Sciences (NIEHS), Research Triangle Park, North Carolina
13. National Eye Institute (NEI)
14. National Heart, Lung and Blood Institute (NHLBI)
15. National Human Genome Research Institute (NHGRI), including the Center for Inherited Disease Research in Baltimore, Maryland
16. National Institute of Mental Health (NIMH)
17. National Institute on Minority Health and Health Disparities (NIMHD)
18. National Institute of Neurological Disorders and Stroke (NINDS)

19. National Institute of Nursing Research (NINR)
20. National Center for Complementary and Integrative Health (NCCIH)
21. National Center for Advancing Translational Sciences (NCATS)
22. The Clinical Center (CC) research complex, including the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Clinical Research Center
23. The National Library of Medicine (NLM)

- B. Each IC is administered by the Institute Director, Scientific Director (SD), and Clinical Director (CD):
1. IC Directors have overall responsibility for their Institutes' intramural activities, but generally delegate authority to the Institutes' Scientific and Clinical Directors.
 2. IC SDs are responsible for the overall direction of and allocation of resources for all the laboratory and clinical research programs carried out in their Institute's intramural laboratories and branches and in the CC research complex.
 3. IC CDs report to the Institute Directors or SDs and are responsible specifically for oversight and conduct of the clinical research programs carried out in the IC's intramural clinical branches.

4. THE NIH HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

The NIH's HRPP is made up of NIH ICs, NIH officials, NIH IRBs, researchers and staff who conduct and support research involving human subjects. The HRPP is divided into three arms; Governance and Advisory Entities, Regulatory/Compliance Arm and Protocol Development/Operations Arm (see **Appendix 1**).

A. Governance and Advisory Entities:

1. The governance arm oversees the NIH HRPP and consists of the Deputy Director for Intramural Research (DDIR) and the Deputy Director for

Intramural Clinical Research (DDICR) who have overall responsibility for the NIH HRPP. The CC Director and the IC SDs and CDs also serve the Governance and Advisory Entities Arm of the HRPP in an advisory capacity. Also serving in an advisory capacity are the following committees: the Medical Executive Committee (MEC); the Human Subjects Research Advisory Committee (HSRAC); the IRB Professional Administrators Committee (IPAC); and the Intramural Clinical Research Steering Committee (ICRSC).

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. See **Section G**, below, for authority and responsibility for the development, maintenance and revision of policies for the NIH HRPP
 3. The DDICR oversees the IRP clinical research program and chairs the ICRSC
- B. The following committees serve in an advisory capacity to the Governance Arm of the HRPP:
1. MEC: is advisory to the Director, Clinical Center, and is comprised of all the CDs and senior members of some Clinical Center medical Departments, services and branches (e.g., Critical Care Medicine, Pediatrics, Surgery). The MEC provides advice and guidance to the Director, Clinical Center and the NIH community about issues that relate directly to clinical care and research support within the IRP. A CD elected by the membership chairs the MEC. It oversees the provision of safe care and protection to research participants. The MEC approves the Medical Administrative Series (MAS) policies, which govern clinical care in the Clinical Center, NIH's research hospital
 2. HSRAC: is chaired by the DDIR, it advises the DDIR about the conduct of human subjects research in the NIH IRP. It is a forum for the dissemination of new information, policies and procedures, including those of the OHRP and the FDA. Membership consists of the IRB Chairs, the Director, CC, the Chief of the CC Department of Clinical Bioethics, the Director, OHSRP (Executive Secretary), , and a representative of the

IPAC. IRB administrative staff and other interested HRPP staff attend as guests.

3. IPAC: This Committee, composed of IRB administrative staff members, is dedicated to ensuring compliance with regulatory standards governing human subjects research by developing and promoting effective and consistent procedures and practices across the NIH IRP.
4. NIH ICRSC: was established as a forum for trans-NIH governance and policy development in the area of human subjects research. The DDICR serves as the Chair of the ICRSC and is appointed by the NIH DDIR. **Voting membership consists of the Chair, two (2) IC Directors and 2 SDs, ex-officio members include: Director CC, Director OHSRP, Chief of the Department of Clinical Bioethics -CC, 4 CDs, 2 tenured Principal Investigators (PI) expert in clinical investigation, 1 IRB Chair and 1 IRB Administrator.** The ICRSC is advisory to the NIH DDIR and is specifically charged with providing guidance in the following areas:
 - a. Standards and strategies for the development, review, and implementation of human subjects protocols, including IRB operations, support, and accountability, and ethical interactions with the pharmaceutical industry (including technology transfer)
 - b. Standards and strategies for the development, review, and implementation of human subjects research more broadly, including the scientific review of protocols, and Boards of Scientific Counselors' review of clinical programs

C. The Regulatory/Compliance Arm

The regulatory/compliance arm is **comprised of the NIH IRBs and** the Office of Human Subjects Research Protections (OHSRP), which carries out the day-to-day operations **and regulatory oversight human research activities** of the HRPP. The IRB Chairs are accountable to and have a reporting responsibility to the OHSRP.

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. Specifically, OHSRP:

- a. Assists various NIH intramural components in administering and managing human subjects research activities to promote the rights and welfare of human subjects and the NIH's research mandate
- b. Provides advice on the federal regulations for the protection of human subjects for the IRP, **establishes HRPP policy and** works with various NIH groups to develop NIH policies and procedures consistent with these regulations
- c. Plans, organizes and conducts educational activities for NIH intramural personnel about human subject protections, including a mandatory computer-based training program for research staff and a computer-based training program specifically for IRB members (**see SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)**).
- d. Attends NIH IRB meetings **for the purpose of quality assurance, as** observers and consultants on human subject protection issues (**see SOP 23 - Quality Management System for the NIH HRPP**)
- e. Assists investigators in identifying and resolving ethical and regulatory issues associated with the design and conduct of their protocols, including studies conducted at non-NIH sites in the U.S. and overseas
- f. Is the sole authority in the IRP for determining which research activities are exempt **or excluded** from **IRB review per** the 45 CFR 46 regulations and maintains a database of such **determinations**. **For more information see SOPs 5 - NIH Research Activities with Human Subjects and Specimens/Data that Do or Do Not Require IRB or OHSRP Review and 6 - Processes for Determinations, Including Exemptions, Made by the Office of Human Subjects Research Protections (OHSRP)**
- g. Assists IRP investigators in negotiating reliance (authorization) agreements with other institutions and **in certain circumstances, extends the NIH FWA to investigators not at an FWA-holding institution; and** maintains a database for such **reliance agreements**. The OHSRP Director has signatory authorization from the DDIR for approval of authorization agreements (reliances) for single protocols. **For more information see SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH**

- h. Reviews current lists (rosters) of all NIH IRB members, maintained by the IRBs, and provides membership updates to the OHRP consistent with SOP 2 - IRB Membership and Structures
 - i. Keeps an updated copy of the NIH FWA
 - j. Notifies OHRP and, as applicable, the FDA of unanticipated problems (UPs), serious or continuing non-compliance, suspensions or terminations that occur on intramural protocols. For more information see SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations and SOP 24 - OHSRP Reporting to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) Regarding Unanticipated Problems, Serious or Continuing Non-compliance or Terminations or Suspensions
 - k. Maintains a web site containing computerized training programs, forms, Frequently Asked Questions (FAQs), and other resources for investigators and IRBs (see References below).
 - l. Initiates and/or assists in the conduct of inquiries and/or investigations concerning the conduct of human subjects research in the IRP (see SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP))
 - m. Acts as liaison with the OHRP on matters pertaining to the NIH HRPP (see SOP 24 - OHSRP Reporting to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) Regarding Unanticipated Problems, Serious or Continuing Non-compliance or Terminations or Suspensions)
2. The Director, OHSRP reports to the DDIR. The OHSRP Director is the designated Human Protections Administrator (HPA) for the NIH FWA. Through written delegated authority from the DDIR, the OHSRP Director coordinates and oversees the NIH HRPP on a day-to-day basis. This includes oversight of the NIH IRB system and IRB Chairs.
3. IRBs: NIH IRBs review and approve research involving human subjects conducted in the IRP (unless the research is exempt from IRB review, pursuant to 45 CFR 46.101 (b)) in accord with the regulatory mandates to protect subjects' rights and safeguard their welfare. NIH IRBs also sometimes

review research activities of NIH staff who are involved in extramural research activities. The NIH IRP maintains 12 IRBs, in part because the NIH ICs are administratively separate organizations with discrete missions and research portfolios. However, all IRB Chairs report to the OHSRP Director and follow the requirements of NIH's FWA, the HRPP Policies, the NIH SOPs for IRBs*, and the CC MAS Policies (see **References** below). The 12 NIH Institutional Review Boards are listed below along with the ICs whose research portfolios they generally review:

- a. NCI IRB (NCI CCR)
- b. NCI Special Studies (NCI DCEG)
- c. NHLBI IRB
- d. NIAID IRB
- e. NIDDK/NIAMS IRB
- f. NICHD IRB
- g. NIEHS IRB
- h. NHGRI IRB
- i. Addictions IRB (NIDA, NIAAA)
- j. Combined Neurosciences Blue Panel IRB (NINDS, NIDCD, NEI, NINR, NCCIH)
- k. Combined Neurosciences White Panel IRB (NIMH)
- l. Combined Neurosciences Purple Panel IRB (NIDCR, NIA)
- m. Any of the NIH IRBs may serve as the Public Health Emergency Research Review Board (PHERRB). For more information see SOP 28 – NIH Public Health Emergency Research Review Board (PHERRB)

4. The CC, NIA, NINR, NIBIB, NIMHD, NLM, NCATS and NCCIH may rely on any NIH IRB listed above, depending on the nature of the protocol and the expertise needed for its review.
5. Each IRB has a Chair and Administrative Support Staff

D. The Protocol Development/Operations Arm:

The CD of each IC conducting human subjects research in the IRP is responsible for:

1. The development of a central clinical investigations database that maintains data specified to be collected in the clinical study (either intervention or natural history);
2. The establishment of a quality assurance (QA) program with infrastructure that ensures that clinical trials are monitored adequately and centrally by the IC (see SOP 23 - Quality Management System for the NIH HRPP);
3. Providing protocol development services for investigators, which may include a Protocol Services Center (PSC), PSC Managers; Protocol Navigators; administrative support; and biostatistics support. Providing these services may be done in cooperation with another Institute through a memorandum of understanding;
4. The review of protocols involving human subjects to assess scientific quality, the importance of clinical practice and the appropriateness of the study to the IC (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs));
5. The provision of necessary personnel, office space proximal to patient care areas, and accompanying resources to support the clinical research infrastructure, including the IRBs; and
6. Education and training of clinical investigators on their roles and responsibilities, including Good Clinical Practice (GCP), (see SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)).

5. THE CC

The 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 hospital's proximity to the IRP's research laboratories facilitates the rapid translation of research from the bench to the bedside. Each IC with a clinical research program participates in the usage and cost of the CC and provides its own infrastructure (laboratories, physical plant, space and personnel, e.g., physicians, nurses, support staff) to sustain its clinical research program.

Some CC programs and departments that contribute to the HRPP include, but are not limited to:

- A. The Office of the Deputy Director for Clinical Care includes the Deputy Director for Clinical Care, for the CC staff, and is responsible for clinical quality and clinical performance improvement.
- B. The Office of Protocol Services (OPS) maintains a protocol data repository for the IRP and provides consultation services to investigators, IRBs, and ICs. OPS works closely with the 12 IRB Offices to conduct a quality review of the IRB-approved protocol application; maintain the repository of NIH site consent/assent documents on the NIH CC website for protocols conducted by NIH investigators (see SOP 12 - Requirements for Informed Consent); and facilitate the flow of data to update systems such as Clinicaltrials.gov and internal CC systems. In conjunction with the IRB Offices, OPS monitors protocols for compliance and inactivates protocols in the hospital system when a lapse in continuing review (CR) occurs. In addition, OPS reports data to the Office of Research on Women's Health (ORWH) on behalf of the IRP, generates inclusion enrollment data for investigators from the Clinical Research Information Service (CRIS), and generates *ad hoc* reports from the protocol repository as requested.
- C. The Medical Record Department maintains medical records of all subjects registered as patients at the NIH CC.
- D. The Pharmacy Department provides pharmaceutical services and research support to research participants and investigators, including: provision of drug information; distribution and dispensing of drugs; investigational drug information development and control; and assisting investigators with

meeting FDA regulatory requirements for filing Investigational New Drug applications. Pharmacy staff members actively conduct and participate in pharmacokinetic studies and various research programs about optimal dosing and appropriate use of investigational and commercially available agents. The MAS policies include guidance for clinical research investigators about the safe management of investigational drugs and other medications used in clinical research in Clinical Care

- E. The CC Department of Bioethics 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. The Department of Bioethics provides advice, upon request, to investigators in the development of protocols and informed consent documents, **assessment of cognitive impairment of subjects via the Ability to Consent Assessment Team (ACAT) comprised of members of the Department of Bioethics and the NIMH Human Subjects Protection Unit (HSPU).**
- F. 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 (**see SOP 22 - Research Subject Information and Services and Research-related Complaints from Research Subjects**).
- G. The CC Nursing Department provides nursing services in support of research protocols for all Institutes. Each Institute also employs its own specialized research nurses who participate in and coordinate research protocols.
- H. The **Office of Patient Recruitment (OPR)** provides information to the public about participation in research being conducted at the Clinical Center, screens callers regarding their eligibility for protocols, and provides information about potentially eligible subjects to PIs.
- I. The Clinical Research Volunteer Program **also comes under OPR and** provides information to interested persons on protocols that enroll healthy

volunteers. It also ensures that such volunteers are properly registered and, when appropriate, compensated.

- J. The Patient Advisory Group, consisting of patient representatives from the ICs that admit patients to the CC; members of this group serve as informal advisors to the CC Director regarding issues of concern to patients.

See the NIH CC website in **References** below for additional information.

6. OTHER NIH COMMITTEES

The Trans-NIH Bioethics Advisory Committee (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 the OHSRP, are also represented.

In addition to IRBs, there are several specialized NIH committees involved in ensuring the safety of IRP research subjects and NIH staff during the conduct of research protocols:

- A. The Radiation Safety Committee (RSC)
- B. The Radioactive Drug Research Committee (RDRC)
- C. The Recombinant DNA Advisory Committee (RAC), Office of Biological Activities (OBA)
- D. The Institutional Biosafety Committee (IBC), Office of Research Services (ORS)

7. AUTHORITY AND RESPONSIBILITY FOR THE DEVELOPMENT, MAINTENANCE AND REVISION OF POLICIES FOR THE NIH HRPP

Delegations of Authority: Authority for day-to-day oversight of the NIH HRRP has been delegated to the NIH DDIR and through the DDIR to the NIH OHSRP. The DDIR is the signatory official for all policies that apply to the NIH HRPP.

- A. **Policy Approval** for all policies that apply to NIH HRPP research: As the signatory official for the NIH FWA, the DDIR approves, prior to implementation, all NIH policies that apply to human subjects research conducted by NIH intramural and extramural scientific staff (termed “HRPP SOPs”, see **References** below)).
- B. **Policy Development:** Individuals, committees, or others within the IRP may submit proposals for new policies. The OHSRP and the HSRAC review the proposals and advise the DDIR on whether the policy should be developed, presented for review, and approved. NIH staff members or committees who plan to propose or revise an HRPP policy consult OHSRP as early as possible to determine if the proposed policy is consistent with the NIH HRPP, or if a similar policy currently exists. If OHSRP determines that the proposed policy is consistent with the NIH HRPP and addresses a need of the HRPP program, OHSRP brings the proposal forward to NIH senior officials, including the DDIR. If they concur, the DDIR and OHSRP develop a plan for development, review and approval by all applicable NIH committees, to be followed by review and final approval by the DDIR.
- C. **Publication of Policies:** The OHSRP posts all human subjects policies and SOPs on its website (see **References** below).
- D. **Maintenance and Revision of HRPP Policies:** All HRPP policies are reviewed continually as needed, and formally every three years by OHSRP. OHSRP recommends any proposed substantive changes to the DDIR. The DDIR may approve the proposed changes or route them for review by applicable NIH committees prior to approval. OHSRP may handle minor changes, such as changes to administrative procedures, checklists, or formatting, internally. OHSRP is responsible for notifying the ICs, the MEC, HSRAC and other affected groups of any approved changes.
- E. **Documentation of Policy Approval:** Each NIH-wide HRPP policy, when officially approved, contains the date of approval and the signature of the DDIR.

REFERENCES

A. The Belmont Report:

<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>

B. FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

C. The Common Rule 45 CFR 46:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

D. FDA Regulations:

1. Part 50:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

2. Part 56:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

3. Part 312:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312>

4. Part 812:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812>

E. NIH HRPP Standard Operating Policies (SOPs):

<http://ohsr.od.nih.gov/OHSR/pnppublic.php>

F. NIH Manual Chapters:

<https://oma1.od.nih.gov/manualchapters/scripts/mcs/browse.asp>

1. NIH Manual Chapter 3014:

<https://oma1.od.nih.gov/manualchapters/intramural/3014/>

G. The Standards for Clinical Research Within the NIH Intramural Research Program: <http://www.cc.nih.gov/ccc/clinicalresearch/index.html>

H. Guidelines for the Conduct of Research in the Intramural Research Program at NIH:
https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research-6_11_07.pdf

I. Guide to Training and Mentoring in the Intramural Research Program at NIH:
<https://oir.nih.gov/sourcebook/mentoring/guide-training-mentoring>

J. NIH HRPP website: <http://ohsr.od.nih.gov/OHSR/index.php>

K. NIH OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

L. NIH Clinical Center (CC) website: <http://intranet.cc.nih.gov>

M. CC MAS Policies: <http://intranet.cc.nih.gov/mec/mas/>

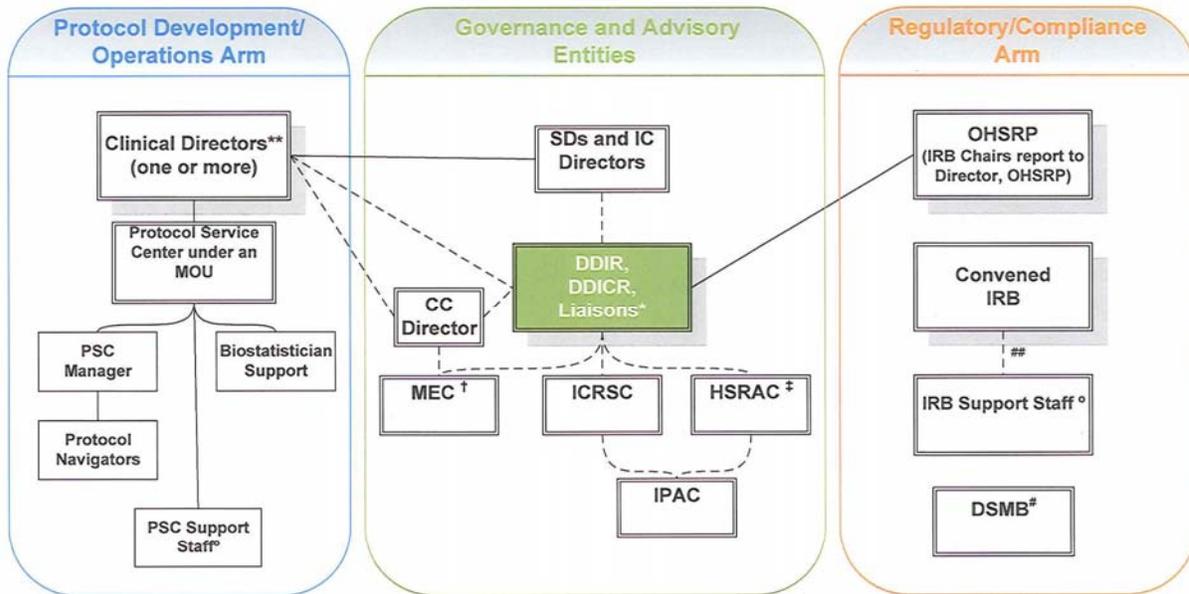
N. Clinical research in the CC: <http://clinicalstudies.info.nih.gov/>

LIST OF APPENDICES

APPENDIX 1: NIH HRPP ORGANIZATIONAL CHART

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**Human Research Protection Program
In the NIH Intramural Research Program**



° Denotes possibility of shared responsibility at the discretion of the IC
 * Liaisons bridge the two arms and communicate with all individuals/components
 **Scientific Review is the responsibility of the ICs
 † Comprised of Clinical Directors
 ‡ Comprised of IRB Chairs
 # Denotes independent outside review bodies responsible to IC Leadership and IRBs for reporting findings
 ## Denotes support but not supervisory relationship

3/10/2011

Figure 1: This chart shows the organization of the Human Research Protection Program as it relates to the NIH Intramural Research Program