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Maintenance of a Federalwide Assurance (FWA) for Research Subject to U.S. Department of Health and Human Services (HHS) Regulations

DEFINITIONS:

1. **Component** - a part of the Institution that may be viewed as a separate organization, but remains part of the legal entity or Institution
2. **Engagement in Human Subjects Research** - In general, an institution is considered engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. Institutions are engaged in a federal Department of Health and Human Services (HHS)-conducted or -supported non-exempt human subjects research project (and, therefore, would need to hold or obtain Office for Human Research Protections (OHRP)-approved Federalwide Assurances (FWAs) and certify institutional review board (IRB) review and approval to HHS) when the involvement of their employees or agents in that project includes engagement in human subject research AND/OR receiving an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.
3. **Federalwide Assurance (FWA)** - an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research. It is approved by OHRP for all human subjects research conducted or supported by HHS. The FWA is also approved by OHRP for federalwide use, which means that other U.S. federal departments and agencies that have adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule) may rely upon the FWA for the research they conduct or support. An FWA is the only type of assurance currently accepted and approved by OHRP. It is required whenever an Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule or a U.S. federal department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.
4. **Human Protections Administrator (HPA)** - the person named on the FWA who serves as the primary point of contact for an institution's system for protecting human subjects.

5. **Human Subject** is defined in 45 CFR 46.102(e)(1) as follows: a living individual about whom an investigator (whether professional or student) conducting research obtains
 - a. data through intervention or interaction with the individual, or
 - b. identifiable private information.
6. **Institution** - is defined in 45 CFR 46.102(f) as any public or private entity or agency (including federal, state, and other agencies).
7. **Institution's employees or agents**- individuals who: (1) act on behalf of the Institution; (2) exercise Institutional authority or responsibility; or (3) perform Institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
8. **Institutional Review Board (IRB)** - an institutional review board established in compliance with the requirements found under 45 CFR 46.
9. **IRB Authorization Agreement (IAA)** – Also known as a Reliance Agreement, is an agreement between an institution providing IRB review and an institution relying on the designated IRB of record. The agreement stipulates that the IRB will meet the human subjects protections requirements of the institution's OHRP-approved FWA, and will follow the institution's written procedures for reporting its findings and actions to appropriate officials at the institution. The IRB agrees to make available relevant minutes of IRB meetings to the institution upon request. The institution agrees to be responsible for ensuring compliance with the IRB determinations and the terms of its OHRP-approved FWA. The agreement must be kept on file by both parties and provided to OHRP upon request.
10. **Investigator** - an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies. Such involvement would include:
 - a. obtaining information about living individuals by intervening or interacting with them for research purposes;
 - b. obtaining identifiable private information about living individuals for research purposes;
 - c. obtaining the voluntary informed consent of individuals to be subjects in research; and
 - d. studying, interpreting, or analyzing identifiable private information or data for research purposes.
11. **Research** is defined in 45 CFR 46.102(d) as follows - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this Policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
12. **Signatory Official** - the person signing the FWA who must have the legal authority to represent the institution named in the FWA, as well as the Institutional components listed in the FWA.

PURPOSE:

OSF Healthcare System (OSF) is committed to protecting the rights and welfare of individuals who participate in Human Subjects Research. This Policy describes how OSF complies with the ethical and legal requirements for the conduct and oversight of Human Subjects Research subject to HHS regulations.

POLICY:

Scope:

This Policy applies whenever OSF becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule, unless the research is otherwise exempt from the requirements of the Common Rule. Federal Departments and Agencies which have adopted the Common Rule, and their CFR numbers, are listed on the OHRP Web site at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>.

Requirement to Maintain an FWA:

Maintenance of FWA

1. Prior to becoming engaged in research subject to HHS regulations, OSF obtains a FWA from HHS through the OHRP.
2. OSF renews its FWA every 5 years, per OHRP requirements.
3. OSF updates its FWA within 90 days after changes occur regarding the legal name of the Institution, the HPA, or the Signatory Official.
4. Any renewal or update that is submitted to, and accepted by, OHRP begins a new 5-year effective period.
5. OSF completes and submits its FWA (new submissions, updates, and renewals) using the electronic submission system available through the OHRP Web site at <http://ohrp.cit.nih.gov/efile/> as required by OHRP.

Signatory Official

1. OSF follows the OHRP guidance in allowing only high-level Institutional officials to serve as Signatory Official on the FWA. The official signing the FWA has the authority to represent OSF. Entities that the Signatory Official is not authorized to represent will not be covered under the FWA. The Signatory Official is the President, Chief Executive Officer, Chief Operating Officer, Chief Clinical Officer, Chief Medical Officer, or other high ranking official.
2. The intent in requiring that the Signatory Official be a high-level individual is two-fold. First, OHRP encourages Institutions to promote a culture of conscience for the ethical conduct of human subjects research at the highest level within the Institution. Second, the Signatory Official should be at a level of responsibility that would allow authorization of necessary administrative or legal action should that be required.
3. OSF follows OHRP recommendations in not allowing a Signatory Official to be the chair or member of any IRB designated under the FWA.

Human Protections Administrator

1. The Institution appoints an individual to be the human protections administrator (HPA) named on the FWA. This individual serves as the primary point of contact for the institution's system for protecting human subjects.
2. The HPA has comprehensive knowledge of all aspects of the institution's system of protections for human subjects, is familiar with the institution's commitments under the FWA, and plays a key role in ensuring that the institution fulfills its responsibilities under the FWA.
3. The HPA is responsible for research compliance oversight with the institution's policy and ethical norms,

including adherence to Catholic moral teaching as expressed in the "Ethical and Religious Directives for Catholic Health Care Services" (ERDs). The HPA seeks consultation from the Ethics Division as needed.

4. The HPA shares responsibility for ongoing ethics education of research stakeholders, including topics on Catholic research ethics and concerns.

Ethical Requirements

1. For both sponsored and non-sponsored human subjects research, OSF abides by ethical principles and Institutional policies and procedures.
2. If there is a conflict between ethical norms and legal or research sponsor expectations, the Ministry Director of Research Administration is notified in consultation with the Ministry Ethics Division. OSF Mission and Catholic health care ethical integrity are primary considerations.

Belmont Report

1. All human subjects research conforms to the ethical principles described in the Belmont Report.
2. These principles are:
 - a. Respect for persons (applied by obtaining informed consent, respecting privacy and confidentiality, and affording additional protections for vulnerable populations);
 - b. Beneficence (applied by weighing risks and benefits);
 - c. Justice (applied by the equitable selection of subjects)
3. A link to the Belmont Report is available in the References section of this Policy.

Ethical and Religious Directives for Catholic Healthcare Services

1. The principles contained in the ERDs are applied in their entirety to all activities conducted at OSF. The directives that apply to research include:
 - a. The inherent dignity of the human person must be respected and protected regardless of the nature of the person's health problem or social status. The respect for human dignity extends to all persons who are served by Catholic health care. ERD#23
 - b. A Catholic health care Institution, especially a teaching hospital, will promote medical research consistent with its mission of providing health care and with concern for the responsible stewardship of health care resources. Such medical research must adhere to Catholic moral principles. ERD#4
 - c. Nontherapeutic experiments on a living embryo or fetus are not permitted, even with the consent of the parents. Therapeutic experiments are permitted for a proportionate reason with the free and informed consent of the parents or, if the father cannot be contacted, at least of the mother. Medical research that will not harm the life or physical integrity of an unborn child is permitted with parental consent. ERD#51
 - d. Catholic health care Institutions should encourage and provide the means whereby those who wish to do so may arrange for the donation of their organs and bodily tissue, for ethically legitimate purposes, so that they may be used for donation and research after death. ERD#63
 - e. Catholic health care Institutions should not make use of human tissue obtained by direct abortions even for research and therapeutic purposes. ERD#66
 - f. The free and informed consent of the person or the person's surrogate is required for medical treatments and procedures, except in an emergency situation when consent cannot be obtained and there is no indication that the patient would refuse consent to the treatment. ERD#26

- g. Free and informed consent requires that the person or the person's surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects, consequences, and cost; and any reasonable and morally legitimate alternatives, including no treatment at all. ERD#27
 - h. Each person or the person's surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed health care decision of the person or the person's surrogate is to be followed so long as it does not contradict Catholic principles. ERD#28
 - i. No one should be the subject of medical or genetic experimentation, even if it is therapeutic, unless the person or surrogate first has given free and informed consent. In instances of nontherapeutic experimentation, the surrogate can give this consent only if the experiment entails no significant risk to the person's well-being. Moreover, the greater the person's incompetency and vulnerability, the greater the reasons must be to perform any medical experimentation, especially nontherapeutic. ERD#31
 - j. Catholic health institutions may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction both about the Church's teaching on responsible parenthood and in methods of natural family planning. ERD#52
2. Additionally, when research collaborations with external individuals or Institutions are pursued, Section 6 of the ERDs pertaining to partnerships are considered before entering into contracts or agreements.
 3. A link to the ERDs is available in the References section of this Policy.

Legal Requirements

1. In addition to compliance with the terms of the FWA, OSF complies with any additional applicable human subjects research regulations and policies of the U.S. federal department or agency which conducts or supports the research being conducted and any other applicable federal, state, local, or Institutional laws, regulations, and policies.
2. When OSF is engaged in non-exempt human subjects research conducted or supported by HHS, OSF complies with the requirements of subparts B, C, D, and E of the HHS regulations at Title 45 Code of Federal Regulations part 46, when applicable, for research involving pregnant women, fetuses, and neonates; prisoners; and children, respectively.
3. OSF cooperates with the OHRP in the event of a Compliance Oversight Evaluation, providing documentation as requested for activities for which OHRP has jurisdiction, as required under HHS regulations at 45 CFR part 5. OSF provides adequate accomodation and access to requested documentation in the event of an OHRP site visit and provides corrective actions to OHRP in a timely manner.

Responsibilities:

Signatory Official

1. The Signatory Official has the authority to take the following actions or delegate these authorities to a designee:
 - a. Oversee the protection of Human Subjects in accord with Catholic teaching on human dignity and legal norms
 - b. Determine what IRBs the Institution will rely upon

- c. Approve and rescind authorization agreements for IRBs
 - d. Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Subjects Research
 - e. Ensure that the research review process is free of undue influence
 - f. Ensure that officials of the Institution cannot approve research that has not been approved by a designated IRB.
 - g. Create Policies and Procedures related to Human Subjects Protections at the Institution that are binding on the Institution
 - h. Impose corrective actions up to and including barring individuals from conducting Human Subjects Research if the Signatory Official concludes such actions are required to maintain compliance
 - i. Disallow research approved by any IRB.
2. Other officials of OSF may decide that an IRB approved study may not be done at the Institution. However, no OSF official may approve non-exempt Human Subjects Research that has not been approved by one of OSF's designated IRBs.

IRBs

1. OSF relies upon external IRBs. External IRBs may be listed in Section 6 of the Institution's FWA. The use of external IRBs requires a thorough vetting of the IRB, including the IRB policies and procedures, and the approval of the Signatory Official.
2. When OSF relies on an external IRB, OSF enters into a Reliance Agreement / Institutional Authorization Agreement (IAA) for IRB review. Any IRB upon which OSF relies must be registered with OHRP and agree to review research in compliance with the terms of OSF's FWA(s) and other applicable Institutional policies.
3. Any IRB upon which OSF relies has written procedures for ensuring compliance with 45 CFR 46 which the IRB will follow.
4. IRBs relied upon by OSF have the authority to:
 - a. Approve, require modifications to secure approval, and disapprove Human Subjects Research overseen and conducted by the Institution for which they are the IRB of record.
 - b. Suspend or Terminate approval of Human Subjects Research that they have determined is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.
 - c. Observe or have a third party observe the consent process and research.

Institution Reporting Responsibilities

1. OSF promptly reports to the IRB and/or appropriate Institutional officials:
 - a. unanticipated problems involving risks to subjects or others;
 - b. serious or continuing noncompliance with the applicable U.S. federal regulations or the requirements or determinations of the IRB(s); and
 - c. suspension or termination of IRB approval.
2. OSF works with the IRB of record to ensure required reporting to the head of any U.S. federal department or agency conducting or supporting the research (or designee), and OHRP occurs promptly.

3. OSF reports to the IRB, prior to implementation, proposed changes in a research activity. Proposed changes are not initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the human subjects.
4. If a project that is suspended or terminated by the IRB involves a drug, device, diagnostic regulated by the FDA, or any other procedure regulated by the FDA, OSF ensures that the FDA is notified of the suspension/termination.

Investigators and Research Staff

1. Investigators and Research Staff of the Institution have the responsibility to:
 - a. Follow all ethical, legal, and Institutional requirements for the responsible conduct of human subjects research
 - b. Comply with the determinations and additional requirements of the IRB and the Institutional Official.
 - c. Complete all required human subjects protections training required by the Institution, IRB of record, and sponsoring Institution.

REFERENCES:

1. [Ethical and Religious Directives for Catholic Health Care Services Fifth Edition United States Conference of Catholic Bishops, Issued by USCCB, November 17, 2009.](#)
2. Office of the Secretary, [United States Department of Health, Education and Welfare \(18 April 1979\). "Protection of Human Subjects; Notice of Report for Public Comment" \(PDF\). Federal Register 44 \(76\): 23191-7. Archived from the original \(PDF\) on 2011-10-17](#)
3. [Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services Part 46 Protection of Human Subjects effective July 14, 2009.](#)

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

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	11/24/2020
Executive Steering Committee	Ronda Long: Coord Clinical Policy	11/17/2020
President, OSF Healthcare	Sister Diane Marie: President-Sister [MF]	10/27/2020
System Chief Medical Officer	Ralph Velazquez: System CMO	10/26/2020
Regulatory/Policies Council	Marci Fletcher: Resource Document Spec	10/21/2020
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	10/13/2020
Notification	Michael Bailey: Coord Clinical Research	10/13/2020

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