Drexel University

Human Tissue and Samples

Directions and FAQs for Application Process:

Frequently Asked Questions:

- Completing the Application to use Human Specimens and Study Registration (HSSR) Form

1. When should I use the HSSR form?
   a. You will need to complete and submit this form with your initial IRB/ORRC application whenever you are collecting and using any of the following human tissues/specimens/fluids classified as Risk Group 1 or 2, in support of your research activities in a laboratory that is NOT CAP certified:
      i. Sera
      ii. Blood products
      iii. Feces/stool samples
      iv. Urine
      v. Sputum
      vi. Organ tissue (complete or incomplete specimens)
      vii. Other human body parts/fluids/secretions

   b. If the human specimens are to be evaluated, tested, or used for research diagnostic purposes in a lab that is NOT College of American Pathologists (CAP) or Clinical Laboratory Improvement Amendment (CLIA) certified.
   c. When the human specimens will be used to validate or evaluate the accuracy of clinical diagnostic processes or procedures in equipment that has not received FDA or appropriate agency approval.

2. When do I need to submit the HSSR form?
   a. The HSSR form should be submitted to Human Research Protection (HRP) at the time you make a formal initial application for an IRB or HRP review. You may also need to resubmit the HSSR form if any of the following apply:
      i. You must update the HSSR if you have amended your original proposal to indicate the addition of new personnel to the project.
      ii. There has been a change in the type(s) of tissues/specimens collected.

3. Does the HSSR form expire or need to be renewed?
   a. No. There is no expiration date. The need for renewal of the HSSR form itself regarding registration of use of human tissue/specimen or fluids is required when you are adding new personnel or a new specimen type to the project.

4. How do I document completion of the annual training requirements for the research team members?
   a. All research team members must document recertification of their Bloodborne Pathogen (BBP) Training and, as necessary, Laboratory Safety Training annually in accordance with Department of Safety and Health policies as follows.

      i. If your proposal was approved as Exempt or by use of the Registration to Obtain Cell Lines and Commercial Blood, you will document your annual

renewal of training using section "I" of the HSSR form. Documentation and reporting of your annual training requirements depends upon the type of IRB approval your proposal received.
ii. If your proposal was approved as an Expedited or Full review there is a requirement for an annual Continuing Review Progress Report (HRP-212), to either continue enrollment, data analysis only, or as a final report. Within the Continuing Review Progress Report form you will document the training renewal dates for all research team members.

4. Does the HSSR form need to be updated or amended once the project has been approved?
   a. Yes. You will need to update and submit the HSSR form whenever there is a change in a research team member or a change in the type of human tissue/specimen/fluid to be collected or studied.

5. What if the human tissue/specimen/fluid is being shipped to a certified lab? Does the PI still need to complete the HSSR form?
   a. No. You are only required to register your proposal for use of Risk Group 1 or 2 human tissue/specimens if the analysis is being done in a NON CAP lab.

6. What if the human tissue/specimen/fluid is classified as Risk Group 3 or 4? Do I still need to submit the HSSR form?
   a. NO. If your proposal will use Risk Group (RG) 3 or 4 specimens, and those specimens will be analyzed by a non-licensed CAP laboratory, you are required to be reviewed in Full by the University BioSafety Committee (UBSC). If you need assistance in determining which risk group your research proposal qualifies for, please use this link: http://www.research.drexel.edu/compliance/biosafety/guidelines.aspx . If your proposal requires Full UBSC review you may find the appropriate application documents and directions at http://www.research.drexel.edu/compliance/biosafety/default.aspx.

- Letter of Determination request (Study or collection of already EXISTING DE-IDENTIFIED human tissue/specimen/fluid without identifiers)

1. What types of research involving human tissue/specimen/fluid qualify for the Letter of Determination (LOD) application?
   a. A LOD request is intended for the use and collection of ALREADY existing human tissue/specimen/fluid or other material derived from a human source, and that the material to be used for purposes of research MUST NOT have any links or identifiers attached that may divulge the identity of the human source.
   b. This applies to human tissue specimens collected from or provided by 1) a publicly available source, 2) Pathology or Private Labs, 3) individual investigators, and/or 4) external entities or institutions.
   c. To qualify for a LOD request the applicant PI must remember that he/she, under NO circumstances, have access to the code or link which may lead to the identification of the human tissue specimen.

d. AND; the investigators and the holder of the link to the identity of the human source of the specimen enter into an agreement prohibiting the release of the link to the investigators under any circumstances, until the individuals are deceased.

2. Who decides what the preexisting time frame should be for the study of human specimens?
   a. The applicant PI will decide the exact time frame from which the already existing specimen will be collected or evaluated. The key to this type of application is that NO specimens may be used in support of this type of application if they have not already been collected. The investigator should be clear within their application that they specify the exact time frame from which the specimens will be studied, (Ex: Specimens collected between January 01, 1999-September 30, 2009).

3. What is the IRB/HRP application process and what forms do I need to complete?

   a. In the following list you will find a description and the links to the necessary forms to include in your initial application for a request for LOD proposal. When applying to the IRB/HRP you will need to submit the original of the necessary, signed and dated forms in an electronic format to HRPP@drexel.edu and Cc BF34@drexel.edu keeping a copy of all forms for your own regulatory binder.

   Please provide the following documents to HRP with an electronic copy:

Project Submission Transmittal Form [PDF]	Only if project is funded
Letter of Determination Application (LOD)	Inclusive of all signatures and dates
Research Proposal with appropriate references (Copy of the Grant, Masters or Ph.D. research proposal)	Must be included in ALL applications
Data Collection Instruments such as the information you will recording regarding the human tissue/specimen/fluid	This may be an Excel Spreadsheet or Word doc of your own design, it must indicate all data points you intend to collect or observe
Application to use Human Specimens and Study Registration (HSSR) form	Must be included in LOD applications for collection and study of human specimens
Written Authorization from OWNER of tissue, specimen or fluid Must be on the Owner's institutional letterhead, signed and dated	Owner/Holder of tissue/specimen/fluid must provide written authorization for the applicant PI to have access to the material, and the written authorization must state that any and all material will be provided to the applicant PI without any identifiers or link to the human source of the material

4. Is there a deadline for an LOD application involving human tissue/specimen/fluid to be received by the IRB/HRP?

   a. NO. There is no deadline to meet for your initial new application to the IRB/HRP. LOD applications are logged into the HRP database and initiated into the review for approval process as soon as they are received.

5. Does an LOD approved protocols involving human tissue/specimen/fluid expire or is there a need to renew my LOD proposal?

a. IRB/HRP approved LOD proposals DO NOT expire and there is no need for a Continuing Review Progress Report (HRP-212). The PI is however required to officially close the study with HRP by completing the Continuing Review Progress Report (HRP-212).

6. Do the HIPAA regulations or a need for a HIPAA Waiver of Authorization apply to an LOD application involving human tissue/specimen/fluid for collection or study?

a. As long as there is absolutely NO link between the human tissue/specimen/fluid provided to the applicant PI from the holder/owner of the material, then the HIPAA regulations and need for a HIPAA Waiver of Authorization do not apply.
(Please note: If your proposal requires a need for a link or identifier to the human source of the tissue to be retained, HIPAA regulations apply and your application will be required to be reviewed and follow the Expedited level of review and approval).

- <u>Application to Obtain Cell Lines and Commercial Blood</u>

1. When and for what types of human tissue/specimen/fluid should I use the Cell Line and Commercial Blood application?

a. Whenever an investigator intends to purchase commercially available cell lines or blood specimens from an external commercial supplier who provides the specimens in a de-identified format with no link to the original human source.

2. Do I need to provide any other documentation with my Application to Obtain Cell Lines and Commercial Blood?

a. YES. The commercial provider of the human tissue/specimen/fluid or blood products must provide the PI with a letter indicating the provider's policies and procedures for the distribution of non-identifiable tissue or coded tissues without a link to the human source.

3. Does my Application to Obtain Cell Lines and Commercial Blood expire, need to be renewed annually or require submission of a final report?

a. NO. These types of research are non-human subjects research and as such do not require any additional reporting or renewal with the IRB or HRP.