Status Active PolicyStat ID 17776115

Origination	5/21/2019
Approved	4/24/2025
Effective	4/24/2025
Next Review	4/23/2028

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

Informed Consent for Research

DEFINITIONS:

1. **Informed Consent for Research:** 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):** 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):** 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):** 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):** 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:** 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:** 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:** Parent's agreement that their Child may participate in Research.
9. **Compound Authorization:** 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:** 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):** 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):** 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):** Living individual about whom an investigator (whether professional or student) conducting Research: (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):** 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):** 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 OSF HealthCare System (OSF). The term “IRB of Record” refers to the IRB upon which OSF relies for a given protocol, and thus is the IRB that has jurisdiction over the conduct of the protocol at the OSF site.
16. **Child:** 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.
17. **Remote Consent:** Also termed **"teleconsent,"** is an IRB approved method of obtaining informed consent using a paper or electronic consent form where the study team and participant are not in the same physical location during the consent process.

18. **Electronic Consent (E-Consent)**: Use of IRB approved electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

PURPOSE:

To describe the OSF HealthCare System (OSF) requirements for obtaining legally effective 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.

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

OSF 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. OSF 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, OSF 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. OSF Mission Partners obtain Assent from subjects in the manner approved by the IRB.
3. OSF Mission Partners comply with the IRB determination of whether and how Assent is to be documented in writing.

Informed Consent Form

1. OSF 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. OSF Informed Consent forms comply with all applicable federal, state and local laws, and adhere to standards set by OSF 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 OSF 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

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

Posting of Clinical Trial Consent Form

When OSF is the awardee on clinical trials supported by a Federal department or agency, when required by the awarding agency, OSF 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, investigators refer to the “OSF Informed Consent Form Language” document for language that aligns with the “Ethical and Religious Directives for Catholic

Health Care Services."

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, OSF includes the Following Additional Elements for Research Subject to International Conference on Harmonization - 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

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:

1. Child abuse or neglect
2. Elder abuse or neglect
3. Infectious diseases

4. HIV

When Using the OSF Short Form Consent Form

1. OSF disallows the use of Short Form Consent Form as a matter of convenience or cost saving. OSF requires investigators and key personnel involved in conceptualizing and designing a protocol to assess reasonable expectation of enrolling subjects who do not speak and/or read English. Reasonable expectation will be assessed on (a) the objectives and design of the study (i.e., the expectation that data will be obtained from subjects who do not speak/read English), and (b) the diversity of the larger population from which the investigator will recruit the target population (i.e., the multicultural composition of the larger community will increase likelihood of encountering an eligible prospective subject who does not speak/read English).
2. Investigators and study teams will be knowledgeable of and comply with the requirements of the IRB of Record regarding the utilization of Short Form Consent Form materials and processes, including, but not limited to:
    a. How to obtain IRB review/approval of materials and processes for using Short Form Consent Form
    b. When Short Form Consent Form process is allowable
    c. Limits on occurrences (i.e., the number of prospective subjects with whom an investigator may use Short Form Consent Form for a particular protocol)
3. An independent interpreter who is fluent in both the prospective subject's language AND English must be present for a prospective subject who does not speak or read English. The investigator or designee may serve as the bilingual interpreter. Research conducted at/within OSF facilities should use OSF-provided interpretation services. Telephonic or video interpreting is allowable when interpreter is not available to be physically present. Family members and friends may not serve as interpreters EXCEPT in the instance of an emergency situation, and then only until an independent interpreter is available. However, adult family members and friends MAY interpret when:
    a. The prospective subject declines OSF interpreter services, AND
    b. The interpretation by a family member or friend does not compromise quality of care or violate confidentiality
4. The OSF 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.
5. 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."
6. OSF ensures that the IRB has approved a written summary of what is to be said to the subject or the LAR. The IRB of Record may allow the IRB-approved English version of the long ICF to serve as the written summary used for the Short Form.
7. OSF requires an impartial witness to be present during the entire oral presentation. The witness serves to attest to the voluntariness of the subject's consent and the adequacy of the

consent process by ensuring that the information was accurately conveyed and that the subject's questions were answered. The witness must be at least 18 years of age (adult; age of majority). The witness must be present physically or virtually (e.g., video conference), and must witness the entire oral presentation as well as the signatures. The witness may NOT be a member of the study team or the person obtaining consent. If possible, then the witness should not be related to the subject's family. The witness may be another staff member, patient advocate, or other person not related to the prospective subject in a manner that may unduly influence the witness or the subject. When using Short Form Consent Form for non-English speaking prospective subject, an independent interpreter may serve as the witness; however, regulations do not require an independent interpreter to serve as the witness. The witness should, at minimum, have sufficient proficiency in the language of the oral presentation to be able to attest to the information that was presented orally to the prospective participant.

8. OSF requires the subject or their LAR and the witness sign and date the Short Form.
9. OSF requires the witness and the person obtaining consent sign and date the written summary.
10. OSF provides a copy of the signed and dated 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, OSF obtains IRB approval of the modifications prior to enrolling subjects using the updated ICF.
2. OSF 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. OSF 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 reasonably expects that the consent interviews will be conducted in a language other than English, OSF investigators use the IRB approved translation of the Informed Consent from.
3. If a non-English speaking potential subject is unexpectedly encountered, investigators will initiate the translation process with the IRB.
4. If circumstances justify enrollment PRIOR to use of the fully translated IRB-approve ICF, then the investigator must consult the IRB of Record on the use of the Short Form Consent Form.
5. OSF follows IRB of Record requirements for the informed consent process for non-English speaking subjects.

Prospective Subjects with Limited English Literacy

1. Unless the IRB of Record approval prohibits enrolling subjects with limited English literacy, 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 and Michigan State law allows an individual to "make their mark" instead of a signature, when necessary, and when the process is properly witnessed. The process is properly witnessed in Illinois when TWO witnesses sign the consent form as attestation that they witnessed the individual making the mark. The process is properly witnessed in Michigan when ONE witness signs the consent form.

2. Investigators must consult the IRB of Record on the use of Short Form Consent Form.

Subjects Physically Unable to Speak or Write

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:

1. Are competent, meaning they retain the ability to understand the concepts, risks, and benefits of the study when it is explained verbally and
2. 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

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." The process is properly witnessed in Illinois when TWO witnesses sign the consent form as attestation that they witnessed the individual making the mark. The process is properly witnessed in Michigan when ONE witness signs the consent form.

Genetic Information Non-Discrimination Act (GINA)

1. When the protections provided by GINA apply to the study, OSF 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)

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

Electronic Consent (E-Consent)

1. The use of an electronic signature in lieu of a traditional handwritten signature may be accepted in the appropriate research context. Federal regulations and guidance and state law must be followed as applicable to the study [e.g., FDA requirement for 21 CFR Part 11; Uniform Electronic Transaction Act (UETA)].

2. The process and tools used to obtain an electronic signature must be detailed and documented in the study protocol or in an attachment when submitted to as required by the IRB for review.

Remote Consent (Teleconsent)

1. Remote Consent is always permitted for studies unless otherwise noted.
2. Remote Consent procedures may include E-Consent procedures, including, but not limited to those described elsewhere in this policy.
3. OSF allows for the use of Remote Consent in the manner approved by the IRB of Record and in compliance with applicable informed consent regulations set forth in 45 CFR part 46 and 21 CFR parts 11, Electronic Record; Electronic Signatures 50, as applicable and 56. The IRB of record may have additional requirements (e.g., use of a witness, documentation).
4. Remote Consent may occur via telephone, conference call, video conferencing, telemedicine, or other methods
5. The subject or their LAR must be provided with a copy of the consent form prior to engaging in the informed consent conversation in order to allow the subject sufficient time to review the consent form and to use it as a reference during the conversation
6. The consent form can be provided to the subject via postal mail, email, fax, or another method. If mailed, two copies must be mailed so the subject or LAR is able to retain a copy for reference when their signed consent form is returned to the site, and they are waiting to receive the final copy with all necessary signatures back from the site.
7. The investigator/designee must discuss the study with the subject via telephone, conference call, video conferencing, telemedicine, or other methods in a manner that resembles an in-person discussion (i.e., pacing, eye-contact, empathy, enunciation).
8. The investigator/designee must implement a method to ensure the identity of the subject or LAR (e.g., verification of state identification or other identifying documents or use of personal questions or visual methods).
9. A witness will be present during the consent discussion. The witness may be a member of the study team; however, to minimize bias or undue influence, the witness should be impartial and independent. The witness must hear both sides of the entire consent discussion. Documentation of the witness will be included in the subject's electronic health record. The requirement for and means of documenting the witness' signature will be determined by the IRB of record in accordance with its policies and in compliance with applicable regulations and GCP standards. A witness is necessary when, but not limited to:
    a. Required by IRB regulations/policies, OR
    b. FDA regulations (i.e., short form informed consent), OR
    c. Good Clinical Practice (GCP) requirement (i.e., an impartial witness is necessary when a subject or LAR cannot read).
10. The consent form must be signed by both the subject or LAR and the investigator/designee.
    a. If the subject or LAR agrees to participation after the consent discussion, they must sign and date the consent form and return it to the investigator. Options include an

electronic system, such as, but not limited to DocuSign or REDCap, or other electronic method, such as, but not limited to scanning, or photographing the signed consent form and sending it electronically it to the investigator. If postal mail is used, a pre-paid, self-addressed envelope should be provided to the subject or LAR to mail the signed consent form back to the investigator.

b. Once the research team receives the signed consent form from the subject or LAR, the investigator/designee who conducted the consent process must sign and date the document using the current date.

c. Investigator/designee must document the reason for performing the informed consent remotely, the method remote consent was conducted, the date of the informed consent discussion, and the date the signed consent form was received. [NOTE: National Cancer Institute (NCI) Central IRB (CIRB) requires this documentation to be under the signature line.]

d. The date the investigator/designee signs the consent form, not the date the consent discussion with the subject or LAR took place, is the official date of informed consent for the subject on the trial.

11. The final consent form must be filed in the designated investigator/site regulatory file location.
12. A copy of the final consent form, signed by the subject or LAR, and the investigator must be sent back to the subject electronically or as a hard copy using an electronic format or a physical delivery method.
13. No research activities related to the study can begin until all steps of the informed consent process are complete.

Pregnant Partners

1. If the protocol states that collection of outcome data on partners of study subjects who become pregnant will occur, OSF consent forms inform subjects of the plan to collect data if their partner becomes pregnant.
2. OSF 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

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

Compound Authorizations

1. OSF may combine a HIPAA Authorization with an Informed Consent form (a compound authorization) only when allowed to do so by the IRB of Record.
2. OSF 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. OSF includes in the Informed Consent form a description of the requirement to issue a tax form 1099 if research payments from OSF, including research and non-research compensation or incentives, total $600 or more per year. Investigators should consult Research Administration for current language.
2. OSF offers the subject the option to receive payment and provide the necessary Social Security Number (SSN) or Taxpayer Identification Number (TIN) in order to receive payment, or to decline payment and not provide the SSN or TIN and opt out of receiving payment.

Other Federal Agencies

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

REFERENCES:

1. Code of Federal Regulations (CFR): HIPAA Administrative Simplification. 45 CFR §160.103 https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-160/subpart-A/section-160.103
2. Code of Federal Regulatoins (CFR): Privacy of Individually Identifiable Health Information. §164.501, §164.508 and §164.512 https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E
3. 21 CFR 50 Protection of Human Subjects https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50
4. 21 CFR 56 Institutional Review Boards https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56
5. 45 CFR 46 https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46.
6. 21 CFR Part 11, Electronic Record; Electronic Signatures https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11
7. 42 CFR 11 Clinical Trials Registration and Results Information Submission https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-11
8. Illinois Health Care Surrogate Act (755 ILCS 40 et seq.).
9. Mental Health Treatment Preference Declaration Act (755 ILCS 43/).
10. Medical Practice Act (410 ILCS 50/3.1).
11. The AIDS Confidentiality Act (410 ILCS 305).

12. The Consent by Minors to Medical Procedures Act (410 ILCS 210).
13. The Control of Communicable Diseases Code (77 Ill. Adm. Code 690)
14. United States Conference of Catholic Bishops. (June 2018). Ethical and Religious Directives for Catholic Health Care Services, Sixth Edition. http://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf
15. The Food and Drug Administration Amendments Act (FDAAA) of 2007 (US Public Law 110-85) https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf.
16. Certificates of Confidentiality https://humansubjects.nih.gov/coc/index
17. The Genetic Information Nondiscrimination Act of 2008 (P.L. 110-233, 122 Stat. 881 (GINA) https://www.gpo.gov/fdsys/pkg/PLAW-110publ233/pdf/PLAW-110publ233.pdf
18. The Genetic Information Nondiscrimination Act of 2008 Information for Researchers and Health Care Professionals https://www.genome.gov/pages/policyethics/geneticdiscrimination/ginainfodoc.pdf
19. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry. https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf.
20. NIH Genomic Data Sharing Policy https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf.
21. Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications.https://osp.od.nih.gov/wp-content/uploads/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf
22. NHGRI Special Informed Consent Considerations, see https://www.genome.gov/27559024/informed-consent-special-considerations-for-genome-research/.
23. 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. https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf.
24. Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers.
25. National Cancer Institute Central Institutional Review Board Standard Operating Procedures. https://www.ncicirb.org/about/cirb-standard-operating-procedures.
26. Illinois Uniform Electronic Transactions Act (815 ILCS/333). https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=4165&ChapterID=67.
27. Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent.

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 Saint Francis Hospital	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
X	OSF Healthcare Divine Mercy Continuing Care Hospital	Greater Peoria Specialty Hospital, LLC
X	OSF Saint Katharine Medical Center	OSF HEALTHCARE SYSTEM

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	4/24/2025
Executive Steering Committee	Amy Olsen: Coord Clinical Policy RN	4/24/2025
System Chief Operating Officer	Michael Cruz: Chief Operating Ofcr-ScpD [MT]	4/3/2025
Regulatory/Policies Council	Michael Theisen: Coord Resource Documents	4/2/2025

Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	3/16/2025
Notification	Heidi Vermillion: Coord Clin Rsrch Bus II	3/12/2025

Applicability

OSF Almost Home Kids, OSF Aviation, OSF Divine Mercy Continuing Care Hospital, OSF Healthcare Foundation, OSF Heart of Mary Medical Center, OSF Holy Family Medical Center, OSF Home Care Services, OSF Little Company of Mary Medical Center, OSF Ministry Services, OSF Ministry Wide, OSF Offices/Clinics, OSF OnCall, OSF PACE, OSF Pointcore, Inc., OSF Sacred Heart Medical Center, OSF Saint Anthony Medical Center, OSF Saint Anthony's Health Center, OSF Saint Clare Medical Center, OSF Saint Elizabeth Medical Center, OSF Saint Francis Hospital, OSF Saint Francis Medical Center, OSF Saint James-John W. Albrecht Medical Center, OSF Saint Katharine Medical Center, OSF Saint Luke Medical Center, OSF Saint Paul Medical Center, OSF St. Joseph Medical Center, OSF St. Mary Medical Center

Standards

No standards are associated with this document