Origination:	*10/22/2018*
Effective:	*7/27/2021*
Approved:	*7/27/2021*
Next Review:	*7/26/2024*
Owner:	*Stephanie Madrigal: Dir Clin Rsrch Admin/Ops*
Category/Chapter:	*Compliance*
Areas/Depts:	*Research*
Applicability:	*OSF All Operating Units*

Research Project Personnel Education Requirements

DEFINITIONS:

OSF Research Projects are activities outside of normal healthcare operations, which have been determined to constitute research, that are conducted at an OSF HealthCare (OSF) location, by or on OSF Mission Partners (MPs), or using/disclosing OSF data or biospecimens from individuals for the purposes of the activity. Research Administration is consulted when it is unclear whether an activity is an OSF Research Project for the purposes of this policy.

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.

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.

FDA Regulated Research are research activities under the governance of applicable FDA regulations codified under Title 21, Chapter 1 of the Code of Federal Regulations (i.e., 21 CFR). FDA regulated research includes, but is not limited to:

1. Clinical trials involving an Investigational New Drug (IND) number OR IND exemption
2. Clinical trials involving an Investigational Device Exemption (IDE) number OR IDE exemption
3. Research ON FDA-approved drugs, devices, biologics, or Humanitarian Use Device [HUD; an approved HUD will have a Humanitarian Device Exemption (HDE) #]
4. Studies conducted to generate data for submission to the FDA (e.g., safety and efficacy/effectiveness).

NIH Funded Clinical Trials are research studies that satisfy ALL of the following criteria:

1. Receiving funding from the NIH
2. Involve living human participants
3. Investigators assign prospectively participants to an intervention
4. Study design evaluates the effect of intervention on participants, and
5. The effect under evaluation is health-related biomedical or behavioral outcome

PURPOSE:

To ensure individuals working on OSF research projects ("investigators and staff") are appropriately educated in the conduct of research.

POLICY:

1. Investigators and staff identified in the IRB submission and/or OSF research application as performing the following study-related tasks will comply with OSF education/training requirements by completion of courses through the web-based education/training services of the Collaborative Institutional Training Initiative (CITI) Program:
    a. Intervening with living human beings (e.g., blood draw, manipulation of body or environment, etc.)
    b. Interacting with living human beings (e.g., interview, online questionnaire, etc.)
    c. Conducting informed consent procedures (e.g., discussions with potential participants, obtain signatures or other documentation of consent, etc.)
    d. Obtaining private identifiable information OR identifiable biospecimens about/from living human beings; and/or
    e. Accessing, sharing, analyzing, or otherwise using private identifiable information, including Protected Health Information (PHI), about living human beings.
2. CITI Program education is completed in four core areas:
    a. Human Subjects Research (HSR);
    b. Conflict of Interest (COI);
    c. Responsible Conduct of Research (RCR); and
    d. Good Clinical Practice (GCP) when applicable
3. When conducting **FDA Regulated Research** OR **NIH Funded Clinical Trials**, investigators and staff must complete Good Clinical Practice (GCP) training in addition to the other three core areas.
4. Investigators and staff complete CITI Program education in the required core areas every three (3) years.
5. This policy applies regardless of whether the investigators and/or staff are employed by OSF. Questions about the applicability of this policy to specific activities are addressed to the OSF Director, Clinical Research Administration.
6. When investigators and staff complete CITI training courses under another institutional affiliation besides OSF HealthCare, the OSF Director, Clinical Research Administration or designee reviews copies of the CITI course Completion Reports to determine if they are acceptable in relation to the OSF versions of the CITI courses.

PROCESS:

Complete CITI Program Education

1. Investigators and staff complete CITI Program education courses under either the OSF HealthCare institution affiliation or another institution's affiliation by:
    a. Registering for a new CITI Program account and affiliating it with OSF HealthCare; or

b. Affiliating an existing CITI Program account with OSF HealthCare; or

c. Accessing Completion Reports for courses completed under another institution's affiliation in CITI.

2. When investigators and staff complete CITI Program education under another institution's affiliation, copies of the CITI Completion Reports are provided to OSF Research Administration for review.
3. Investigators and staff complete CITI Program education courses in the required areas every three (3) years at a minimum.

Confirm CITI Program Education Completion

1. OSF Research Administration confirms that all investigators and staff identified in the initial IRB submission and/or OSF research application have completed the CITI Program education requirements prior to allowing the application to proceed to IRB review.
2. When investigators and staff complete CITI Program education courses under the OSF HealthCare institution affiliation, the information is accessed and confirmed by Research Administration in the CITI Program system.
3. When investigators and staff complete CITI Program education under another institution's affiliation, copies of the CITI Completion Reports are reviewed by the OSF Director, Clinical Research Administration or designee to determine if they are acceptable.
4. Consequences of not meeting the requirements of this policy include, but are not limited to:
   a. Delay of OSF permission to conduct new research projects
   b. Investigators and staff being administratively removed from the research project
   c. Temporary suspension of research project enrollment and/or conduct

HYPERLINK:

www.citiprogram.org

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
X	OSF Saint Clare Medical Center	OSF HEALTHCARE SYSTEM

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	7/27/2021
Executive Steering Committee	Ronda Long: Coord Clinical Policy	7/22/2021
President, OSF Healthcare	Sister Diane Marie: President-Sister	7/6/2021
System Chief Medical Officer	Ralph Velazquez: System CMO	7/6/2021
Regulatory/Policies Council	Marci Fletcher: Resource Document Spec	6/30/2021
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	6/21/2021
Notification	Heidi Vermillion: Coord Research Admin	6/21/2021