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OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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SOP Title: INVESTIGATOR RESPONSIBILITIES

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

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SOP 19 INVESTIGATOR RESPONSIBILITIES

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SOP 19 INVESTIGATOR RESPONSIBILITIES

19.1 PURPOSE

This policy describes the roles and responsibilities of investigators, particularly Principal Investigators (PIs), in the conduct and supervision of research protocols involving human subjects. Additional requirements for PIs conducting research regulated by the Food and Drug Administration (FDA) are provided in SOP 15 "Research Regulated by the FDA: General Procedures for Both IND and IDE Applications". Generally, most Human Research Protection Program (HRPP) Standard Operating Policies (SOPs) also contain sections listing specific PI responsibilities. PIs are reminded to review the applicable section(s) when reviewing a SOP on a particular topic.

19.2 POLICY

It is the policy of the NIH HRPP that each protocol approved by an NIH Institutional Review Board (IRB) has a single Principal Investigator (PI) who is responsible for its design and conduct. Upon IRB approval, the PI may delegate specific aspects of the conduct of the research to other members of the research team but he/she retains overall responsibility.

19.3 DEFINITIONS, QUALIFICATIONS AND RESPONSIBILITIES OF INVESTIGATORS

19.3.1 Investigator

An "investigator" is any individual who is involved in conducting human subjects research (HSR) studies. Such involvement includes: (1) obtaining information about living individuals by intervening or interacting with them for research purposes; (2) obtaining identifiable private information about living individuals for research purposes; (3) obtaining voluntary informed consent of individuals to be subjects in research, or (4) studying, interpreting, or analyzing identifiable private information or data for research purposes. For more information see **References** for the link to the OHRP FAQ, "Who are "investigators"?".

The PI may also designate investigators who are not engaged in HSR (e.g. laboratory investigator who does not handle identifiable materials but is making a

major contribution to the science, or a biostatistician who does not work with identifiable information).

The PI must list all investigators on the NIH application and in the protocol, as applicable (See SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH).

See “Policy & Guidance for Investigators” in **References** below and SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications, for the FDA’s definition of an investigator.

19.3.2 General Responsibilities of Investigators

The following responsibilities are applicable to any investigator:

A. The ethical treatment of the participants

B. Complying with the requirements of the SOPs of the NIH HRPP

C. Meeting the HRPP training requirements as specified in SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)

D. Not engaging in human subjects research until proof of IRB-approval has been provided by the PI

E. Complying with the terms of the IRB-approved protocol (see **19.5.4** below) and PI instruction (see **19.5.1** below)

F. When vulnerable populations are involved in the protocol, the investigator should be familiar with the requirements specified in NIH HRPP SOPs: 14A - Research Involving Vulnerable Subjects (General Considerations);14B- Research Involving Pregnant Women, Human Fetuses and Neonates; 14C- Research Involving Prisoners; 14D- Research Involving Children; 14E - Research Involving Adults Who Are or May Be Unable to Consent; and 14F - Research Involving NIH Staff as Subjects

G. Ensuring that changes to NIH IRB-approved protocols and/or consent documents are not initiated without prospective IRB approval unless necessary to eliminate apparent immediate hazards to the subject (see

SOP 10 - Amendments to IRB-approved Research and SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations).

H. Reporting unanticipated problems and events (e.g. deviations, adverse events, and non-compliance) as soon as possible, to the PI, so that the PI can comply with the requirements of SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations

I. Complying with the requirements of SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff, as applicable

J. When designated by the PI as a party able to obtain informed consent, it is obtained and documented before research participation begins, consistent with the IRB-approved protocol (see SOP 12 - Requirements for Informed Consent).

K. Ensuring that adequate and accurate research records are kept and retained as required by this SOP (see **19.5.3** below) and other applicable policies.

L. When drugs, biological products, and devices are being investigated or used, managing these agents as required FDA regulations (such as, 21 CFR 312 and 21 CFR 812, see SOP 15 - Research Regulated by the FDA: General Procedures for Both IND and IDE Applications) or other regulations, as applicable. When using these agents at the NIH/CC compliance with the MAS 80-3 (rev.) policy, “The Use of Investigational or New Drugs in Clinical Research” (see **References** below), as applicable.

19.3.3 Principal Investigator (PI)

Within the Intramural Research Program (IRP), the Principal Investigator (PI) has overall responsibilities for the study. The PI is responsible overall for the design and conduct of the IRB-approved research protocol. There can be only one PI for each protocol (see **19.2, 19.4** and **19.5**).

When the PI is the Lead PI for an NIH multisite study, the requirements set forth in **19.3.4** below and HRPP SOPs: SOP 20 - NIH HRPP Requirements for Collaborative Research, SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH, SOP 20B - NIH IRB Responsibilities When Reviewing Local Context Considerations for Offsite Research, SOP 20C - Responsibilities

When the NIH Intramural Research Program Serves as a Coordinating Center for a Multi-site Trial also apply, as applicable.

When NIH investigators are "engaged" in human subjects research per 45 CFR 46, the PI must designate these individuals as sub-investigators as appropriate: Adjunct Principal Investigator (API), Medical Advisory Investigator (MAI), Lead Associate Investigator (LAI) or Associate Investigator (AI) on the protocol as members of the research team (see below). The PI may also designate investigators who are not engaged in HSR as AIs. All investigators must be listed on the NIH application (see **19.3.1** above).

The Principal Investigator is responsible for assuring that all investigators are qualified by education, training, and experience needed to perform their delegated roles in conduct of the study (see **19.5.1**).

At the NIH, consultants or students may not be PIs. The following requirements determine who may be a PI:

A. **NIH employees including Public Health Service (PHS) commissioned officers assigned to the NIH:** To be a PI, an NIH employee will have appropriate credentialing. At the NIH Clinical Center (CC), a PI will be a member of the senior or junior medical, research; adjunct or affiliate staff (see **References** below for the link to the Medical Staff Bylaws). Non-CC NIH employees must comply with the credentialing requirements, as applicable, of their Institute/Center (IC). Consult the IC Clinical Director (CD) for direction, including when conducting research at a site other than an NIH site (e.g. a community hospital, private clinic, or in another country).

   When the PI is not a member of the senior or junior medical staff, or when an IRB, IC CD, or the Director, CC consider it warranted, a Medical Advisory Investigator must be identified in the protocol and approved by the IRB (see **19.3.6**).

B. **Non-NIH Federal employees:** Non-NIH Federal employees may serve as PIs on an NIH protocol on a case-by-case basis with the following conditions:

   1. The Deputy Director for Intramural Research (DDIR) must approve in writing a request for a non-NIH Federal employee to serve as a PI. The

DDIR's approval is submitted with the protocol to the appropriate NIH IRB for review and approval.

2. There must be an official letter in the IRB office's protocol file (and a copy kept by the PI) from the individual's employing agency stating that the activities at the NIH are a part of his/her official duties.

3. The protocol must also list an NIH Accountable Investigator (see **19.3.9**).

4. Applicable medical staff credentialing requirements for the research site will be met.

5. The DDIR may make exceptions in writing to the above conditions.

C. **Non-NIH, non-Federal employees:** Extramural researchers (e.g., in academia, practicing at a community hospital) may serve as Adjunct Principal Investigators on a protocol where the PI is an NIH employee (see **19.3.5**).

19.3.4 Lead PI

Lead Principal Investigator (Lead PI): The investigator with overall responsibility for overseeing a multisite study, submitting the protocol to the IRB of record and ensuring all engaged sites have the most current version of the IRB-approved protocol. The Lead PI can also be a Site PI.

NIH investigators serving as the Lead PI of a multisite study must also comply with the requirements of the following HRPP SOPs, as applicable: SOP 20 - NIH HRPP Requirements for Collaborative Research, SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH, SOP 20C - Responsibilities When the NIH Intramural Research Program Serves as a Coordinating Center for a Multisite Trial, SOP 20D - Collaborations Involving Non-NIH Employees Working on NIH Protocols.

19.3.5 Adjunct Principal Investigator (API)

An API is an individual who is not an NIH employee and who shares some responsibilities with the NIH PI at the NIH or for multisite studies also conducted at the NIH Clinical Center. Such a protocol may also be carried out at the API's employment site, at which s/he would serve as the Site PI. If the protocol has an

API, there must be a named NIH PI who is an employee and who will be responsible for the conduct of the protocol and who will ensure the conflict of interest requirements have been addressed consistent with SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff (see **19.5** below). The relationship between the API and the NIH PI will allow for the conduct of collaborative protocols (see SOP 20D - Collaborations Involving Non-NIH Employees Working on NIH Protocols).

19.3.6 Medical Advisory Investigator (MAI)

When the PI is not a member of the senior or junior medical staff, or when an IRB, IC CD, or the Director, CC considers it warranted, a MAI must be identified in the protocol and approved by the IRB. The MAI must be an appropriately qualified member of the medical staff at the research site and is responsible for assisting the Principal Investigator in the development of clinical aspects of the protocol and/or for providing direct medical care to protocol participants. There is only one MAI per protocol.

19.3.7 Lead Associate Investigator (LAI)

An individual who plays a leading role in the formulation, writing, and implementation of a clinical research protocol under the mentorship of the protocol's PI is a LAI. A LAI may be a physician, a dentist, a Doctor of Philosophy (PhD), an (Registered Nurse) RN, or a member of the allied health professions or a trainee. There is only one LAI per protocol.

19.3.8 Associate Investigators (AI)

Individuals, other than the PI, who make substantial contributions to the conception, design of the study, and execution of the study including, but not limited to, obtaining informed consent from protocol participants, the acquisition of data, or to the analysis and interpretation of data. Also referred to as "sub-investigator" by FDA regulations, for more information, see **References** below.

Staff, who are engaged in HSR, must be designated as investigators (e.g., AIs, APIs, LAIs or MAIs, as applicable, see **19.3.1** and **19.3.3** above). However, the PI also has the discretion to designate non-engaged investigators as AIs. There may be several AIs on a protocol. NIH employees, contractors, NIH trainees, students and non-NIH collaborators may serve as AIs.

19.3.9 Accountable Investigator

Accountable Investigators are tenured, tenure-track investigators, senior clinicians or Staff Clinicians who are responsible and accountable for the expenditure of resources for clinical research protocols.

19.3.10 Research Contact (RC)

The person(s) to whom potential research subjects may be referred for participation in a particular research protocol

19.4 GENERAL RESPONSIBILITIES OF THE PI

The PI is responsible for designing and personally conducting, or properly supervising the conduct of the IRB-approved protocol. The PI is also responsible for protecting the rights, safety, and welfare of the research participants. The PI ensures that the research is conducted in an ethical manner consistent with:

A. The Belmont Report (see **References** below);

B. Relevant federal regulations (e.g. Common Rule (45 CFR 46) and Food and Drug Administration (FDA) regulations (e.g., 21 CFR parts 50, 56, 312 and 812), as applicable);

C. FDA E6 Guidance for Industry Good Clinical Practice: Consolidated Guidance (referred to as GCP for the purposes of this SOP)as applicable (see **References** below);

D. The Standard Operating Procedures (SOPs) of the NIH Human Research Protection Program (HRPP) (see **References** below);

E. When conducting research at the NIH CC, the Medical Administrative Series (MAS) Policies (see References below);

F. The Standards for Clinical Research Within the NIH Intramural Research Program (IRP) (see **References** below); and

G. Other NIH requirements, as appropriate such as those of the: Radiation Safety Committee, the Recombinant DNA Advisory Committee (RAC), and the NIH Biosafety Committee (see **References** below).

19.5 SPECIFIC RESPONSIBILITIES OF THE PI

The PI ensures that:

A. Research involving human subjects begins only after NIH IRB review and approval (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)) or, when appropriate, after the NIH Office of Human Subjects Research Protections (OHSRP) grants a written determination that IRB review is not required (see SOP 6 - Processes for Determinations Made By The Office Of Human Subjects Research Protections (OHSRP)). Guidance has been sought from the IRB and/or OHSRP if it is unclear whether or not the research involves human subjects. See SOP 5 - NIH Research Activities with Human Specimens and Data.

B. The research is conducted in accordance with the NIH IRB-approved protocol, including the approved recruitment and consent procedures.

C. The contents of protocols and supporting documents submitted for initial review (IR), Continuing Review (CR), or amendments meet NIH criteria as provided in: SOPs 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs); SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards ; SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols; SOP 9 - Continuing Review by the Convened IRB and SOP 10 - Amendments to IRB-Approved Research.

D. The NIH IRB Review Standards (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)) will be used in his/her oral presentation of the initial protocol to the IRB as required by the NIH HRPP SOPs.

E. When informed consent is required, it is obtained and documented before research participation begins, consistent with the IRB-approved protocol (see SOP 12 - Requirements for Informed Consent).

F. When drugs, biological products, and devices are being investigated or used, they are managed as required by FDA regulations (such as, 21 CFR

312 and 21 CFR 812, see SOP 15 - Research Regulated by the FDA: General Procedures for Both IND and IDE Applications) or other regulations, as applicable. Use of these agents at the NIH/CC will comply with the MAS 80-3 (rev.) policy, "The Use of Investigational or New Drugs in Clinical Research" (see **References** below), as applicable.

G. Changes to NIH IRB-approved protocols and/or consent documents are not initiated without prospective IRB approval unless necessary to eliminate apparent immediate hazards to the subject (see SOP 10 - Amendments to IRB-approved Research and SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations).

H. Unanticipated problems (UPs) involving risks to subjects or others (including adverse events and protocol deviations) are reported to the IRB in accordance with requirements set forth in SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations and SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP).

I. The protocol includes a proposed Data Safety Monitoring Plan (DSMP) consistent with the requirements of SOP 17 - Data and Safety Monitoring. When applicable, Data and Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC) or other monitoring individual or group reports are submitted promptly to the IRB for review (see SOP 17 - Data and Safety Monitoring).

J. The CR submission to the IRB is submitted with sufficient time to allow for IRB review and approval prior to the expiration of the current IRB approval, and with sufficient opportunity for response by the PI to any stipulations of the IRB (see SOP 9 - Continuing Review by the Convened IRB).

K. When the research protocol ends, the PI submits a final report to the appropriate NIH IRB. Ongoing data or specimen collection and analysis are not permissible after study closure. Once a study is closed, the PI will no longer be required to obtain CR for that protocol. If access to specimens or data is anticipated for future use, the investigator should make provisions prior to closing the original protocol (see SOP 11A - Closure of an IRB-approved protocol and SOP 11 - Suspensions and Terminations of IRB Approval and Administrative Holds, as applicable).

L. Adequate and accurate research records are kept and retained as required by this SOP (see **19.5.3** below) and other applicable policies.

M. Upon request for monitoring and/or oversight of the research, research records are made available to the IRB, OHSRP, the IC Quality Improvement Program, and when applicable, the DSMB, the sponsor, the DHHS Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA) (see SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP) and SOP 23, - Quality Management System for the HRPP").

N. The PI is responsible for complying with the conflict of interest requirements set forth in SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff .

O. When conducting collaborative research at a non-NIH institution, or when a non-NIH investigator, engaged in HSR wishes to rely on an NIH IRB, or when conducting multi-site research using a single IRB review, the need for a Reliance (also referred to as an Authorization) Agreement is considered. The NIH PI must comply with the requirements set forth in SOPs SOP 20 - NIH HRPP Requirements for Collaborative Research and SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH.

19.5.1 Training and Supervising the Conduct of the Research Protocol/Study

A. The PI is responsible for the design and conduct of the IRB-approved research protocol. S/he may delegate study-related tasks but must ensure that investigators and other study personnel to whom tasks are assigned are appropriately trained and supervised.

B. The intensity of the PI's supervision will take into account the experience and qualifications of research study personnel, the nature of the research, and the subject population. Through training and supervising the conduct of the research, the PI ensures that study personnel:

1. Are qualified by training and experience, and credentialed, as necessary, to perform study-related tasks that have been assigned to them.

2. Are aware of regulatory and policy requirements and standards for the conduct of human subjects research.

3. Have a complete understanding of the details of the protocol relevant to the tasks they will be performing. This may include:

   a. Inclusion/exclusion criteria in the protocol

   b. Consent requirements, as applicable

   c. Risks and benefits of the protocol

   d. SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations reporting requirements

   e. Data management

4. Follow the IRB-approved protocol.

5. Are informed of any pertinent changes to the protocol during the conduct of the study and are educated or given additional training, as appropriate.

C. IRB approval may be required for protocol-related activity delegations. For example, the IRB approved protocol must identify who, in addition to or instead of the PI, will obtain informed consent from subjects. These delegated persons or categories of persons must fulfill requirements in **19.5.1.B** or as provided in the IRB-approved protocol.

D. The PI ensures and/or certifies that research personnel have completed of all NIH training requirements consistent with SOP 25 - Training Requirements for the NIH HRPP, including protocol-specific training as necessary.

19.5.2 Adequate Resources to Conduct the Research

The PI will conduct the research only when adequate resources to protect research subjects exist. These resources may include:

A. Access to population(s) that allow recruitment and enrollment of subjects consistent with the IRB-approved protocol.

B. Sufficient time to be devoted by the PI and other research staff to conduct and complete the research.

C. Adequate numbers of qualified and trained staff.

D. Adequate budget, facilities, and space.

E. Access to medical or psychological care for problems that may arise during subjects' participation in research.

19.5.3 Research Records Management

A. General considerations: **"**The Standards for Clinical Research in the NIH Intramural Research Program" (see **References** below) specify that each IC sponsoring clinical research should develop a central clinical investigation database that maintains all data specified to be collected in the protocol. The ICs provide data-management infrastructures to maintain their central data registries; to enhance existing databases; to provide eligibility checklists; to record patient randomization and entry into protocols; to provide report generation, data warehousing, and data entry forms; and, to monitor data collection.

B. PI responsibilities include but are not limited to:

1. Ensuring the accuracy, completeness, legibility, and timeliness of the data.

2. Following internal procedures for the appropriate documentation of research related tests and procedures.

3. Maintaining the confidentiality of data at all times

C. FDA-regulated research: Data collection, record-keeping and record retention will be consistent with the GCP (see **References** below) and requirements set forth in SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications.

D. Retention of research records: Records retention will be consistent with NIH Manual Chapter 1743, Keeping and Destroying Records, and other applicable policies (see **References** below).

19.5.4 Protocol Compliance

A. General considerations: Routine monitoring of the conduct of research protocols is a requirement of the NIH HRPP. This includes monitoring by the PI and the research team and through the Institute or Center's (IC) quality assurance/quality improvement (QA/QI) plan. Also, "not-for-cause" and "for cause" audits may be conducted by the NIH, FDA, OHRP, or sponsor. For more information, see Sop 23 - Quality Management System for the HRPP.

B. PI cooperation: The PI is responsible for ensuring the cooperation of all research personnel with the IC QA/QI plan and NIH (or other) monitoring and audit activities. This includes, but is not limited to, preparing for routine monitoring or other required audits and being available as needed, (see SOP 23 - Quality Management System for the HRPP).

C. FDA regulated research: IC, PI and research staff compliance activities for these protocols will be consistent with the requirements set forth in SOP 15 - Research Regulated by the Food and Drug Administration: General Procedures for Both IND and IDE Applications, SOP 15A - Research Regulated by the Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products), or SOP 15B - Research Regulated by the Food and Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications, as applicable.

19.5.5 Administrative Hold, Suspensions and Terminations

A. Administrative hold**:** A Principal Investigator may request an administrative hold on a study when he/she wishes temporarily to stop or as a preliminary step before permanently stopping some or all approved research activities. An administrative hold may be in response to a directive from a sponsor, monitoring entity or the FDA or other review body. Administrative holds are not suspensions or terminations. Studies on administrative hold require CR by the IRB prior to the expiration date. The procedures for initiating administrative holds, suspensions, and

terminations are found in SOP 11 - Suspensions and Terminations of IRB Approval and Administrative Holds."

B. Suspensions or terminations by study sponsors: The PI promptly reports any study that is suspended or terminated prematurely (by the sponsor, etc.) for any reason to the IRB and appropriate institutional officials (see SOP 11- Suspensions and Terminations of IRB Approval and Administrative Holds).

REFERENCES

A. Policy & Guidance for Investigators: http://www.hhs.gov/ohrp/

B. The Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

C. Common Rule (45 CFR 46): http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

D. CFR 50 - Informed Consent and Children: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50

E. CFR 56 - Institutional Review Boards: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

F. CFR 312 - INDs: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312

G. 21 CFR 812 - IDEs: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812

H. FDA E6 Guidance for Industry Good Clinical Practice: Consolidated Guidance: (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf).

I. The Standards for Clinical Research Within NIH Intramural Research: (http://clinicalcenter.nih.gov/ccc/patientcare/pdf/cc_research_standards.pdf)

J. Medical Administrative Series (MAS) Policies: http://intranet.cc.nih.gov/mec/mas/index.shtml

K. Standard Operating Procedures (SOPs) for the Human Research Protection Program (HRPP): https://federation.nih.gov/ohsr/nih/pnp.php

L. MAS 80-3 (rev.) The Use of Investigational or New Drugs in Clinical Research: http://cc-internal.cc.nih.gov/policies/PDF/M80-3.pdf

M. NIH Manual Chapter 1743, Keeping and Destroying Records, and other applicable policies: http://oma.od.nih.gov/manualchapters/management/1743/

N. Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572): http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf

O. Medical Staff Bylaws: http://cc-internal.cc.nih.gov/policies/PDF/Bylaws.pdf