I. Overview

A. Purpose: The purpose of this policy is to:
   1. Inform investigators how to collaborate with the Ochsner Health System (OHS) in the following capacities:
      - Ochsner employed investigators sharing OHS data and services with researchers employed by an outside institution
      - Non-Ochsner employed investigator requesting OHS data and services for their own research initiatives with or without an Ochsner employed site investigator;
   2. Govern approvals of data sharing pursuant to the terms of applicable Data Sharing and Use Agreements and IRB requirements

B. Scope: This policy applies to requests by Ochsner and non-Ochsner Partners (institutions involved in the conduct of research as defined at 45 C.F.R. § 64.10 of the HIPAA Regulations) to conduct research using Ochsner’s infrastructure for:
   1. Obtaining any data;
   2. Conducting observational or interventional studies

C. Regulatory requirements: All approved research requests are subject to:
   1. Data Sharing and Use Agreements that must be executed before data is shared with non-Ochsner investigators
   2. Applicable IRB approval requirements based on the type of study

II. Sharing Ochsner Patient Data with External Individuals/Entities for Research Purposes

1. Identify the Type of Data to Be Shared
   i. Protected Health Information (PHI): PHI is individually identifiable health information about the past, present, or future treatment of a patient or the payment for that treatment.
   ii. De-Identified Data: Does not identify the individual and no reasonable basis to believe the information can identify the individual. All of the following identifiers must be excluded:
      1. Names
      2. All geographic subdivisions smaller than a state, including:
         a. Street address
         b. City
         c. County
         d. Precinct or Parish
      3. ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if:
         a. The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
         b. The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
      4. All elements of dates (except year) for dates that are directly related to an individual, including:
         a. Birth date
b. Admission date
c. Discharge date
d. Death date
e. Age and all elements of dates (including year) for individuals age 89 or older

5. Social security numbers
6. Medical record numbers
7. Health plan beneficiary numbers
8. Telephone and fax numbers
9. Email addresses
10. Full-face photographs and any comparable images
11. Biometric identifiers, including finger and voice prints
12. Device identifiers and serial numbers
13. Account numbers
14. Certificate/license numbers
15. Vehicle identifiers and serial numbers, including license plate numbers
16. Web Universal Resource Locators (URLs) and Internet Protocol (IP) addresses; and
17. Any other unique identifying number, characteristic, or code.

iii. **Limited Data Set**: A limited data set excludes specified direct identifiers.

1. All of the following identifiers must be excluded:
   a. Names
   b. Postal address information, other than town or city, State, and zip code
   c. Telephone numbers
   d. Fax numbers
   e. Electronic mail addresses
   f. Social Security numbers
   g. Medical record numbers
   h. Health-plan beneficiary numbers
   i. Account numbers
   j. Certificate and license numbers
   k. Vehicle identifiers and serial numbers, including license plate numbers
   l. Device identifiers and serial numbers
   m. Web Universal Resource Locators (URLs)
   n. Internet Protocol (IP) address numbers
   o. Biometric identifies including fingerprints and voice prints
   p. Full-face photographic images and any comparable image.

2. **Obtain Authorization for the Data Sharing Arrangement**

   i. **Individual Authorization or IRB Waiver of Authorization**

   1. **Required** to use/share PHI or Limited Data Set with external individuals/entities for research purposes
2. Individual authorization or IRB waiver is **not required** to use/share de-identified information

3. Consult IRB for additional guidance
   ii. **Agreement** - one of the following agreements is **required** to govern the data use/sharing arrangement **prior to any** health information (including de-identified data) being used/shared with an external individual or entity. **Always consult Research Legal to determine which Agreement is appropriate to govern your proposed data use/sharing arrangement.**

   1. **Clinical Trial Agreement (CTA)**
      a. Entered into between Ochsner and the sponsor of a clinical trial
      b. Sets forth the rights and responsibilities of both parties, including those related to confidentiality and data security

   2. **Service Agreement (SA)**
      a. Entered into between entities when one will perform a service that falls outside the scope of the conduct of the clinical trial, e.g., data abstraction
      b. Sets forth the rights and responsibilities of both parties, including those related to confidentiality and data security

   3. **Business Associate Agreement (BAA)**
      a. Entered into between a Covered Entity and its Business Associate
         i. **Covered Entity** - a health plan, health care clearinghouse, or health care provider that *transmits* information electronically in connection with a covered transaction (Ochsner is a Covered Entity)
         ii. **Business Associate** - a party who *receives* protected health information to perform a service for the Covered Entity
      b. The BAA includes provisions that explain a business associate is directly liable under the HIPAA rules and subject to civil, and in some cases, criminal penalties for misuse of PHI

   4. **Data Security Agreement (DSA)** - this is the proper agreement if:
      a. None of the above agreements apply to the proposed data use/sharing arrangement AND
      b. PHI will be shared with an external individual/entity

   5. **Data Use Agreement (DUA)** – this is the proper agreement if:
      a. None of the above agreements apply to the proposed data use/sharing arrangement AND
      b. A Limited Data Set or De-Identified Data will be shared with an external individual/entity
   
   iii. All agreements must include an **appendix with a list of data elements** required for the full execution of the study.

**III. Regulatory Requirements**

Ochsner Health System supports shared or ceded IRB review for multi-institutional studies. Prior to IRB submission, investigators are encouraged to contact Ochsner IRB personnel for guidance on IRB procedures
using shared review platforms. The IRB processes for various research scenarios are summarized in Table 1.

Table 2: Regulatory Requirements by Research Scenario for Multi-Institutional Studies using Ochsner Data

<table>
<thead>
<tr>
<th>Research Design</th>
<th>Collaboration Framework</th>
<th>IRB Framework</th>
<th>Agreements Required</th>
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</thead>
<tbody>
<tr>
<td>Deidentified data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observational</td>
<td>Lead investigator at Ochsner; Co-investigators at outside institution</td>
<td>IRB Exemption(s) obtained through Ochsner IRB</td>
<td>SA DUA</td>
</tr>
<tr>
<td>No individual patient</td>
<td>Lead investigator at outside institution with Ochsner site PI</td>
<td>Lead IRB identified; ceded or shared review by data contributing institutions with investigators</td>
<td>SA DUA</td>
</tr>
<tr>
<td>consent</td>
<td>Lead investigator LSUHSC-S without Ochsner PI – data limited to NL hospitals</td>
<td>IRB Exemption(s) obtained through LSUHSC-S with Ochsner IRB ceding review</td>
<td>Master Ochsner LSUHSC-S DUA/biospecimens</td>
</tr>
<tr>
<td>Limited dataset</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Observational</td>
<td>Lead investigator at Ochsner; Co-investigators at outside institution</td>
<td>Ochsner is lead IRB; ceded or shared review by co-investigator</td>
<td>SA DUA</td>
</tr>
<tr>
<td>No individual patient</td>
<td>Lead investigator at outside institution with Ochsner site PI</td>
<td>Lead IRB identified; ceded or shared review by data contributing institutions with investigators</td>
<td>SA DUA</td>
</tr>
<tr>
<td>consent</td>
<td>Lead investigator LSUHSC-S without Ochsner PI – data limited to NL hospitals</td>
<td>IRB Exemption(s) obtained through LSUHSC-S with Ochsner IRB ceding review</td>
<td>Master Ochsner LSUHSC-S DUA/biospecimens</td>
</tr>
<tr>
<td>Identifyable data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interventional trial</td>
<td>Lead investigator at Ochsner; Co-investigators at outside institution</td>
<td>Ochsner is lead IRB; ceded or shared review by co-investigator</td>
<td>CTA (if applicable) SA BAA DSA</td>
</tr>
<tr>
<td>Prospective</td>
<td>Lead outside investigator from any institution requesting OH data – Ochsner site PI required</td>
<td>IRB Exemption(s) obtained through outside institution with Ochsner IRB ceding review (EXCEPT if OH only data study IRB Exemption(s) obtained through Ochsner)</td>
<td>Master DUA between Ochsner and outside institution</td>
</tr>
<tr>
<td>Patient recruitment/consent</td>
<td>Lead investigator at outside institution with Ochsner site PI</td>
<td>IRB Exemption(s) obtained through outside institution with Ochsner IRB ceding review</td>
<td>Master Ochsner LSUHSC-NO DUA</td>
</tr>
</tbody>
</table>
### Data Governance

Ochsner Health data is available to investigators to support research projects.

Health professional trainees (e.g. medical students, residents, fellows) may not serve as principal investigators on IRB protocols. Projects for trainees must include a faculty member as the Principal Investigator.

All requests for use of limited data sets or identifiable data for research must include an Ochsner employed site Investigator. Exceptions to this requirement as it applies to LSUHSC-Shreveport (North Louisiana facilities) and LSUHSC-New Orleans (Kenner facility) are detailed in Section III, Table 2.

Pursuant to these requirements as it related to data from Ochsner facilities, data requests (excluding studies limited to LSUHSC-S/North Louisiana or limited to LSUHSC-NO/Kenner with PIs from the respective institutions):

1. No data, regardless of type, will be released without the Ochsner Health Data Management Committee approval, as set forth in the Requesting Research Services section (V) and fulfillment of applicable regulatory requirements as summarized in the Regulatory Requirements section (III) above.
2. Once Ochsner Health Data Management Committee approves participation and applicable regulatory requirements are met, data can be released.
3. Ongoing data releases throughout the course of project requires Ochsner Health Data Management Committee and approval.
4. Additional data requests beyond those expressly defined in the applicable IRB and Data Sharing and Use Agreements, if applicable, will need to be assessed and regulatory requirements fulfilled before data sharing can occur.
5. All data transfer will occur in a secure encrypted capacity (e.g. via Globalscape not email or any other media).
V. Requesting Data for Research

To request data, submit a Research Information Analytics Request through the REDCap survey. The REDCap data request form is designed to capture the most important information which the analysts will need to begin processing the request. The REDCap is also used for tracking the status of requests as well as required for Ochsner Research Department operating and audit reports.

All data requests must include the approved IRB protocol number and specification as to whether the data will be shared with a third party entity. In accordance with Section II, data use agreements must be fully executed prior to any data being released to a third party entity.

General tips to consider when requesting data include:
1. Specify your primary objectives and inclusion/exclusion criteria for your target population.
2. Specify time frame of patient observations
3. Specify location, department of facility
4. Consider Epic Tools like Slicer Dicer to obtain the MRNs for your patient population.
5. Provide applicable codes (e.g. diagnoses; procedures; drug class)

For additional information on the full scope of services available, refer the following websites on Ochweb (ochsnerhealth.sharepoint.com):
1. Center for Outcomes Research
   a. Research Steps & Services Overview
2. Office of Epidemiology & Biostatistics
3. Clinical Research Informatics
4. Research Information Analysts