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## Application assistance for use of human specimens in research

Office of Human Subject Research Protection, Northeastern University

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## APPLICATION ASSISTANCE FOR USE OF HUMAN SPECIMENS\* IN RESEARCH

[Northeastern University's Office of Human Subject Research Protection \(HSRP\)](#) review is necessary whether you collected these samples or you received the samples from another source. Upon review, HSRP will determine whether the research qualifies for exemption or needs approval. Please use the standard [Application for Approval form](#) for HSRP review.

The National Institutes of Health website includes "[FAQs about Research Using Human Specimens, Cell Lines or Data Information](#)" and is very helpful in presenting issues involved in using human specimens. It may assist you in preparing your submission. The URL can be accessed at: [http://grants.nih.gov/grants/policy/hs/faqs\\_specimens.htm](http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm).

**If you are collecting the samples yourself**, all the questions on the standard form need to be answered.

Below is a partial list of issues that may need additional consideration in your submission. The nature of your research will determine the level of protection and information that are necessary. For example, genetic information that can be linked to a particular individual requires judicious management. Further information may be requested.

### **Qualifications of personnel conducting sampling procedure**

#### **Infection control in obtaining and managing samples**

#### **Identification of samples**

Anonymous if possible

Use coding if anonymity not feasible. Describe coding and linkage procedures.

Documentation that links codes to names should be maintained separately.

Destroy links to identifiers as soon as possible.

Describe confidentiality in entering and maintaining data

#### **Use of samples**

Identify what the samples will be used for

State the limits of their use

For example, *The blood will be tested for the presence of.... No other testing will be done. All unused blood will be destroyed within two weeks of testing.*

Who will have access to this information?

Who will be informed about the results of testing? Other researchers? Physician?

Subject? Subject's family?

#### **Disposition of samples**

Will the samples be destroyed? When? If not, why not?



**If you will obtain human specimens from another source**, you will use the standard application form but some of the questions will not apply. Include:

**Source of the samples.** For example, Brigham and Womens Hospital, or a tissue bank  
Provide a document from the site about the source of the samples. If specimens are collected prospectively, a copy of the Informed Consent and Health Information Use and Disclosure Authorization to be used must be included. For example, if specimens are discarded tissues following surgery for lung cancer, you will need to provide a copy of the IRB approval from the hospital and a copy of the Informed Consent and Health Information Use and Disclosure Authorization used (not each signed consent). If tissues are from a tissue bank, provide documentation from the bank about the samples.

**Are the samples identifiable?**

Are the samples from deceased persons?

Are the samples identified by name? Are they identified with a code that links to an individual?

Is there any way that the sample can be linked to an individual by you *or anyone else*?

**If these specimens had**

- a) **already been collected at the time you wrote your protocol, and**
- b) **there is no way that the specimen can be linked to any individual by you or anyone else, and**
- c) **you provide documentation of the source of the samples; the study will qualify as Exempt. See *Policies*\*\*, Appendix E, Exempt #4, Categories of Review**

For samples that are identifiable, provide information from Identification, Use, and Disposition of Samples from above.

**If the study does not qualify for exemption as identified above, it may qualify for expedited review by the Chair of the Northeastern University Institutional review Board if it is determined by HSRP to be minimal risk. See *Policies*\*\* Appendix E Expedited Status #5. If it cannot be expedited, it will be reviewed by the full committee.**

\*Examples of human specimens are: blood, cells, saliva, tissue samples, hair or nail clippings, DNA

\*\* *Policies and Procedures Concerning the Protection of Human Subjects*  
[http://www.research.neu.edu/facts\\_rates\\_forms\\_policies/policies/documents/humansubjectspolicymanual.pdf](http://www.research.neu.edu/facts_rates_forms_policies/policies/documents/humansubjectspolicymanual.pdf).