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Owner	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops
Category/ Chapter	Compliance
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FERPA Regulations in Research

DEFINITIONS:

- 1. **De-Identified Record** is a record from which all Personally Identifiable Information has been removed.
- 2. **Directory Information** means information contained in an Education Record that would not generally be considered harmful or an invasion of privacy if disclosed. Each educational institution has the authority to determine what information is included as Directory Information within the limits of FERPA regulations.
- Disclosure or Disclose means to permit access to or the release, transfer or other communication of
 personally identifiable information contained in education records by any means, including oral, written
 or electronic means to any party except the party identified as the party that provided or created the
 record.
- 4. Education Records are those records that are:
 - a. Directly related to a student; and
 - b. Maintained by an educational institution or by a party acting for the institution.
 - c. Education Records do not include:
 - i. Records that are kept in the sole possession of the maker, are used only as a personal memory aid, and are not accessible or revealed to any other person except a temporary substitute for the maker of the record.
 - ii. Records of the law enforcement unit of an educational institution, subject to the provisions of § 99.8.
 - iii. Records relating to an individual who is employed by an educational institution, that:
 - 1. Are made and maintained in the normal course of business;
 - 2. Relate exclusively to the individual in that individual's capacity as an employee; and
 - 3. Are not available for use for any other purpose.

- iv. Records relating to an individual in attendance at the institution who is employed as a result of his or her status as a student are education records and not excepted under paragraph (b)(3)(1) of this definition.
- v. Records on a student who is 18 years of age or older, or is attending an institution of postsecondary education that are:
 - 1. Made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or para-professional acting in his or her professional capacity or assisting in a para-professional capacity;
 - 2. Made, maintained, or used only in connection with treatment of the student; and
 - 3. Disclosed only to individuals providing the treatment (not including remedial educational activities or activities that are part of the program of instruction at the institution.
- vi. Records created or received by an educational agency or institution after an individual is no longer a student in attendance and that are not directly related to the individual's attendance as a student.
- vii. Grades on peer-graded papers before they are collected and recorded by a teacher.
- 5. Eligible Student is a student who has reached 18 years of age or is attending an institution of postsecondary education.
- 6. **Family Educational Rights and Privacy Act (FERPA)** is a Federal law that protects the privacy of student Education Records. This law applies to all schools, agencies and institutions that receive funds under an applicable program of the U.S. Department of Education (ED).
- 7. Legitimate Educational Interest or "need to know" is the need to access an education record in order to perform a teaching or administrative task that is specified in the position description or contract agreement of an academic official, perform a task related to a student's education or to discipline of a student, provide a service or benefit related to the student or student's family, or maintain the safety and security of campus. An example would be an academic advisor to a student reviewing the student's record on what courses have been completed. This is related to the task of advising the student. The advisor would not be authorized to view records that are not relevant to the task at hand.
- 8. **Parent** includes a natural parent of a student, a guardian or an individual acting as a parent in the absence of a natural parent or guardian.
- 9. Personally Identifiable Information (PII) includes, but is not limited to, a student's name; name of student's parent or other family members; the address of a student or student's family; a personal identifier, such as the student's social security number, student identification number, including any portion thereof, or biometric record; other indirect identifiers, such as a student's date of birth, place of birth and mother's maiden name; other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; or information requested by a person who the educational institution reasonably believes knows the identity of the student to whom the education record relates.
- 10. **Records Custodian** is the staff member responsible for student records within the area where the record is located.
- 11. **School Official** is a person employed by the College in an administrative, supervisory, academic or research, or support staff position (including law enforcement unit personnel and health staff); a person or company with whom the College has contracted (such as an attorney, auditor, or collection agent); a person serving on the College Board; or a student serving on an official committee, such as a disciplinary or grievance committee, or assisting another school official in performing his or her tasks, who acts in

the student's educational interest within the limits of their "need to know" in order to perform a specific task and whose responsibilities reasonably require access to student records..

12. **Student** is an individual who is presently enrolled and attending, or has been enrolled and attended the OSF College of Health Sciences or other academic institution/program, and for whom OSF HealthCare or other academic institution/program maintains records.

PURPOSE:

To ensure that all human subjects research studies conducted under the auspices of OSF involving student Education Records are conducted in accordance with the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) and OSF policies.

POLICY:

- 1. Investigators conducting human subject research under the auspices of OSF that involves access to Education Records will comply with relevant Family Educational Rights and Privacy Act (FERPA) regulations, and policies and procedures for human subject protection.
- 2. OSF retains the authority to determine what information may be accessed from an OSF Education Record.
- 3. If OSF denies an investigator access to information in an OSF Education Record, then a Human Subject Protection Program (HSPP) / Institutional Review Board (IRB) cannot overrule the decision.
- 4. The OSF HSPP and the IRB of record assesses FERPA requirements when reviewing research studies that involve access to student Education Records.
- 5. OSF investigators must comply with FERPA regulations for obtaining consent or obtaining exception to consent to access Education Records for research.
 - a. Consent
 - i. Parents consent to the disclosure of their children's Education Records. These rights transfer to the student when he or she becomes an Eligible Student (e. reaches the age of 18 or attends a school beyond the high school level).
 - Eligible Students or parents provide signed and dated written consent before Personally Identifiable Information (PII) from Education Records is disclosed, unless the disclosure falls within one of the exceptions set forth in 34 CFR 99.31.
 - iii. Informed consent forms (ICFs) for OSF studies involving Education Records include the following elements:
 - 1. Specification of the records that may be disclosed;
 - 2. A statement of the purpose of the disclosure; and
 - 3. Identification of the party or class of parties to whom the disclosure will be made.
 - iv. OSF investigators will use the OSF "FERPA Consent for Research" template
 - b. Exceptions to Obtaining Consent
 - i. Access to DE-IDENTIFID information: Education records are released without consent provided a school official (other than the investigator) with appropriate access strips the records of all personally identifiable information.
 - Access to IDENTIFIABLE information: Personally identifiable information from an OSF Education Record of a student may be disclosed without the student's consent when

- 1. The information is "directory information" as defined by policy [Saint Anthony College of Nursing "Directory Information (368)]:
 - a. Student's current and previous name(s)
 - b. Student's date of birth
 - c. Dates of attendance
 - d. Enrollment status
 - e. Degree earned
 - f. Previous Institutions of Higher Education Attended
 - g. Honors and Awards Earned
- 2. The disclosure is to investigators who have been determined to have Legitimate Educational Interest (see Definitions) by the records custodian.
- 3. The disclosure is to organizations conducting studies for, or on behalf of, OSF to:
 - a. Develop, validate, or administer predictive tests.
 - b. Administer student aid programs.
 - c. Improve instruction.
- 6. When research studies propose to access Education Records without parental/student consent, the HSPP and IRB of record:
 - a. considers whether the records access meets the criteria for a waiver of informed consent at 45 CFR 46.116, and if so,
 - b. notifies investigators of their responsibilities to obtain exception(s) to parental/student consent at each educational institution from which education records access is requested.

PROCESS:

- OSF investigators who plan to conduct research involving educational records from other institutions must contact each institution from which s/he proposes to access student records and follow that institution's FERPA policy and procedures.
- 2. Investigators who wish to access de-identified OSF student education records submit a request for student data to the appropriate School Official who serves as the Records Custodian.
 - a. The request identifies the purpose of the data request, all requested data points and any related IRB study associated with the data request.
 - b. The investigator enters into a data agreement with the appropriate School Official who serves as the Records Custodian of the Education Records, to which the investigator seeks access for use of the data.
 - c. OSF Education Records are stripped of all personally identifiable information by a School Official (other than the investigator) with appropriate access, including:
 - i. Student's name and other direct personal identifiers, such as the student's social security number or student number.
 - ii. Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth and mother's maiden name.
 - iii. Biometric records, including one or more measurable biological or behavioral

characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.

- iv. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.
- 3. An investigator who plans to obtain identifiable OSF student Education Records as a School Official with Legitimate Educational Interest requests an exception to FERPA. The request is submitted to the appropriate School Official who serves as the Records Custodian of the Education Records, to which the investigator seeks access..
 - a. The request identifies the purpose of the data request, all requested data points and any related HRPP/IRB study associated with the data request.
 - b. The investigator enters into a data agreement with the appropriate School Official who serves as the Records Custodian of the Education Records, to which the investigator seek access.
- 4. A school district or postsecondary institution that wishes to access identifiable OSF student education records to develop, validate, or administer predictive tests, administer student aid programs or improve instruction requests an exception to FERPA. The request is submitted to the appropriate School Official who serves as the Records Custodian of the Education Records, to which the investigator seeks access.
 - a. The request identifies the purpose of the data request, all requested data points and any related HRPP/IRB study associated with the data request.
 - b. The investigator enters into a data agreement with the appropriate School Official who serves as the Records Custodian of the Education Records, to which the investigator seeks access. The data agreement specifies:
 - i. The determination of the exception;
 - ii. The purpose, scope, and duration of the study;
 - iii. The information to be disclosed;
 - iv. That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(1)(6) on re-disclosure and destruction of information;
 - v. That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests;
 - vi. The data storage and security plan (e.g., locked storage cabinet, encrypted and/or password protected e-files, etc.);
 - vii. That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
 - viii. The time period during which the organization must either destroy or return the information.

REFERENCES:

- 1. 34 CFR 99 Family Educational Rights and Privacy Act https://www.ecfr.gov/cgi-bin/text-idx?SID=c8901a9ed23422b70af2540fde438ebc&mc=true&node=pt34.1.99&rgn=div5#se34.1.99_131.
- 2. 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.

- 3. 20 U.S.C. § 1232g Family Educational and Privacy Rights <u>https</u>://www.govinfo.gov/app/details/ USCODE-2011-title20/USCODE-2011-title20-chap31-subchapIII-part4-sec1232g.
- 4. Saint Anthony College of Nursing: Directory Information (368).

HYPERLINK:

- 1. <u>https</u>://www.ecfr.gov/cgi-bin/textidx?SID=c8901a9ed23422b70af2540fde438ebc&mc=true&node=pt34.1.99&rgn=div5#se34.1.99_131
- 2. https://studentprivacy.ed.gov/?src=fpco
- 3. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

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:
Х	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
Х	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
Х	OSF Saint James - John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
Х	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
Х	OSF Saint Anthony's Health Center	OSF HEALTHCARE SYSTEM
Х	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
Х	OSF St. Francis Hospital & Medical Group	ST FRANCIS HOSPITAL
Х	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
Х	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
Х	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM
Х	OSF Saint Paul Medical Center	Mendota Community Hospital
Х	OSF Heart of Mary Medical Center	OSF HEALTHCARE SYSTEM
Х	OSF Sacred Heart Medical Center	OSF HEALTHCARE SYSTEM
Х	OSF Little Company of Mary Medical Center	OSF HEALTHCARE SYSTEM
Х	OSF Saint Clare Medical Center	OSF HEALTHCARE SYSTEM

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	10/3/2022
Executive Steering Committee	Sara Sutton: Coord Clinical Policy RN [MT]	9/22/2022

President, OSF Healthcare	Sister Diane Marie: President- Sister [MT]	8/11/2022
System Chief Medical Officer	Ralph Velazquez: System CMO	8/11/2022
Regulatory/Policies Council	Michael Theisen: Resource Document Spec	8/10/2022
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	8/1/2022
Notification	Heidi Vermillion: Coord Research Admin	8/1/2022

