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

Scientific Research Data

DEFINITIONS:

Scientific Research Data - For the purpose of this policy, "Scientific Research Data" includes but is not limited to recorded factual material (in any media or format), biological and other research material, and the associated processes (including protocols, procedures, equipment descriptions, diagrams, work flow charts, etc.) that are commonly accepted in the scientific community as both necessary and sufficient to document and support research findings. Scientific Research Data dos NOT include any of the following:

1. Preliminary analyses (e.g., laboratory notebooks, preliminary analyses, completed case report forms), drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples);
2. Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and
3. Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study

PURPOSE:

1. Accurate and appropriate documentation of the results of research is an essential feature of any research project. OSF HealthCare System (OSF) and its investigators share an interest in assuring that Scientific Research Data are accurately recorded, appropriately used, retained for the required period of time, and available for review under the appropriate circumstances. In addition, increased mobility among researchers has resulted in the need to provide for guidelines governing continued access to Scientific Research Data. This Policy is written to address these issues at OSF.
2. This Policy applies to all OSF Mission Partners (MPs), OSF students, and any other individual involved in the design, conduct or reporting of research at OSF. It applies to all Research Data created by those individuals, regardless of the type of research or the source of support for the project.

POLICY:

Ownership

1. OSF is the owner or joint owner of all Scientific Research Data that is created or collected by its employees, students, contractors, collaborators, and non-OSF investigators to whom this Policy applies, except when the creation or collection of such data is governed by a written agreement or contract to the contrary. The OSF Intellectual Property and Technology Transfer Policy may apply as well.
2. OSF's ownership of Scientific Research Data extends from OSF's obligation to be legally and financially accountable for issues related to Scientific Research Data. These obligations include the responsibility to investigate allegations of research misconduct; to protect the right of researchers to access Scientific Research Data they collect; to ensure appropriate protections for human subjects in research; to secure and protect intellectual property rights; and to provide and protect Research Data as required by terms and conditions of awards.

Rights and Responsibilities

On behalf of OSF, the Principal Investigator (PI) is the custodian of the Scientific Research Data and is ultimately responsible for meeting the collection and retention requirements relating to Scientific Research Data. However, because other members of the research team such as, but not limited to co-/sub-investigators, trainees (e.g., students), and research staff (e.g., Research Coordinator) may have obligations for Scientific Research Data collection and retention, this policy uses the term "investigator" to refer to all such team members.

Collection and Retention

1. Investigators are responsible for the orderly collection, retention, cataloguing, handling (e.g., sharing, transmitting), and proper storage of Scientific Research Data. Investigators will also ensure retention of complete records to document the methods used; accuracy of the Scientific Research Data collected and interpreted; and compliance with award terms and OSF requirements, including appropriate protections for human subjects in research and safeguards for protecting privacy and confidentiality of research subjects.
2. Principal investigators are ultimately responsible for retention of Research Data consistent with OSF Policies, applicable regulations, editorial or publication standards, and terms of contracts or awards. See the OSF Retention and Destruction of Documents Policy for additional information.
3. Whenever possible, the original Scientific Research Data are part of the research record. Scientific Research Data are ordinarily retained in the Principal Investigator's lab, office, or the unit where data are created, but in any event, in facilities owned or leased by OSF, on devices or in databases owned or sanctioned by OSF, and consistent with any sponsored agreements and Institutional Review Board (IRB) approvals.

Access

1. As owner or joint owner of the Scientific Research Data, OSF has the right to access the original Scientific Research Data to ensure that OSF meets its obligations of legal, ethical, and financial accountability. The investigator(s) will provide such access to OSF upon request. The investigator(s) provide access to authorized representatives of extramural sponsors of the research and/or to designated government officials, where such access is deemed appropriate by OSF to ensure its accountability for the Scientific Research Data. The PI also facilitates requests for access to Research Data by members of the research

team who were involved significantly in the design, conduct, or reporting of the Scientific Research Data.

2. When a collaboration comes to an end, and Scientific Research Data were created during the collaboration, each member of the collaboration retains access to that data.

Security

OSF Policies for data security are followed in conjunction with this Policy.

Sharing of Research Data

Data collected or created in the conduct of research developed with federal funds is shared upon request for non-commercial purposes in accordance with data management and sharing policies adopted by federal agencies. It is the responsibility of the PI to follow the requirements imposed by any sponsors of research and, as applicable, the informed consent document, HIPAA Authorization, and conditions of IRB approval.

Incoming Transfer

1. A newly hired OSF employee may bring pre-existing Scientific Research Data to OSF only after an appropriate written data agreement is in place. The newly hired OSF employee should contact Research Administration for information about data agreements.
2. An OSF employee, student, contractor, collaborator, or non-OSF investigator may receive existing Scientific Research Data from a non-OSF investigator where OSF would become responsible for the security, retention, or other requirements associated with the Scientific Research Data, only after a written agreement is in place. The providing AND receiving individuals associated with the data transfer should contact Research Administration for information about data agreements.
3. If the incoming transfer involves the transfer of private, identifiable human subject Scientific Research Data to OSF, in addition to the written agreement, OSF HSPP's permission is required.

Outgoing Transfer

1. When a Principal Investigator (PI) leaves OSF and wishes to move the project to another institution, the PI may not remove nor grant to others the right to remove the original data from OSF without the express prior written approval of an ad hoc subcommittee of the Research Oversight Council. PI should contact Research Administration to discuss details.
2. When the Scientific Research Data have been collected conducting human subjects research, the OSF HSPP reviews and approves the transfer prior to final signoff by the subcommittee.
3. Prior to any Scientific Research Data transfer, a written agreement is in place between OSF and the PI's new institution in which the new institution;
    a. accepts its custodial responsibilities for the Scientific Research Data,
    b. agrees to obtain its own IRB approval prior to using any private, identifiable human subject Scientific Research Data collected at OSF, and
    c. agrees to give OSF access to the original data in the event that should become necessary.
4. Prior to leaving OSF, the PI identifies in writing to his or her departmental executive officer or equivalent person those Scientific Research Data records he or she has in his or her custody at the time and those Scientific Research Data records the PI wishes to take to the new institution. If transfer of the original Scientific Research Data is not approved, the PI may take a copy of the Scientific Research Data at his/her expense;

5. Outgoing transfer of Scientific Research Data may be restricted by the need to protect proprietary rights, by contractual confidentiality obligations, or as restricted by law (e.g., HIPAA), conditions of IRB approval, or regulation.
6. In the case of industry-initiated clinical trials, Scientific Research Data is not transferred without explicit written permission from the sponsor.

Dispute Resolution

Disputes regarding Scientific Research Data are resolved by an ad hoc subcommittee of the Research Oversight Council.

REFERENCES:

1. Intellectual Property and Technology Transfer Policy. OSF Ministry policy. Business Operations.
2. Allegations of Research Misconduct Policy. OSF Ministry policy. Compliance.
3. Retention and Destruction of Documents. OSF Ministry policy. Compliance.
4. Security of OSF Sanctioned Portable Computing Devices (MIS-54). OSF Ministry policy. Information Management.
5. Integrity Controls During Transmission (MIS-ST-36). OSF Ministry policy. Information Management.
6. Encryption and Decryption (MIS-ST-31). OSF Ministry policy. Information Management.
7. Electronic Communications (104). OSF Ministry policy. Human Resources. Retrieved February 10, 2020.
8. Blum, Carol. (March 1, 2012). *Access to, Sharing and Retention of Research Data: Rights & Responsibilities.* Council on Government Relations (COGR) website https://www.cogr.edu/sites/default/files/access_to_sharing_and_retention_of_research_data-_rights_%26_responsibilities.pdf
9. Steneck, Nicholas H. (August 2007). *ORI Introduction to the Responsible Conduct of Research.* Office of Research Integrity (ORI) website https://ori.hhs.gov/ori-introduction-responsible-conduct-research
10. National Science Foundation. (October 4, 2021). Proposal & Award Policies & Procedures Guide: Data Sharing Policy. National Science Foundation (NSF) website https://www.nsf.gov/pubs/policydocs/pappg22_1/pappg_11.jsp#XID4
11. National Institutes of Health. (January 25, 2023). NIH Data Sharing Policy and Implementation Guidance. NIH Grants & Funding website https://sharing.nih.gov/data-management-and-sharing-policy/about-data-management-and-sharing-policies/data-management-and-sharing-policy-overview
12. Title 2 - Grants and Agreements Part 215 - UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND AGREEMENTS WITH INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, AND OTHER NON-PROFIT ORGANIZATIONS (OMB CIRCULAR A-110). (January 1, 2012). https://www.govinfo.gov/content/pkg/CFR-2012-title2-vol1/pdf/CFR-2012-title2-vol1-part215.pdf
13. Health Insurance Portability and Accountability Act of 1996 (HIPAA). (August 21, 1996). https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996
14. Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). (October 30, 2009). https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/enforcementrule/enfifr.pdf
15. Coded Private Information or Specimens Use in Research, Office for Human Research Protections (OHRP) Guidance. (October 16, 2008) https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html

16. U.S. Department of Health & Human Services, Office for Human Research Protections. *Terms of the Federalwide Assurance.* https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html
17. Federal Acquisition Regulations, FAR 52.215-2, Audit and Records – Negotiation. (March 16, 2023). https://www.acquisition.gov/far/52.215-2#:~:text=(a)%20As%20used%20in%20this,or%20in%20any%20other%20form.
18. Federal Acquisition Regulations, FAR 52.227-14, Rights in Data - General, Alt. V. (March 2023). https://www.acquisition.gov/far/52.227-14

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
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

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	6/22/2023
Executive Steering Committee	Amy Olsen: Coord Clinical Policy RN	6/22/2023
President, OSF Healthcare	Sister Diane Marie: President-Sister	6/7/2023
System Chief Medical Officer	Ralph Velazquez: System CMO	5/26/2023
Regulatory/Policies Council	Michael Theisen: Resource Document Spec	5/17/2023
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	5/8/2023
Notification	Heidi Vermillion: Coord Research Admin	5/3/2023