Chapter 3
Institutional Policy & Shared Responsibilities for the Protection of Human Subjects

As a matter of institutional policy HSS meets the requirements of the DHHS human subject protection regulations for all of its research, without regard to source of funding or other support. HSS also complies with the requirements of FDA regulations where applicable.

It is HSS’s responsibility to assure Federal Agencies in writing that HSS will comply with all federal laws and regulations governing the protection of human research subjects. As part of its written Assurance to the government, HSS must develop policies and procedures for conducting human subject research in a responsible and ethical fashion. HSS’s policies and procedures for implementing the requirements for protecting human subjects are provided in this and subsequent chapters of this manual.

I. The Federalwide Assurance. HSS maintains a Federalwide Assurance (FWA) of Protection for Human Subjects (see Terms of Assurance in Appendix IV) approved by the DHHS Office for Human Research Protections (OHRP). The President and Chief Executive Officer (CEO) of HSS serves as the Human Subject Signatory Official for the Institution’s FWA.

The FWA authorizes HSS to conduct human subject research that is supported by DHHS or any of the other Federal “Common Rule” agencies. One component of the FWA designates the Institutional Review Board (IRB), or Institutional Review Boards (IRBs), officially recognized and designated to review HSS’s research.

The FWA covers all human subject research conducted (i) by any employee or agent of the Institution; or (ii) in any component of the Institution. Thus, any investigator who (i) acts as an employee or agent of any Institutional component, or (ii) conducts research within any Institutional facility or with Institutional equipment or resources is bound by HSS’s human subject protection policies and requirements.

All Institutional components are covered under the Institutional FWA and are authorized to cite HSS’s FWA number in communicating with Federal agencies.

HSS currently operates, and has designated under its FWA, one Institutional Review Board (IRB) to accommodate the volume of its human subject research. Under its FWA, HSS may designate additional internal or external IRBs as it deems necessary. No Institutional component may operate or designate an IRB without concurrence of HSS’s President and Chief Executive Officer (CEO), who serves as the Human Subject Signatory Official under the Institutional Federalwide Assurance for Protection of Human Subjects, or without Institutional compliance oversight.

II. Important Definitions for the Protection of Human Subjects.
A. **Agent.** For the purposes of this policy, an agent of the Institution is any individual who (i) acts on behalf of HSS or any component of HSS, or (ii) represents herself/himself as affiliated with HSS or any of its component in (a) the planning, design, conduct (including data analysis), or support of research; (b) the solicitation of funds or in-kind support for research; (c) the recruitment of research subjects; (d) obtaining the informed consent of research subjects; or (e) the publication or presentation of research results.

B. **Institutional Review Board (IRB).** An IRB is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. In accordance with the Common Rule, DHHS regulations, and FDA regulations, the IRB has responsibility for approving, requiring modification in (to secure approval), or disapproving research. The IRB also has the authority to suspend or terminate research for continued noncompliance with the Common Rule, DHHS regulations, and FDA regulations, or its own findings, determinations, and initial and continuing review procedures (see Chapter 4 of this manual for details of IRB authorities and responsibilities).

C. **Research.** Federal regulations at 45 CFR 46.102(d) define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

D. **Engaged in Research.** Federal Guidance on Institutional Engagement in Research (Dated October 16, 2008 [http://www.hhs.gov/ohrp/policy/engage08.html](http://www.hhs.gov/ohrp/policy/engage08.html)) states “In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

E. **Human Subject.** Federal regulations at 45 CFR 46.102(f) define human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.”

F. **Investigator.** HHS regulations at 45 CFR part 46 use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of HSS IRB policies and procedures, HSS will rely on the OHRP interpretation of investigator which states “an ‘investigator’ to be any individual who is involved in conducting human subjects research studies. Such involvement would include:...
• Obtaining information about living individuals by intervening or interacting with them for research purposes;

• Obtaining identifiable private information about living individuals for research purposes;

• Obtaining the voluntary informed consent of individuals to be subjects in research; and

• Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, research coordinators, research assistants, teachers, and students, among others. Some research studies are conducted by more than one investigator.

However, there are instances when an individual may not be considered an investigator as they are not considered “engaged” in research. These individuals are considered not engaged in research if their involvement in a research project is limited to one of the following:

• Performing a service or duty that are typically a part of routine care in their job capacity (such as a radiologist or a phlebotomist)

• A receptionist who offers an IRB approved research information sheet or recruitment flyer to a patient in the waiting area.

• When an employee receives identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

For further guidance from OHRP of when an institution and its employees and agents are considered either engaged or not engaged in human subjects research, please visit the following site:

http://www.hhs.gov/ohrp/policy/engage08.html

For Additional Non-Engaged Scenarios Guidance from OHRP please consult the following site:

http://www.hhs.gov/ohrp/policy/Correspondence/nonengageexamples2011.html

The FDA defines an investigator (21 CFR Part 50.3 Subpart A Definitions and 21 CFR Part 56.102 Subpart A Definitions) as “an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or
dispensed to, or used involving, a subject, or in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.

**It is HSS IRB policy that one investigator is to be designated the “principal investigator” with overall responsibilities for the study.**

**G. Private Information.** Federal regulations define private information to include any information that an individual can reasonably expect will not be made public, and any information about behavior that an individual can reasonably expect will not be observed or recorded.

**H. Identifiable.** Federal regulations define identifiable to mean that the identity of the individual subject is or may readily be ascertained by the investigator or associated with the information.

**I. Minimal Risk.** Federal regulations at 45 CFR 46.102(f) and 21 CFR 56.102(i) define minimal risk to mean that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**J. Minimal Risk for Prisoners.** In the case of research involving prisoners, federal regulations at 45 CFR 46.303(d) define minimal risk as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**III. Responsibilities within HSS.** The ethical conduct of research is a shared responsibility. It requires cooperation, collaboration, and trust among all Institutional components and administrators, investigators and their research staff, the subjects who enroll in research, and the IRB.

**A. Board of Directors (or Trustees).** The Board of Trustees has ultimate authority for the oversight and monitoring of the Institutional Policy for the Protection of Human Subjects. To avoid any conflicts of interest in the research area, the IRB reports directly to the Board of Directors (or Trustees). The IRB prepares an informational report to the Board of Directors (or Trustees) annually. The Institution’s President and Chief Executive Officer (CEO), the Institutional Compliance Officer, the Institution’s Legal Counsel and the IRB Chairperson have direct access to the Board of Directors (or Trustees) if needed to fulfill HSS’s responsibilities for protecting human research subject.

**B. Human Subject Signatory Official.** The HSS President and Chief Executive Officer (CEO) serves as the Human Subject Signatory Official for assuring Federal Agencies that HSS complies with all Federal regulations governing the protection of human
research subjects. Consequently, the President/CEO is fully responsible for overseeing the protection of human subjects within HSS, including:

1. Overseeing the development and implementation of Institutional policies governing HSS’s designated IRB, all human subject research, and all investigators and research personnel at HSS.

2. Maintaining open channels of communication among all parties involved in the human subject protection process at HSS.

3. Ensuring that the IRB is provided with sufficient meeting space and staff to support its substantial review and record keeping responsibilities.

4. Overseeing the operation and administration of the IRB and determining that the IRB functions in accordance with the assurances provided in compliance with all Federal, State, and local laws and regulations that govern human subject protection in the conduct of research.

5. Establishing and maintaining policies to ensure that the Institution’s Signatory Official, Legal Counsel, Compliance Officer, and IRB Chairperson are promptly notified regarding (i) any unanticipated problem involving risks to subjects or others; (ii) any serious or continuing non-compliance with IRB requirements by research investigators; or (iii) any for-cause suspension or termination of IRB approval.

6. Ensuring notification of OHRP and FDA of such incidents in accordance with applicable Federal regulations. Such notice will be accomplished in coordination with the Institution’s Legal Counsel, Compliance Officer, and IRB Chairperson.

7. Overseeing implementation of a research compliance monitoring process that provides monitoring reports, as appropriate, to the Institution’s Signatory Official, Legal Counsel, Compliance Officer, and IRB Chairperson.

C. **Human Protections Administrator.** The Director, Clinical Research Administration serves as the Human Protections Administrator under HSS’s FWA. The Human Protections Administrator is the Institutional official to whom the FWA Signatory Official delegates day-to-day oversight of the institution’s human research protection program under the FWA.

D. **Principal Investigators.** As the individual responsible for the implementation of research, the principal investigator bears direct responsibility for protecting every research subject. Only one individual can be listed as Principal Investigator on an IRB protocol application submission. This responsibility starts with protocol design, which must minimize risks to subjects while maximizing research benefits. In addition, the principal investigator and all members of the research team must comply with the findings, determinations, and requirements of the IRB. The principal investigator must
also be responsible for the adequacy of both the informed consent document and the informed consent process, regardless of which members of the research team actually obtain and document consent. Principal Investigators must ensure:

1. That all human subject research which they conduct at HSS or its components, or as employees or agents of HSS has received prospective review and approval by the IRB.

2. That continuing IRB review and approval of the research are secured in a timely fashion.

3. That the research is conducted at all times in compliance with all applicable Federal, State, and local regulatory requirements and with the determinations of the IRB.

4. That the investigator has reviewed HSS’s FWA, this IRB Policy and Procedure Manual, DHHS Regulations for Protection of Human Research Subjects, relevant FDA regulations, and the Belmont Report.

5. That no changes in approved research are initiated without prior approval of the IRB, except where necessary to eliminate apparent immediate hazards to subjects; and no research may be continued beyond the IRB-designated approval period.

6. That the IRB is notified promptly of (i) any injuries or unanticipated problems involving risks to subjects or others; (ii) any serious adverse events experienced by subjects, (iii) any adverse events reported to the study sponsor; and (iv) any serious or continuing noncompliance with applicable regulatory requirements or determinations of the IRB of which they become aware.

7. That a final report is made to the IRB and to the sponsor within three months after the completion or discontinuance of a research project, or of withdrawal of the exemption for a research project.

8. That complete and accurate records are maintained regarding all communications with the IRB, the sponsor, and any Federal Agency, and that such records are made available to the Institution’s Human Subject Signatory Official and/or Compliance Officer immediately upon request.

E. Other Members of the Research Team. Every member of the research team is responsible for protecting human subjects. Co-investigators, which may include surgeons and other physicians, study coordinators, nurses, research assistants, and all other research staff, have a strict obligation to comply with all IRB determinations and procedures; adhere rigorously to all protocol requirements; inform investigators of all adverse reactions or unanticipated problems involving risks to subjects or others; oversee the adequacy of the informed consent process; and take whatever measures are necessary to protect the safety and welfare of subjects.
Researchers at every level are responsible for notifying the IRB promptly of any serious or continuing noncompliance with applicable regulatory requirements or determinations of the IRB of which they become aware, whether or not they themselves are involved in the research. Researchers may also notify the Institution’s Human Subject Signatory Official, Compliance Officer, or Legal Counsel directly of any compliance concerns they may have.

F. **Research Subjects.** Subjects may be viewed as having certain responsibilities as well. They can be expected to make every effort to comprehend the information researchers present to them so that they can make an informed decision about their participation in good faith. While participating, they should also make every reasonable effort to comply with protocol requirements and inform the investigators of unanticipated problems. Subjects always have the right to withdraw from their participation in research at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.