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

## Informed Consent for Research

### DEFINITIONS:

1. **Informed Consent for Research** - the process by which investigators respect autonomy and honor human dignity by ensuring that subjects, to the degree that they are capable, or their legally authorized representative be given the opportunity to choose whether or not to participate in Research after receiving all relevant information about the Research. Hereafter referred to in this policy as Informed Consent.
2. **Legally Authorized Representative (LAR)** - an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research.
3. **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.
4. **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.
5. **Clinical Trial (DHHS definition)** means a Research study in which one or more Human Subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
6. **Minimal Risk** - means that the probability and magnitude of harm or discomfort anticipated in the Research are not greater in and of themselves than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
7. **Assent** - an affirmative agreement to participate in research given by a subject who is unable to give Informed Consent due to age or lack of decisional capacity. An investigator should not interpret a subject's failure to object as "assent" unless the subject has also affirmatively agreed to be in the Research.
8. **Parental Permission** – a parent's agreement that their Child may participate in Research.
9. **Compound Authorization** – An authorization for use or disclosure of protected health information (PHI) that has been combined with another document or authorization (such as when an Informed Consent form is combined with an Authorization).

10. **Short Form** – a written consent form stating that the elements of informed consent have been presented orally to the subject or the subject's Legally Authorized Representative.
11. **Certificate of Confidentiality (CoC)** - A Certificate of Confidentiality helps researchers protect the privacy of research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.
12. **Genetic Information Non-Discrimination Act (GINA)** - The Genetic Information Nondiscrimination Act of 2008 (GINA) is a Federal law that prohibits discrimination in health coverage and employment based upon genetic information.
13. **Human Subject (DHHS)** - means a living individual about whom an investigator (whether professional or student) conducting rResearch: (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.
14. **Human Subject (FDA)** - 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.
15. **Institutional Review Board (IRB)** - 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 non-exempt research activities involving human subjects occurring at OSFHC.
16. **Child** – a person who has not attained the legal age for consent to treatments or procedures involved in clinical investigations. Legal age for consent is determined under the applicable law of the jurisdiction in which the research will be conducted. The law of the site of the research will determine the legal age of consent of the participant. One under the legal age for consent is also referred to as a "Minor." In Illinois, a Minor is generally defined as an individual under the age of 18 years (325 ILCS 45/2(c)) with exceptions as described in the statute.

## PURPOSE:

1. This Policy describes the OSF HealthCare (OSFHC) requirements for obtaining informed consent from living research subjects or their Legally Authorized Representative (LAR) prior to their participation in research. These requirements honor human dignity, ensuring a legal and ethical Informed Consent process.
2. This Policy applies to all Human Subjects Research (HSR) conducted at OSFHC or by OSFHC Mission Partners. The legal and ethical bases for this Policy are the principles of the *Belmont Report*, the *Ethical and Religious Directives for Catholic Health Care Services* (6<sup>th</sup> ed.), and applicable federal rules and regulations published and enforced by the Office for Human Research Protections (OHRP; 45 CFR 46) and the Food and Drug Administration (FDA; 21 CFR 50), both of which are within the Department of Health and Human Services (DHHS). OSFHC has filed a Federalwide Assurance (FWA) with DHHS as an attestation to comply with federal regulations applicable to federally funded/supported/conducted HSR. Depending on the type of research project, or the source of support/funding for the study or institution at which the study will be conducted (e.g., Department of Education), other federal (e.g., HIPAA, FERPA, etc.) and local (e.g., state law) requirements may apply.
3. Unless an Institutional Review Board (IRB) approves a waiver or alteration of informed consent procedures, OSFHC requires a research protocol to consist of appropriate informed consent procedures as a condition of institutional permission/approval.

# POLICY:

1. No investigator involves a living human being as a subject in Human Subjects Research covered by this Policy unless:
  - a. The investigator has obtained the legally effective Informed Consent or Assent as applicable, of the subject or the subject's LAR, or
  - b. The investigator has obtained a waiver of informed consent from the Institutional Review Board (IRB), or
  - c. The regulations at 21 CFR 50.23 *Exception from general requirements* or 21 CFR 50.24 *Exception from informed consent requirements for emergency research* apply.
2. Investigators seek consent only under circumstances that provide the prospective subject or their LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. Information given to the subject or the LAR is in a language and format understandable to the subject or the LAR.
4. The prospective subject or the LAR is provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. Informed Consent begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the Informed Consent is organized and presented in a way that facilitates comprehension.
6. Informed Consent as a whole presents information in sufficient detail relating to the research, and is organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.
7. No informed consent process, whether oral or written, includes any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability or negligence.

## **Informed Consent by Legally Authorized Representative**

1. OSFHC Mission Partners obtain informed consent from a Legally Authorized Representative (LAR) only if the IRB has approved use of a LAR.

## **Waivers of Informed Consent**

1. OSFHC Mission Partners are not required to obtain and/or document informed consent from subjects if the IRB has approved a waiver of Informed Consent process for the Research.
2. When an IRB approves an Informed Consent process which does not include, or which alters, some or all of the elements of Informed Consent, OSFHC complies with the IRB determinations regarding the required elements and manner of documentation.
3. The waiver of Informed Consent criteria the IRB applies are described at 21 CFR 50.23 and 45 CFR 46.116

## **Assent to Research Participation**

1. An IRB may require Assent procedures for Research involving minor subjects and research involving adults with diminished decision making capacity.
2. OSFHC Mission Partners obtain Assent from subjects in the manner approved by the IRB.
3. OSFHC Mission Partners comply with the IRB determination of whether and how Assent is to be documented in writing.

## **The Informed Consent Form**

1. OSFHC uses only IRB approved Informed Consent forms which contain the required elements of consent, as appropriate, for the type of study and the regulations which apply to that study.
2. OSFHC Informed Consent forms comply with all applicable federal, state and local laws, and adhere to standards set by OSFHC and applicable IRB(s).

## **Informed Consent form required elements**

1. A statement that the study involves research
2. An explanation of the purpose(s) of the research
3. The expected duration of the subject's participation
4. A description of the procedures to be followed
5. Identification of any procedures which are experimental
6. A description of any reasonably foreseeable risks or discomforts to the subject
7. A description of any possible financial costs to the subject
8. A description of any benefits to the subject or to others which may reasonably be expected from the research
9. A description of any payment or item given to the patient for participation in research, including when the subject will receive such and possible income tax implications
10. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
11. The extent, if any, to which confidentiality of records identifying the subject will be maintained
12. How to contact the investigator for questions, concerns, and complaints
13. How to contact someone independent of the investigator for questions, concerns, complaints, and subject rights
14. An explanation of whom to contact in the event of a research-related injury
15. A statement that participation is voluntary
16. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
17. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
18. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

### **Additional elements required for research involving more than Minimal Risk**

1. An explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
2. An explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained

### **Additional elements required for FDA-regulated research**

1. A statement that the FDA may inspect the records
2. For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials, the following statement: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." See OSFHC Policy "Registration of Clinical Trials"
3. The consent form does not give the subject the option of having data removed if it was already collected

### **When appropriate**

1. An explanation that the research may involve risks to the subject which are currently unforeseeable
2. An explanation that the research may involve risks which are currently unforeseeable to the unborn child if the subject is or may become pregnant
3. An explanation of anticipated circumstances under which the subject's participation may be stopped without the subject's consent
4. An explanation of any additional costs to the subject that may result from participation in the research
5. An explanation of the consequences of a subject's decision to withdraw from the research
6. An explanation of procedures for orderly termination of participation by the subject
7. An explanation that any new findings that may relate to the subject's willingness to continue participation will be provided to the subject
8. A statement about the approximate number of subjects involved in the study
9. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
10. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
11. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

12. An explanation of the amount, schedule, and form of all payments to the participant

### **Broad Consent**

1. OSFHC does not allow Broad Consent as described at 45 CFR 46.116.

### **Posting of clinical trial consent form**

1. When OSFHC is the awardee on clinical trials supported by a Federal department or agency, when required by the awarding agency, OSFHC posts the IRB-approved Informed Consent form (ICF) on a publicly available Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

### **Pregnancy and Infertility Language as applicable**

1. When a Research protocol requires pregnancy prevention or when infertility is a risk of participating in the research, OSFHC Mission Partners consult Research Administration for the currently approved ICF language.
2. Research that does not allow subjects to practice abstinence as an effective means of pregnancy prevention will not be approved. If the study does not allow this contact Research Administration for assistance.

### **When required, OSFHC includes the following additional elements for research subject to International Conference on Harmonisation - Good Clinical Practice (ICH-GCP) E6 R2**

1. A description of the IRB and its role
2. A description of the reasonably foreseeable risks to an unborn child or nursing infant, if any
3. When there is no intended clinical benefit to the subject, a statement to that effect
4. A description of the trial treatment(s) and the probability for random assignment to each treatment
5. A description of the trial procedures to be followed, including all invasive procedures
6. A description of the subject's responsibilities
7. A description of the alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks
8. The anticipated prorated payment, if any, to the subject for participating in the trial
9. A description of the compensation and/or treatment available to the subject in the event of trial-related injury (not tied to risk level)
10. A statement that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.
11. A statement about the expected duration of the subject's participation in the trial
12. A statement that the monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's LAR is authorizing such access

## **When Additional State Reporting Requirements exist**

1. If the finding of a reportable event is anticipated as part of the research and the reportable event is not incidental to the research, the investigator informs subjects during the Informed Consent process about the possibility of disclosure of the event if it occurs. The ICF includes a statement explaining that confidentiality may be breached due to State or local reporting laws, including instances of:
  - a. Child abuse or neglect
  - b. Elder abuse or neglect
  - c. Infectious diseases
  - d. HIV

## **When using the OSFHC Short Form Consent Form**

1. The OSFHC Short Form consent forms contain a statement that all of the elements of informed consent required by 21 CFR 50.25 and 45 CFR 46.117(b)(2) have been presented orally to the subject or the subject's LAR.
2. If applicable, the Short Form consent form contains the exact statement "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
3. OSFHC ensures that the IRB has approved a written summary of what is to be said to the subject or the LAR.
4. OSFHC requires a witness to be present during the entire oral presentation.
5. OSFHC requires the subject or their LAR and the witness sign and date the Short Form.
6. OSFHC requires the witness and the person obtaining consent sign and date the written summary.
7. OSFHC provides a copy of the written summary and the short form to the subject or the LAR.

## **Modifications to the IRB approved Informed Consent form**

1. When protocol revisions or other updates to the research require changes to the ICF, OSFHC obtains IRB approval of the modifications prior to enrolling subjects using the updated ICF.
2. OSFHC complies with IRB determinations regarding whether modifications to the protocol require investigators to obtain Informed Consent from previously enrolled subjects using the updated ICF.

## **Non-English Speaking Subjects**

1. OSFHC uses ICFs that are in a language understandable to the subject or their LAR.
2. When the study targets a population of non-English speaking subjects or the investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, OSFHC investigators use the IRB approved translation of the Informed Consent form.
3. If a non-English speaking potential subject is unexpectedly encountered, investigators will initiate the translation process with the IRB.
4. OSFHC follows IRB requirements for the informed consent process for non-english speaking subjects.

## **Illiterate English-Speaking Subjects**

1. Unless the IRB approval prohibits enrolling illiterate subjects, a person who speaks and understands

English, but does not read and write, can be enrolled in a study by "making their mark" on the consent form. Illinois State law allows an individual to "make their mark" instead of a signature, when necessary, and when the process is properly witnessed.

### **Subjects Physically Unable to Speak or Write**

1. With IRB approval, a person who can understand and comprehend spoken English, but is physically unable to speak or write, can be entered into a study if they:
  - a. Are competent, meaning they retain the ability to understand the concepts, risks, and benefits of the study when it is explained verbally and
  - b. The consent form documents the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study.

### **Blind Prospective Subjects/ Prospective Subjects with Motor Difficulties**

1. Subjects with motor difficulties who are able to fully engage in the consent process but are unable to write their name may "make their mark."

### **Genetic Information Non-Discrimination Act (GINA)**

1. When the protections provided by GINA apply to the study, OSFHC Mission Partners consult Research Administration for the currently approved ICF language.
2. Investigators ensure that descriptions of the reasonably foreseeable risks of genetic research and any statements describing the extent to which confidentiality of records identifying the subject will be maintained do not overstate the protections provided by GINA.

### **Certificate of Confidentiality (CoC)**

1. When a CoC applies to the study, OSFHC Mission Partners consult Research Administration for the currently approved ICF language.

### **Electronic or e-Consent**

1. OSFHC allows the use of e-Consent in the manner approved by the IRB and in compliance with 21 CFR Part 11, Electronic Record; Electronic Signatures, as applicable.

### **Pregnant Partners**

1. If the protocol states that collection of outcome data on partners of study subjects who become pregnant will occur, OSFHC consent forms inform subjects of the plan to collect data if their partner becomes pregnant.
2. OSFHC complies with the IRB determinations regarding the need to obtain consent from the pregnant partner for her participation and permission from one or both parents for participation of the infant.

### **Minors who Age Up**

1. Unless consent has been waived, OSFHC obtains the consent of subjects who reach the age of majority during the research in the manner directed by the IRB.

### **Compound Authorizations**

1. OSFHC may combine a HIPAA Authorization with an Informed Consent form (a compound authorization) only when allowed to do so by OSFHC Policy.

2. OSFHC ensures that when the provision of research-related treatment is conditioned on an authorization, and the compound authorization also contains an authorization for a secondary research activity, such as collecting samples for storage in a biobank for future use, the compound authorization:
  - a. Clearly differentiates between the conditioned (research related treatment) and unconditioned (biobanking) components; and
  - b. Provides the subject with an opportunity to opt in to the research activities described in the unconditioned authorization.

## **Subject Payment**

1. OSFHC includes a description of the requirement to issue a tax form 1099 if research payments from this or multiple studies total \$600 or more per year in the Informed Consent form.
2. OSFHC offers the subject the opportunity to provide their Social Security Number (SSN) or Taxpayer Identification Number (TIN) in order to receive payment, or to decline to provide the SSN or TIN and opt out of receiving payment.

## **Other Federal Agencies**

1. OSFHC includes additional elements of Informed Consent as required when conducting research sponsored by other Federal Agencies, such as the Department of Defense (DoD).

## **REFERENCES:**

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4. HIPAA Authorizations: General Rules (CC-400). Ministry HIPAA policy retrieved August 2018.
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7. 21 CFR 50 Protection of Human Subjects <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=50> retrieved August 2018.
8. 21 CFR 56 Institutional Review Boards <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=56> retrieved August 2018.
9. 45 CFR 46 Basic HHS Policy for Protection of Human Research Subjects <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html> retrieved August 2018.
10. 21 CFR Part 11, Electronic Record; Electronic Signatures <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11> retrieved August 2018.
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14. The AIDS Confidentiality Act (410 ILCS 305).

15. The Abused and Neglected Child Report Act (325 ILCS 5/1).
16. The Consent by Minors to Medical Procedures Act (410 ILCS 210).
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24. A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators. <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#nonenglish> retrieved August 2018.
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*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:*

		<b>Name as listed with Medicare:</b>
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	5/21/2019
Board of Directors	Danielle McNear: EXECUTIVE ASSISTANT	5/21/2019
President, OSF Healthcare System	Sister Diane Marie: PRESIDENT	5/7/2019
Ministry Chief Medical Officer	Ralph Velazquez: SYSTEM CHIEF MEDICAL OFFICER	4/26/2019
Human Protection Administrator (HPA) Listed on FWA	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	4/24/2019
Executive Director, Research Administration	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	4/24/2019
Research Compliance Officer	Heather Hermann: RESEARCH COMPLIANCE OFFICER	4/24/2019
Policy Review Group	Marci Fletcher: RESOURCE DOCUMENT SPECIALIST	4/23/2019
Notification Step	Stephanie Madrigal: DIR CLINICAL RSRCH ADM & OPR	4/22/2019