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.

PURPOSE:

To ensure individuals working on OSF research projects (“research project personnel”) are appropriately educated in the conduct of research.

POLICY:

1. Research project personnel identified in the IRB submission and/or OSF research application complete education courses through the Collaborative Institutional Training Initiative (CITI) Program.
2. CITI Program education is completed in four core areas:
   a. Human Subjects Research (HSR);
   b. Conflict of Interest (COI);
   c. Good Clinical Practice (GCP); and
   d. Responsible Conduct of Research (RCR).
3. Research project personnel complete CITI Program education in the required core areas every three (3) years.
4. This policy applies regardless of whether the principal investigator (PI) or research 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.

5. When research project personnel 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. Research project personnel 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 research project personnel complete CITI Program education under another institution’s affiliation, copies of the CITI Completion Reports are provided to OSF Research Administration for review.

3. Research project personnel 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 research project personnel 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 research project personnel 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 research project personnel 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. Research project personnel 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:
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<th>Step Description</th>
<th>Approver</th>
<th>Date</th>
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<td>Education/Communication Step (Human Protection Administrator (HPA) Listed on FWA)</td>
<td>Stephanie Madrigal: DIR CLINICAL RSRCH ADM &amp; OPR</td>
<td>10/22/2018</td>
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<tr>
<td>Board of Directors</td>
<td>Danielle McNear: EXECUTIVE ASSISTANT</td>
<td>10/22/2018</td>
</tr>
<tr>
<td>President, OSF Healthcare System</td>
<td>Sister Diane Marie: PRESIDENT</td>
<td>10/4/2018</td>
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<tr>
<td>Ministry Chief Medical Officer</td>
<td>Ralph Velazquez: SYSTEM CHIEF MEDICAL OFFICER</td>
<td>10/3/2018</td>
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<tr>
<td>Human Protection Administrator (HPA) Listed on FWA</td>
<td>Stephanie Madrigal: DIR CLINICAL RSRCH ADM &amp; OPR</td>
<td>10/2/2018</td>
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<tr>
<td>Executive Director, Research Administration</td>
<td>Stephanie Madrigal: DIR CLINICAL RSRCH ADM &amp; OPR</td>
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<tr>
<td>Research Compliance Officer</td>
<td>Heather Hermann: RESEARCH COMPLIANCE OFFICER</td>
<td>9/27/2018</td>
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<tr>
<td>Policy Review Group</td>
<td>Christen Bergstresser: RESOURCE DOCUMENT SPECIALIST</td>
<td>9/25/2018</td>
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<tr>
<td>Notification Step</td>
<td>Stephanie Madrigal: DIR CLINICAL RSRCH ADM &amp; OPR</td>
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