SHARING OF OCHSNER PATIENT INFORMATION WITH EXTERNAL INDIVIDUALS/ENTITIES FOR RESEARCH PURPOSES

I. Identify the Type of Data to Be Shared

a. 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.
   Examples of PHI:
   i. Medical Record
   ii. Laboratory Report
   iii. Hospital Bill

b. 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:
   i. Names
   ii. All geographic subdivisions smaller than a state, including:
       1. Street address
       2. City
       3. County
       4. Precinct or Parish
       5. 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
   iii. All elements of dates (except year) for dates that are directly related to an individual, including:
       1. Birth date
       2. Admission date
       3. Discharge date
       4. Death date
       5. Age and all elements of dates (including year) for individuals age 89 or older

iv. Social security numbers
v. Medical record numbers
vi. Health plan beneficiary numbers
vii. Telephone and fax numbers
viii. Email addresses
ix. Full-face photographs and any comparable images
x. Biometric identifiers, including finger and voice prints
xi. Device identifiers and serial numbers
xii. Account numbers
xiii. Certificate/license numbers
xiv. Vehicle identifiers and serial numbers, including license plate numbers
xv. Web Universal Resource Locators (URLs) and Internet Protocol (IP) addresses; and
xvi. Any other unique identifying number, characteristic, or code.

c. **Limited Data Set:** A limited data set excludes specified direct identifiers.
   i. All of the following identifiers must be excluded:
      1. Names
      2. Postal address information, other than town or city, State, and zip code
      3. Telephone numbers
      4. Fax numbers
      5. Electronic mail addresses
      6. Social Security numbers
      7. Medical record numbers
      8. Health-plan beneficiary numbers
      9. Account numbers
     10. Certificate and license numbers
     11. Vehicle identifiers and serial numbers, including license plate numbers
     12. Device identifiers and serial numbers
     13. Web Universal Resource Locators (URLs)
     14. Internet Protocol (IP) address numbers
     15. Biometric identifiers including fingerprints and voice prints
     16. Full-face photographic images and any comparable image.
   ii. A limited data set can be used/shared with external individuals/entities with a Data Use Agreement.

II. Obtain Authorization for the Data Sharing Arrangement
   a. **Individual Authorization or IRB Waiver of Authorization**
      i. **Required** to use/share PHI or Limited Data Set with external individuals/entities for research purposes
      ii. Individual authorization or IRB waiver is **not required** to use/share de-identified information
      iii. Consult IRB for additional guidance
   b. **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.**

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

ii. **Service Agreement (SA)**
   1. 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
   2. Sets forth the rights and responsibilities of both parties, including those related to confidentiality and data security

iii. **Business Associate Agreement (BAA)**
   1. Entered into between a Covered Entity and its Business Associate
      a. **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)
      b. **Business Associate** - a party who receives protected health information to perform a service for the Covered Entity
   2. 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

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

v. **Data Use Agreement (DUA)** – this is the proper agreement if:
   1. None of the above agreements apply to the proposed data use/sharing arrangement AND
   2. A Limited Data Set or De-Identified Data will be shared with an external individual/entity

**III. Observe HIPAA Minimum Necessary Rule when using/sharing PHI:** Access, Use, and Disclose the MINIMUM amount of patient information you need to conduct the research.

**IV. When sharing data with external individuals/entities via email:**

a. **Observe proper encryption procedures:** Electronic files containing patient PHI should only be sent to external individuals/entities in encrypted format, using Globalscape or equivalent system. **Consult IS for additional guidance.**
b. **Include the following disclaimer on email**

   PRIVACY NOTICE: This communication, including its attachments, may contain privileged and confidential information, including patient information protected under federal and state privacy laws, and is intended solely for the use of the recipient(s) named above. Any review, dissemination, distribution, or duplication of this communication and/or its attachments outside of Ochsner Health System requires prior approval from Ochsner’s Institutional Review Board or Compliance and Privacy Department. If you are not the intended recipient, you are hereby notified that any review, dissemination, distribution, or duplication of this communication and/or its attachments is strictly prohibited. If you are not the intended recipient, please notify Ochsner Health System’s Compliance & Privacy Department immediately by email at compliance@Ochsner.org and delete this communication, including its attachments, from your system.

V. **When sharing data with external individuals/entities via fax:**

   a. Fax information only if there is no other way to transmit the data (secure email, other electronic methods, etc.).

   b. Always use a Ochsner branded coversheet that contains the name and contact information of the sender and instructions for what to do if the fax is received in error.

   c. **Ensure that your fax coversheet contains the following disclaimer**

      CONFIDENTIALITY NOTICE: The accompanying facsimile is intended solely for the use of the receipt designated above. Document(s) transmitted herewith may contain information that is confidential and privilege. Delivery, distribution of dissemination of this communication other than to the intended recipient is strictly prohibited. **If you are another healthcare provider and have received this facsimile in error, please properly dispose and notify the sender. If you are NOT a healthcare provider and have received this facsimile in error, please notify Ochsner Health System’s Compliance & Privacy Department immediately by email at compliancefaxes@Ochsner.org.**

   d. Always confirm fax numbers with the recipient.

   e. Confirm receipt of the fax with the recipient.

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**Revision history for auditors:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
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<tbody>
<tr>
<td>December 2021</td>
<td>Added confidentiality notice to be included with a facsimile</td>
</tr>
<tr>
<td>June 2018</td>
<td>Guidance published</td>
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