Origination:	*11/26/2018*
Effective:	*12/21/2020*
Approved:	*12/21/2020*
Next Review:	*12/21/2023*
Owner:	*Stephanie Madrigal: Dir Clin Rsrch Admin/Ops*
Category/Chapter:	*Compliance*
Areas/Depts:	*Research*
Applicability:	*OSF All Operating Units*

Ministry Research Administration Project Permission

DEFINITIONS:

1. **Clinical Investigation** (FDA definition) means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration, or is not subject to requirements for prior submission to the Food and Drug Administration, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
2. **The Code of Federal Regulations (CFR)** is the codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States.
3. **Human Subject** (DHHS definition) means a living individual about whom an investigator (whether professional or student) conducting research: obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
4. **Human Subject** (FDA definition) means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.
5. **Institutional Review Board (IRB)** is a committee whose primary responsibility is to protect the rights and welfare of human research subjects. It has the authority to approve, require modifications, or deny all research activities involving human subjects occurring at OSF HealthCare.
6. **OSF Research Projects** are activities outside of or in conjunction with normal healthcare operations, which have been determined to constitute research or a clinical investigation, that are conducted at an OSF HealthCare (OSF) location, by or on OSF Mission Partners (MPs), or using/disclosing data and/or biospecimens obtained from and/or about individuals or OSF for the purposes of the activity. Research Administration is consulted when it is unclear whether an activity constitutes an OSF research project for the purposes of this policy.
7. **Principal Investigator (PI)** is a scientist or health care professional that has accepted full responsibility for the scientific, administrative, ethical, legal, technical, operational and fiscal aspects for the management of a clinical investigation conducted at OSF HealthCare.
8. **Research** (DHHS definition) means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable 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.

PURPOSE:

1. To ensure OSF HealthCare (OSF) research projects are evaluated according to organizational, operational and regulatory considerations and receive OSF permission to be conducted prior to being initiated.
2. To ensure that changes of research projects for which OSF has granted permission are evaluated according to organizational, operational, and regulatory considerations, and receive OSF permission prior to implementation.

POLICY:

1. Prospective Principal Investigators (PIs) are responsible for preliminary determinations, including documenting and filing with project records, on whether project activities constitute research and thus is an OSF research project. Research Administration is consulted when it is unclear whether an activity, including usability testing, constitutes research.
2. OSF research projects are evaluated by the appropriate Institutional/Signatory Official (IO), or designee, for scientific validity and facility feasibility prior to submission to an institutional review board (IRB) for review and/or initiating the project.
3. OSF research projects are evaluated by the Research Administration Department ("Research Administration") and receive permission to proceed prior to submission to an institutional review board (IRB) for review and/or initiating the project.
4. PIs of OSF research projects are responsible for following the OSF application and evaluation process prior to initiating projects and prior to implementing changes of PI. This can be delegated by the PI to another individual.
5. Personnel working on OSF research projects complete CITI Program education prior to working on the projects (see Research Personnel Education Policy).
6. This policy applies regardless of whether the PI or project personnel are employed by OSF. Questions about the applicability of this policy to specific activities are addressed to the OSF Director, Clinical Research Administration.
7. OSF research projects align with the Ethical and Religious Directives (ERD) for Catholic Health Care Services.
8. OSF research projects are guided by the ethical principles as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("The Belmont Report").
9. OSF research projects follow all applicable state, federal and institutional rules and regulations that govern the conduct of research including, but not limited to:
    a. Department of Health and Human Service (DHHS) regulations at 45 CFR 46: Protection of Human Subjects
    b. Food and Drug Agency (FDA) regulations at 21 CFR 50: Protection of Human Subjects; 21 CFR 56: Institutional Review Boards; 21 CFR 54: Financial Disclosure; 21 CFR 312: Investigational Drugs; 21 CFR 600: Biological Products; and 21 CFR 812: Investigational Devices

c. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) E6 R2

d. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule")

10. Research Administration terminates the evaluation and permission granting process for studies that do not respond to requests for information within 30 calendar days.

PROCESS:

1. PIs, or their designee, send applications to conduct new OSF research projects, or to implement changes of OSF-permitted research projects, to the OSF Research Administration Department for evaluation prior to initiating the new project or implementing the change. Forms and procedures for sending the applications can be found on the OSF HealthCare Research website at https://www.osfhealthcare.org/research/.
2. PIs, or their designee, provide to Research Administration all information requested to complete the evaluation process.
3. PIs receive permission to conduct the new research project, or implement the change of research, from Research Administration prior to submitting to the IRB of record for review/approval.

REFERENCES:

1. United States Conference of Catholic Bishops. (June 2018). Ethical and Religious Directives for Catholic Health Care Services, Sixth Edition. Retrieved July 9, 2018 from http://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf.
2. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Retrieved July 9, 2018 from https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.
3. Code of Federal Regulations Title 45: Public Welfare, Part 46: Protection of Human Subjects. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt45.1.46&rgn=div5.
4. Code of Federal Regulations Title 21: Food and Drugs, Part 50: Protection of Human Subjects. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt21.1.50&rgn=div5.
5. Code of Federal Regulations Title 21: Food and Drugs, Part 54: Financial Disclosure by Clinical Investigators. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt21.1.54&rgn=div5.
6. Code of Federal Regulations Title 21: Food and Drugs, Part 56: Institutional Review Boards. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt21.1.56&rgn=div5.
7. Code of Federal Regulations Title 21: Food and Drugs, Part 312: Investigational New Drug Application. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt21.5.312&rgn=div5.
8. Code of Federal Regulations Title 21: Food and Drugs, Part 600: Biological Products. Retrieved July 9,

2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ab5eb0f39d316bb04bf13f9e1596d897&mc=true&node=pt21.7.600&rgn=div5.

9. Code of Federal Regulations Title 21: Food and Drugs, Part 812: Investigational Device Exemptions. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?SID=ec99a60404011f6cc7d0ed42491d53ed&mc=true&node=pt21.8.812&rgn=div5.
10. Code of Federal Regulations Title 45: Public Welfare, Part 164: Security and Privacy. Retrieved July 9, 2018 from https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr164_main_02.tpl.

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
X	OSF Little Company of Mary Medical Center	OSF HEALTHCARE SYSTEM

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	12/21/2020

Step Description	Approver	Date
Executive Steering Committee	Ronda Long: Coord Clinical Policy	12/17/2020
President, OSF Healthcare	Sister Diane Marie: President-Sister	11/10/2020
System Chief Medical Officer	Ralph Velazquez: System CMO	11/10/2020
Regulatory/Policies Council	Marci Fletcher: Resource Document Spec	11/4/2020
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	10/27/2020
Notification	Michael Bailey: Coord Clinical Research	10/27/2020