

<b>Principal Investigator</b>	Name	Phone
	Title	E-mail
	Address	
<b>Primary Contact</b> (if not Principal Investigators)	Name	Phone
	Title	E-mail
	Address	
<b>Name and Description of Human Derived Material Being Sent or Received</b>		
<p><b>Information About The External Party:</b> (Company/Institution Materials are being <u>Sent</u> to or <u>Received</u> From):</p> <p><b>Contact Person:</b></p> <p><b>Name of Institution:</b></p> <p><b>Address:</b></p> <p><b>Phone Number:</b></p> <p><b>E-mail:</b></p>		

**Please provide the following information:**

**INTRODUCTORY QUESTIONS:**

- Does the material contain any fetal or embryonic material?
  - Yes, the material contains fetal and/or embryonic material
  - No, the material DOES NOT contain fetal material
- When was the material collected (mm/dd/yyyy)
- Are you receiving human derived materials or sending human derived materials?
  - Receiving human derived materials
  - Sending human derived materials

**IF YOU ARE SENDING HUMAN DERIVED MATERIALS:**

- Was the human derived material harvested/culled as a part of research or during a standard clinical procedure?
  - Research
  - Clinical procedure
- If the material was obtained as a part of a research protocol which of the following apply:
  - The material was obtained using an informed consent form that allowed the material to be used for future research purposes (attach copy of stamped consent)
  - The material was obtained with patient HIPAA authorization that specifically referred to this proposed transfer of material (attach copy of approved authorization)

The material was obtained under an IRB waiver of informed consent (attach copy of waiver of informed consent)

6. If the material you are sending was obtained as a part of a standard clinical procedure, did the patient consent to the collection of the material, and the possibility of its use for future research?

Yes, the patient consented to the collection of the material and the possible future use of the tissue

No, the patient did not consent to the collection of the material and possible future distribution of the material

**FOR ALL HUMAN DERIVED MATERIAL TRANSFERS:**

7. Specify any identifier(s) that will be transferred with the material and **please complete the attached table: "Identifiable Information."**

8. Does any information transferred with the material contain either a direct identifier or a link to allow the re-identification of the individual?<sup>1</sup>

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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**Please complete the following checklist related to specific identifiers of the material to be collected (if you are receiving material), used or disclosed (if you are sending material).**

Direct Identifiers		Identifiable Information	Indirect Identifiers (Limited Data Set)	
Used/ Collected (check if yes)	Disclosed (check if yes)		Used/ Collected (check if yes)	Disclosed (check if yes)
<input type="checkbox"/>	<input type="checkbox"/>	Names		
<input type="checkbox"/>	<input type="checkbox"/>	Street Address, Apartment #, Precinct, or other geocode more geographically specific than zip code.		
		City/Town, State and Zip Code <i>(Note: for the records to be considered de-identified only the first three digits of the zip code can be used<sup>2</sup>)</i>	<input type="checkbox"/>	<input type="checkbox"/>
		All elements of dates (except year) for dates directly related to an individual (e.g. date of birth/death, dates of admission/discharge etc.)	<input type="checkbox"/>	<input type="checkbox"/>
		Ages less than 90, and "90 and above" for those over 90.	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	Telephone numbers, including fax		
<input type="checkbox"/>	<input type="checkbox"/>	E-mail addresses		
<input type="checkbox"/>	<input type="checkbox"/>	Social security numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Medical record numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Health plan beneficiary numbers, or any other account numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Certificate/license numbers, & vehicle identifiers and serial numbers, including license plate numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Implanted device identifiers and serial numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Web Universal Resource Locators (URLs)		
<input type="checkbox"/>	<input type="checkbox"/>	Internet Protocol (IP) address numbers		
<input type="checkbox"/>	<input type="checkbox"/>	Biometric identifiers, including finger and voice prints or any audio recordings		

<sup>1</sup> The code or other means of record identification should not be derived from or related to information about the research subject and should not otherwise permit re-identification of the subject.

<sup>2</sup> The first three digits of the zip code may be used as long as the population in that region is greater than 20,000. If the geographic unit is less than 20,000 only state may be used.

Direct Identifiers		Identifiable Information	Indirect Identifiers (Limited Data Set)	
Used/ Collected (check if yes)	Disclosed (check if yes)		Used/ Collected (check if yes)	Disclosed (check if yes)
<input type="checkbox"/>	<input type="checkbox"/>	Full face photographic images and any comparable image, including video recordings		
<input type="checkbox"/> None of the Direct Identifiers noted above will be collected			<input type="checkbox"/> None of the Indirect Identifiers noted above will be collected	

## PRINCIPAL INVESTIGATOR'S ASSURANCE

**▶ THIS SECTION MUST BE COMPLETED BY THE PRINCIPAL INVESTIGATOR AND THE PRINCIPAL INVESTIGATOR MUST CERTIFY THE FORM BY CHECKING THE FINAL BOX BELOW AND ENTERING HIS/HER NAME.**

I certify that the information provided in this Human Derived Materials Transfer Screening form is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the privacy rights and welfare of human subjects and the ethical conduct of this research project/protocol.

I agree to comply with all University of Pennsylvania policies and procedures and all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Permitting performance of the project only by qualified personnel according to the research project/protocol;
- Acquiring the necessary review by the University of Pennsylvania's IRB if I will be involved in the conduct of the research project;
- Maintaining as secure any protected health information collected for this research project/protocol, and not sharing access to such information with any individual without prior review and approval of the IRB and/or privacy officer unless such subset has been created to exclude all identifiable demographic information as defined in this document, or unless additional data use agreements have been obtained for distribution of limited data sets.
- Forbidding attempts to re-identify the subjects from the data collected pursuant to this transfer, and attempts to contact the subjects or their family members.

I have completed the required educational program on ethical principles and regulatory requirements in human subjects research and HIPAA as necessary prior to initiating the research.

**▶  PI'S Certification :** \_\_\_\_\_  
Name

Date: \_\_\_\_\_

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## Definitions

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**“De-identified Data”** Data that is “de-identified” under HIPAA is not regulated by HIPAA and may, accordingly, be used or disclosed for research and other purposes without patient authorization. Data is “de-identified” under HIPAA if the following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

- **Names**
- **All geographic subdivisions smaller than a State**, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census, (a) the geographical 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 of fewer people is changed to 000.
- **All elements of dates (except year)** for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or order.
- **Telephone numbers**
- **Fax numbers**
- **Electronic mail addresses**
- **Social security numbers**
- **Medical record numbers**
- **Health plan beneficiary numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers and serial numbers**
- **Web Universal Resources (URLs)**
- **Internet Protocol (IP) address numbers**
- **Biometric identifiers, including finger and voice prints**
- **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**, except that a code may be assigned to allow information de-identified by removal of all above information to be re-identified provided that: (a) the code is not derived from or related to the information from and the individual and is not otherwise capable of being translated so as to identify the individual; and, (b) the code is not used for any other purpose nor disclosed to any outside entity

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**“Disclosure”** means the release, transfer, provision of access to, or divulging of protected health information by any means to persons or entities outside of UPHS / SOM or other covered entity.

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**“Limited data set”** Members of a covered entity may use or disclose data contained in a “limited data set” for research purposes, without obtaining individual authorization, **provided that UPHS / SOM enters into a data use agreement with the recipient of the limited data set signed on behalf of the Trustees of the University of Pennsylvania by the UPenn Office of Research Services.** A “limited data set” **excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:**

- **Names**
- **Postal address information, other than town or city, State, and zip code**
- **Telephone numbers**
- **Fax numbers**
- **Electronic mail addresses**
- **Social security numbers**
- **Medical record numbers**
- **Health plan beneficiary numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Implanted device identifiers and serial numbers**
- **Web Universal Resource Locators (URLs)**
- **Internet Protocol (IP) address numbers**
- **Biometric identifiers, including finger and voice prints**
- **Full face photographic images and any comparable image**

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**“Protected Health Information (PHI)”** Protected health information (PHI) is defined under the HIPAA regulations as information that is a subset of health information, including demographic information collected from an individual, and: (1) is created by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (i) that identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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**“Use”** means to collect, share, employ, apply, utilize, examine, or analyze PHI within UPHS / SOM.