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Effective:	4/21/2020
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Owner:	<i>Stephanie Madrigal: Dir Clin Rsrch Admin/Ops</i>
Category/Chapter:	<i>Compliance</i>
Areas/Depts:	<i>Research</i>
Applicability:	<i>OSF All Operating Units</i>

Research Data

DEFINITIONS:

1. **Research Data** - For the purpose of this policy, "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.

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 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 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 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 Research Data extends from OSF's obligation to be legally and financially accountable for issues related to Research Data. These obligations include the responsibility to investigate allegations of research misconduct; to protect the right of researchers to access 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

1. On behalf of OSF, the Principal Investigator (PI) is the custodian of the Research Data and is ultimately responsible for meeting the collection and retention requirements relating to Research Data. However, because other members of the research team (Co-PI, senior researchers, program staff, trainees, or students) may have obligations for 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, and proper storage of Research Data. Investigators will also ensure retention of complete records to document the methods used; accuracy of the 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 Research Data is part of the research record. Research Data is ordinarily retained in the investigator’s lab, office, or the unit where it is 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 Research Data, OSF has the right to access the original Research Data to ensure that OSF meets its obligations of legal 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 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 Research Data.
2. When a collaboration comes to an end, and Research Data was created during the collaboration, each member of the collaboration retains access to that data.

Security

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

Sharing of Research Data

1. 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 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 Research Data to OSF only after a written agreement is in place.
2. An OSF employee, student, contractor, collaborator, or non-OSF investigator may receive existing

Research Data from a non-OSF investigator where OSF would become responsible for the security, retention, or other requirements associated with the Research Data, only after a written agreement is in place.

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.
2. When the Research Data has been collected conducting human subjects research, the IRB reviews and approves the transfer prior to final signoff by the subcommittee.
3. Prior to any 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 Research Data,
 - b. agrees to obtain its own IRB approval prior to using any identifiable human subject 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 Research Data records he or she has in his or her custody at the time and those Research Data records the PI wishes to take to the new institution. If transfer of the original Research Data is not approved, the PI may take a copy of the Research Data at his/her expense, except as 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.
5. In the case of industry-initiated clinical trials, Research Data is not transferred without explicit written permission from the sponsor.
6. An individual researcher (other than the PI) who leaves OSF may request copies of Research Data for any part of the project in which s/he was significantly involved in the design, conduct, or reporting of research. In such circumstances, subject to the restrictions described above, a copy of the Research Data may be provided to the individual within a reasonable time period after the request at the departing individual's cost. In no event will the original Research Data be provided to any such individual.

Dispute Resolution

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

REFERENCES:

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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:

		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

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Education/Communication Step (Human Protection Administrator (HPA) Listed on FWA)	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	4/21/2020
Board of Directors	Danielle McNear: Executive Assistant	4/21/2020
President, OSF Healthcare System	Sister Diane Marie: President-Sister	3/25/2020
Ministry Chief Medical Officer	Ralph Velazquez: System CMO	3/25/2020
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	3/13/2020
Research Compliance Officer	Heather Hermann: Compliance Ofcr-Research	3/13/2020

Step Description	Approver	Date
Policy Review Group	Marci Fletcher: Resource Document Spec	2/28/2020
Notification Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	2/25/2020

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