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Owner: *Stephanie Madrigal: Dir Clin Rsrch Admin/Ops*
Category/Chapter: *Compliance*
Areas/Depts: *Research*
Applicability: *OSF All Operating Units*

Establishment and Authority of OSF Human Subject Protection Program (HSPP)

DEFINITIONS:

1. **Research** - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities that meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes.
2. **Human Subject** - Defined by the Revised Common Rule (i.e., Final Rule, 2018) is a living individual about whom an investigator conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)].
3. **Human Subject Research** - A systematic investigation, including research development, testing and evaluation that involves human subjects, and is designed to develop or contribute to generalized knowledge.
4. **Human Subject Protection Program (HSPP)** - Interdepartmental, interdisciplinary programming that promotes and protects the rights and well-being of all human subject research stakeholders through policies and procedures that ensure scientific validity, ethical permissibility, operational feasibility, financial and contractual responsibility, and cultural sensitivity in the conduct of human subject research.

PURPOSE:

This policy establishes the existence and authority of the OSF Human Subject Protection Program (HSPP).

POLICY:

1. OSF HealthCare (OSF) hereby establishes and authorizes the Human Subject Protection Program (HSPP) as an office within the OSF Research Administration Department in order to foster a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of OSF.
2. The principles (i.e., respect for persons, beneficence, and justice) set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report) and the current edition of the Ethical and Religious Directives for Catholic Health Care Services will guide

the review and conduct of research. The actions of OSF will also conform to all applicable federal, state, and local laws and regulations.

3. The responsibilities of the HSPP include, but are not limited to:
 - a. Safeguard and promote the health and welfare of human research subjects by ensuring the protection of their rights, safety, and well-being;
 - b. Provide to the research community guidance and support in the conduct of human subject research (HSR);
 - c. Assist the research community in ensuring compliance with federal, state, local, and institutional laws, rules, regulations, policies, and procedures that are relevant to the conduct of HSR;
 - d. Provide timely and high quality education;
 - e. Develop, conduct, and evaluate regular quality assurance practices (e.g., monitoring, auditing, etc.); and
 - f. Facilitate excellence in HSR as an integral component of the OSF research enterprise.
4. The HSPP has jurisdiction over all human subject research conducted under the auspices of OSF, regardless of funding source or performance site. Research under the auspices of the institution includes research:
 - a. Conducted at any OSF facility;
 - b. That engages OSF as per federal guidance on “engagement” (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>);
 - c. Conducted by or under the direction of any employee or agent of this organization (including students) in connection with his or her organization responsibilities;
 - d. Conducted by or under the direction of any employee or agent (including students) of this organization using any property or facility of this organization; or
 - e. Involving the use of this organization's non-public information to identify, contact, or study human subjects.
5. This policy obligates all investigators conducting HSR under the auspices of OSF in any location, domestic or foreign, to conform to professional, organizational, local, and national principles and standards of ethical conduct that are at least equivalent to those promulgated by the U.S. Department of Health and Human Services (DHHS).
6. The HSPP administration and operations personnel include, but are not limited to:
 - a. The Institutional Official (IO)
 - b. HSPP Manager
 - c. HSPP Staff
 - d. OSF Research Administration
7. The Institutional Official (IO) and HSPP shall draft, vet, promulgate, and enforce standard operating procedures (SOPs) that operationalize this policy. The SOPs shall serve as the governing procedures for the conduct and review of all HSR conducted under the auspices of OSF.

This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by

OSF Healthcare System. The hospitals covered by this policy are:

		Name as listed with Medicare:
X	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
X	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
X	OSF Saint James – John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
X	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
X	OSF Saint Anthony's Health Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
X	OSF St. Francis Hospital & Medical Group	ST FRANCIS HOSPITAL
X	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
X	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Paul Medical Center	Mendota Community Hospital
X	OSF Heart of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Sacred Heart Medical Center	OSF HEALTHCARE SYSTEM

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step (Human Protection Administrator (HPA) Listed on FWA)	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	11/4/2019
Board of Directors	Danielle McNear: EXECUTIVE ASSISTANT	10/21/2019
President, OSF Healthcare System	Sister Diane Marie: PRESIDENT	10/8/2019
Ministry Chief Medical Officer	Ralph Velazquez: SYSTEM CHIEF MEDICAL OFFICER	10/2/2019
Executive Director, Research Administration	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	9/26/2019
Research Compliance Officer	Heather Hermann: RESEARCH COMPLIANCE OFFICER	9/26/2019
Policy Review Group	Marci Fletcher: RESOURCE DOCUMENT SPECIALIST	9/17/2019

Step Description	Approver	Date
Notification Step	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	8/15/2019

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