02.0 Roles in the Protection of Human Research Subjects at Florida Hospital

2.1 The Institutional Official
The Institutional Official at Florida Hospital, as designated by the President of the hospital, is the Chief Scientific Officer of Florida Hospital.

It is the responsibility of the Institutional Official (IO) to oversee the Hospital’s compliance with federal regulations pertinent to human subjects research. The official document pledging this responsibility, the Federal-wide Assurance document, is approved by OHRP at DHHS. The Institutional Official shall be responsible for all required institutional reports to sponsors and federal agencies.

The FWA requires the development and adoption of policies and procedures for conducting human subject research and the appointment of an institutional official to oversee this process.

The Institutional Official maintains ultimate responsibility for considering complaints or concerns about the Human Research Protection Program.

2.2 Vice President for Research
The Vice President for Research is the hospital’s appointed liaison among the departments with research oversight. The Vice President administers, supports, guides and oversees the work of the FHIRB to uphold ethical and regulatory standards and practices in human subjects research at FH. The VP reports to the Institutional Official for human subjects protection issues and to Senior Vice President for administrative matters. Recognizing the importance of uniting administrative support with human research subjects protection, the Hospital has appointed the Chief Scientific Officer to serve as Institutional Official. As part of the FWA process, an institution is asked to identify a “Human Protections Administrator” (HPA) to serve as the primary institutional contact person for OHRP. The Hospital has designated the Vice President of Research to be the Hospital’s HPA. All HRPP staff and IRB members, including the IRB Chair, report to the Vice President of Research to the Institutional Official.

The VP holds regular meetings of the administrative staff and the IRB Chair to monitor and improve operational processes. The goals of these meetings are to measure and improve the effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, State, and local laws of the HRPP. The VP also mandates a program of ongoing monitoring and auditing of record keeping as well as the conduct of the research for Quality Improvement (QI). The goals of the QI program are to keep HRPP staff and investigators attentive to applicable regulations and Hospital policies as well as to correct procedural errors to achieve the hospital’s goal of maintaining protections for subjects enrolled in research.

2.3 Institutional Review Board (IRB)
The IRB was established by the Hospital and falls under the aegis of Adventist Health System, Sunbelt dba Florida Hospital. The IRB is an appropriately constituted group that the Hospital has designated to review and monitor research involving human subjects. The IRB shall receive all protocols in which the use of human subjects in research is proposed, regardless of the source of funding for such protocols. The IRB shall review and have the authority to approve, require modifications to secure approval or, disapprove research conducted by the Hospital; to suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that had been associated with unexpected harm to participants; and to observe or have a third party observe the consent process and the conduct of the research. The IRB shall exercise these authorities as it deems appropriate, consistent with the various federal regulations and Hospital policies that govern its work. No research with human subjects shall take place at Florida Hospital without the prior approval of the IRB.

The Hospital’s IRB has two panels with expertise required for the review of the Hospital’s widely varied human subjects research studies. Within this document, the term “the IRB” is used to refer to the Florida Hospital IRB and its panels.
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2.4 Principal Investigator (PI)
The principal investigator is the individual responsible for the conduct of research and, as such, must personally conduct or supervise the research. The PI is responsible for ensuring that the research study is accurate and complete before submitting it for IRB review; that IRB approval is obtained prior to initiation of research or before making any changes or additions to the research; that the IRB is informed of new information (e.g., from study sponsor) or changes to information previously presented to the IRB, and work with the IRB to determine if and how new information should be communicated to subjects; that progress reports are submitted to the IRB as required; that all non-compliance is reported to the IRB; and that all unanticipated problems or serious adverse events involving risk to human subjects are reported to the IRB. These responsibilities extend to research determined by the IRB to be exempt. The PI has the ethical obligation to protect the rights and welfare of participants in exempt studies as well as in studies that are subject to continuing IRB review. The PI is also responsible for ensuring that all members of the research team comply with the findings, determinations, and requirements of the IRB, including adequate performance of the informed consent process. These requirements apply in all forms of human subject research, even those determined to qualify for exemption.

The role of PI implies administrative and fiscal responsibility as well as sufficient expertise for the research.

2.5 Other Investigators
Other investigators may be students who are employees, employees in postdoctoral training programs, or fellows who have the primary research responsibility for an application submitted to the IRB. These investigators may take a leading role in the research, but do not have ultimate administrative and fiscal responsibility for the project. All investigators must be privy to all correspondence sent by the IRB that pertains to a project on which the investigator is listed.

2.6 Research team members
Every member of the research team is responsible for protecting human, reporting all non-compliance to the IRB, and for complying with all IRB findings, determinations and requirements. Team members must complete human subject research training as required by the IRB’s “Policy on Education and Certification of Investigators and Research Team Members Involved in Human Subjects Research.”

2.7 Other Hospital reviewers
In addition to IRB review, Florida Hospital human subjects research studies may be reviewed by other hospital committees and individuals charged with responsibility for evaluation of specific component research compliance issues. These may include one or more of the following committees, groups or individuals, when applicable. Review or approval by each committee or individual is generally required prior to IRB approval.

2.7.1 Conflict of Interest committee
2.7.2 Institutional Biosafety Committee
2.7.3 Radiation Safety and Lab Safety Program personnel
2.7.4 Institutional Privacy and Security Officer
2.7.5 Office of Research Administration
2.7.6 Cancer Center protocol review committee
2.7.7 Department or school level review committees
2.7.8 Legal Counsel
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The factual information, evaluations and recommendations of these research review units may be very useful to the IRB’s consideration of the rights and welfare of human subjects within the context of the specific Florida Hospital research study. IRB staff may return an application to the PI if relevant reviews have not been initiated or completed prior to IRB review.

The FHIRB retains final responsibility and authority to approve each FH research study that involves human subjects.