

**HAC Policies and Procedures**

**Genetic Research on Human Biological Specimens**

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### Genetic Research on Human Biological Specimens

#### What's The Purpose Of The Human Biological Specimens For Research Guidance?

The overall purpose of [HAC Form 103](#), Human Biological Specimens for Genetic Research, is to protect the rights and confidentiality of subjects involved in genetic research at MCG, while facilitating the investigator's ability to carry out his/her research program.

#### When Was The Original Policy Approved?

1999

#### Can Identified Samples Use The Subject's Initials As Part Of The Code?

No.

#### Does the HAC Use Specific Definitions and Terminology in Reviewing Human Genetic Research?

Coded (linked or identifiable) samples - Samples are unidentified for research purposes but can be linked to sources through a code rather than with personally identifying information. Subjects' initials may **not** be used.

Genetic research - Research that involves the analysis of human chromosomes or DNA from an individual or family members for the purpose of deriving information concerning the presence, absence or mutation of genes, DNA markers, gene products, or inherited characteristics. Genetic Research also includes biochemical measurements of proteins or other molecules that are done with the intent of collecting information about inheritable conditions.

Identified specimens - Personal identifiers (e.g. name or patient number) are attached to specimens such that the researcher can link biological information directly to the individual from whom the material was obtained.

Prospective study - Study using specimens that will be obtained from subjects in the future.

Retrospective study - Study using specimens that have already been collected when the research is proposed; may be specimens "left over" from diagnostic or clinical testing or specimens collected for a previous research project.

Specimen - Human biological material that is stored in a repository.

Sample - Human biological material as it is used in research.

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Unidentified (or anonymous) samples or specimens - Samples or specimens were collected without identifiers and are impossible to link to sources, or if identifiable information was collected, it was not maintained and cannot be retrieved.

Unlinked (or anonymized) samples or specimens - Samples or specimens may have been initially identified but samples used for research lack identifiers or codes and cannot be linked to sources. Samples may be linked to clinical, pathological and demographic information before identifiers are removed, as long as information does not invalidate anonymity.

These definitions are based on the Report and Recommendations of the [National Bioethics Advisory Commission](#) (8/99) and by the [American Society of Human Genetics](#) (ASHG).

### **What are the IRB Requirements for Retrospective Studies with Unidentified Samples?**

If using *unidentified samples*, the study is not subject to federal regulations and informed consent is not required.

### **What Forms Are Required For Retrospective Studies With Unidentified Samples?**

Submit [HAC Form 101](#), Protocol Information, requesting exemption and [HAC Form 103](#), Human Biological Specimens for Genetic Research.

### **What are the IRB Requirements for Retrospective Studies with Coded or Identified Samples?**

Informed consent must be obtained if using *coded or identified samples*.

### **What Forms Are Required For Retrospective Studies With Coded Or Identified Samples?**

Submit [HAC Form 101](#), Protocol Information, and [HAC Form 103](#), Human Biological Specimens for Genetic Research. The informed consent document(s) must be attached to [HAC Form 103](#), Human Biological Specimens for Genetic Research.

### **Is Expedited Review Allowed With Coded Or Identified Samples?**

Yes. Expedited review is allowed if the research presents no more than minimal risk to the patient or subject.

### **What Level Of Review Is Required If Subject Information Or Personally Identifiable Information Will Be Released?**

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Review by the full HAC (rather than expedited) is required when subject information or personally identifiable information is to be released.

### **If The Study Will Use Unlinked Samples, Is The Study Subject To Federal Regulations?**

The study may not be subject to federal regulations when the process of unlinking is absolutely sound. However, it is more likely the study will be subject to federal regulations but may still be eligible for exemption from full review.

### **Is Informed Consent Required For Unlinked Samples?**

No. If the protocol is not eligible for exempt review because of the possibilities of being identified, the informed consent requirement may be waived if deemed appropriate by the HAC. Please see the section on waiver of written informed consent.

### **Can Other Stored Subject's Samples That Were Obtained Under These Guidelines Be Used By Us, By Other MCG Investigators And/Or Investigators From Other Sites?**

Stored subject samples in the form of tissue or isolated DNA or protein and obtained under the auspices of these guidelines, may be used by other investigators at MCG or elsewhere if approval is granted by the IRB at each institution (HAC here at MCG). Each new use requires a new IRB approved protocol.

Justification for this use of retrospective samples must be addressed in [Section 3](#) of the [HAC Form 103](#), Human Biological Specimens for Genetic Research. Expedited review is allowed.

### **What Are The IRB Requirements For Prospective Studies With Unidentified Samples?**

The study is not subject to federal regulations if using *unidentified samples* and informed consent is not required. Submit [HAC Form 101](#), Protocol Information, requesting exemption, and [HAC Form 103](#), Human Biological Specimens for Genetic Research.

### **What Are The IRB Requirements For Prospective Studies With Coded Or Identified Samples?**

Informed consent must be obtained if using *coded or identified samples*, submit [HAC Form 103](#), Human Biological Specimens for Genetic Research and the informed consent document. Expedited review is allowed if the research presents no more than minimal risk to the patient or subject. If subject information or personally identifiable information is to be released, full HAC review (rather than expedited) is required.

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### What Are The HAC Requirements For Prospective Studies With Unlinked Samples?

The study may not be subject to federal regulations when the process of unlinking is absolutely sound. However, it is more likely the study will be subject to federal regulations but may still be eligible for exemption from full review. Submit HAC Form 101, Protocol Information, requesting exemption, and HAC Form 103, Human Biological Specimens for Genetic Research. If subject information or personally identifiable information is to be released, full HAC review (rather than expedited) is required.

### What Are The Requirements For Waiver Of Written Informed Consent For Prospective Studies With Unlinked Samples?

The requirement for the informed consent document may be waived if all the following conditions are met:

- a. The proposed use of the specimen presents no more than a minimal risk (physical or psychosocial) to the subject or patient. Minimal risk means all three of the following conditions are met: (i) that the study adequately protects the confidentiality of personally identifiable information obtained during the study; (ii) the study does not involve the inappropriate release of information to third parties; and (iii) that the study design contains a plan for whether and how to reveal findings to the subjects or their physicians, should any finding merit such disclosure.
- b. Reasons are presented showing that it is not practical to conduct this research without a waiver of informed consent; and
- c. A waiver of informed consent will not adversely affect the subject's rights.

### Is There Any Specific Information That Should Be In The Informed Consent Document For Genetic Research Studies?

Yes. The following information or statements should be included in the ICD for genetic research studies:

- It should be indicated if samples are to be used as unlinked, coded, or identified.
- If samples are to be identified or identifiable, information will not be provided to anyone other than the subject; however, absolute confidentiality cannot be guaranteed.
- Subjects should be advised that at times, unexpected findings might arise, e.g. identification of a newly discovered medical risk.
- Subjects should be advised that if misidentified parentage were discovered as a result of this study, this information would not be disclosed to the subject, any family member, or anyone other than the investigators.
- The investigator must state whether the sample will be used exclusively in the study under consideration, e.g. a specific disease, gene, or genetic factor, or for other related conditions as well. Blanket consent for any or all genes or medical

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conditions is not implied. The informed consent may present the following options:

- (i) Coded or identified samples may be used only for this study;
  - (ii) Coded or identified samples may be used only for this study, with further contact required to request permission to use the sample for other studies;
  - (iii) Coded or identified samples may be used for any study relating to the original condition or disease but further permission is required to use the sample for other types of studies,
  - (iv) Coded or identified samples may be used for any kind of future study.
- Subjects should be informed if the sample is to be stored for later study or shared with other researchers as unlinked, coded, or identified samples.
  - Any risk to the individual or to an associated group should be disclosed in the informed consent document.

### Use of Social Security Number as an Identifier

The HAC does not allow the use of the social security number as an identifier for a research protocol. The HAC does not allow the use of initials as an identifier.

### What Are The Most Common Mistakes On HAC Form 103, Human Biological Specimens For Genetic Research?

1. Not enough information regarding the origin of the specimens.
2. Incomplete description of what will be analyzed.
3. Incomplete procedure descriptions for isolating DNA.
4. Identifiers contain subject initials.

### Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at [HAC@mcg.edu](mailto:HAC@mcg.edu) or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.