

Collection and/or Study of Human Specimens Policy

APPLICABILITY

These guidelines apply to:

1. De-Identified, coded, and identified specimens.
2. Existing and prospectively collected specimens.
3. Specimens stored for future research or with potential for commercial uses.
4. Specimens obtained from, or provided to, collaborating institutions.
5. Genetic research

IMPORTANT NOTE: The use of commercially available cell lines (those purchased through catalogues) is not considered human subject research and, therefore, is not governed by 45 CFR 46 or 21 CFR 50&56 and does not come under the jurisdiction of the CCI/IRB.

I. DEFINITIONS

A. HUMAN SPECIMEN

A human specimen consists of any sample of hair, skin, cells, blood, tissue, organ, bodily fluid, excreted or secreted material or derivative substance obtained from a patient or volunteer that may or may not contain living or desquamated cells.

B. DE-IDENTIFIED SPECIMEN

A human specimen that contains none of the 18 identifiers defined by the HIPAA regulations, is not coded, and cannot be linked back in any way to the original donor. The 18 HIPAA identifiers consist of the following data elements: Name; Address; All Elements of dates (except year); Telephone Number; Fax Numbers; E-mail Addresses; Social Security Number; Medical Record Number; Health Plan Beneficiary Number; Account Number; Certificate/License Number; Vehicle Identifiers and Serial Numbers including License Plate Numbers; Device Identifiers and Serial Numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) Address Numbers; Biometric Identifiers including Voice/Fingerprints; Photos; or other unique number, characteristics or code (except as specified in I.C.)

C. CODED SPECIMEN

A human specimen that is recorded in such a manner that subjects cannot be identified by the researcher directly or through identifiers linked back to the original donor. The code must not utilize any personal information of the subject, such as the 18 HIPAA identifiers listed in 'B', initials or the last 4 digits of the Social Security number, etc.

D. IDENTIFIED SPECIMEN

A human specimen that contains identifiers, such as the 18 identifiers listed above in 'B' that make it possible for the investigator to link it back to the original donor.

E. GENETIC TEST

New York Civil Rights Law Section 79-1 defines a genetic test as:

1. "Any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or individual's offspring; such term shall also include DNA profile analysis. 'Genetic test' shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation. The CCI/IRB also includes any measurement of certain metabolites associated with heritable diseases as a genetic test.
2. "Genetic Predisposition shall mean the presence of a variation in the composition of the genes of an individual or an individual's family member which is

scientifically or medically identifiable and which is determined to be associated with an increased statistical risk of being expressed as either a physical or mental disease or disability in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder."

F. HUMAN SUBJECT RESEARCH

1. A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
2. Intervention includes both physical procedures by which data are gathered and manipulation of the subject or subject's environment that are performed for research purposes.
3. Interaction includes communication or interpersonal contact between investigator and subject.
4. Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

G. NOT HUMAN SUBJECT RESEARCH

The analysis of prospectively collected, de-identified specimens or those identified with a code not derived from individual personal information, does not constitute human subject research under the HHS human subjects regulations (45CFR Part 46) if:

1. The specimens are not obtained from an intervention with the subject specifically for the investigator's research, and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the specimens pertain.

H. EXEMPT RESEARCH

As provided in the Department of Health and Human Services Code of Federal Regulations, 45 CFR 46.101 (b), the use of existing specimens, de-identified or containing a code that is not derived from individual personal information (See Sections I.B and C), qualifies as Exempt research, category 4. (The specimens must exist at the time the protocol is reviewed.)

I. NON EXEMPT RESEARCH

Research projects that have been determined to involve human subjects and are not exempt under HHS regulations at 45 CFR 46.101 (b) as defined in I.H.

J. ENGAGED IN HUMAN SUBJECT RESEARCH

1. Once an activity is determined to involve non-exempt human subjects research, it must be determined whether the institution (AECOM/MMC/NBHN) is engaged in that research, because certain regulatory requirements apply.
2. AECOM/MMC/NBHN researchers are engaged in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; or (2) identifiable private information about the subjects of the research [45 CFR 46.102(d),(f)].
3. Institutions whose employees or agents obtain identifiable private information or identifiable specimens from other institutions for the purposes of a non-exempt human subjects research project, without directly interactive with human subjects, still are considered engaged in human subjects research.
4. Obtaining identifiable private information means receiving or accessing identifiable specimens for research purposes. Obtain is interpreted to include an investigator's use, study, or analysis for research purposes of identifiable specimens already in the possession of the investigator.
5. Example of 'Engaged':
Institutions whose employees or agents intervene or interact for research

purposes with any human subjects of the research by performing invasive or noninvasive procedures, such as: blood draw; collecting buccal mucosa cells using a cotton swab; asking someone to provide a specimen by voiding or spitting into a specimen container, obtaining informed consent.

K. NOT ENGAGED IN HUMAN SUBJECT RESEARCH

1. Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.
2. Institutions whose employees or agents consult or collaborate on the human subjects research by obtaining coded private information or human biological specimens from an institution engaged in the research that retains a link to individually identifying information (such as name or social security number), if the consultants or collaborators and the holder of the key enter into an agreement prohibiting the release of the key to the consultants or collaborators under any circumstances.

II. REVIEW REQUIREMENTS

A. CCI/IRB Review - Not Required

De-identified or coded specimens sent to another institution when AECOM/MMC/NBHN is not involved in the research do not require CCI/IRB review. The PI is required to submit:

1. A Material Transfer Agreement
2. Written confirmation that the specimens are de-identified or coded, and that AECOM/MMC/NBHN is not involved in the research.
3. For coded specimens include a written statement that the key to the code will not be released.

For information regarding Material Transfer Agreements, see Section VII.

B. CCI/IRB Review - Required

1. Research using de-identified or coded specimens when AECOM/MMC/NBHN is involved in the research requires review by CCI/IRB. Submit the following to the appropriate CCI/IRB:
 - a. Exempt Application Form indicating the research classification (Exempt 4, Not Engaged or Not Human Research).
 - b. Detailed protocol
 - c. A written agreement from the holder of the code that the key to the code will not be released to the investigator under any circumstances, when properly coded specimens are received from or sent to another institution for human research,
 - d. A copy of the sending or receiving institution's written authorization, IRB approval letter, or exempt verification.
 - e. Note: All materials listed above must accompany the CCI/IRB Exempt Application Form. See Section VII for MTA requirements.
2. Identified Specimens
 - a. All AECOM/MMC/NBHN research utilizing identified specimens requires Expedited or, in some cases, Full Review as determined by the CCI/IRB. Researchers are required to submit to the CCI/IRB the appropriate Research Application and required documents for review. The CCI/IRB will provide researchers with written approval when review is complete.
 - b. Research involving identified specimens sent to another institution when AECOM/MMC/NBHN is not involved in the research requires CCI/IRB review. Submit the following to the appropriate CCI/IRB.
 - i. CCI/IRB Exempt Application Form
 - ii. A copy of the receiving institution's written authorization, IRB approval letter or exempt verification.

- iii. A copy of the informed consent under which the specimens were collected.
 - iv. A HIPAA Authorization form or a HIPAA Waiver request.
- NOTE: See Section VII for MTA requirements.

III. INFORMED CONSENT: WHAT IS REQUIRED?

- A. Informed consent is required for the prospective collection of identifiable specimens for research purposes. When appropriate, the CCI/IRB may approve a consent waiver.
- B. Informed consent may be waived for:
 1. The use of de-identified specimens or those identified with a code that is not derived from individual personal information and are either left over from standard clinical care or have been collected from subjects enrolled in another protocol.
 2. The use of identifiable specimens collected from subjects enrolled in another protocol, provided that the research participant gave consent for future research.
 3. For leftover identified surgical specimens, the surgical consent that authorizes the use of the material for research may be sufficient. The decision whether or not to require a protocol-specific informed consent document is made by the CCI/IRB.
- C. The informed consent document must contain all the elements required in 45 CFR 46. In addition for specimen research include language as relevant to each protocol, regarding the items listed below.

For genetic research refer to numbers 7 through 9 below and to Appendix 'A' for sample consent language. Refer to Appendix 'B' for template language for the use of identified specimens for future research and Appendix 'C' for template language for the use of de-identified specimens for future research.

1. Specimens collected specifically for research purposes.
2. The potential for future research use (which may or may not be known).
3. Whether or not the specimens will be destroyed at some point in the future. (Researchers are required to know whether or not specimens collected under sponsored protocols will be stored for future research. If the specimens will be sent to the sponsors/agencies and will not be kept for future research, sponsors/agencies are required to provide written documentation to the investigator that the specimens will be destroyed, and when (e.g., after the assay is complete, or once the study is complete.)
4. Subject's right to withdraw consent at any time for future use of their specimens, when required by the sponsor.
5. Results that have the potential for some commercial value in the future and that subjects will not receive payment for such commercial value.
6. Results that have the potential to affect a research participant's insurability.
7. **GENETIC RESEARCH** - For Genetic research as defined under section I. E. of this policy, the consent language must be customized for each genetic test. NY CLS 79-2(b) defines what the informed consent document must stipulate, as outlined below.

Written informed consent to a genetic test shall consist of written authorization that is dated and signed and includes at least the following:

- a. a general description of the test;
- b. a statement of the purpose of the test;
- c. a statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent.
- d. a statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult their physician or pursue genetic counseling;
- e. a general description of each specific disease or condition tested for;

- f. the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease. If no level of certainty has been established, this subparagraph may be disregarded;
 - g. the name of the person or categories of persons or organizations to whom the test results may be disclosed;
 - h. a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and
 - i. the signature of the individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.
8. For Genetic research as defined under section I.E. of this policy, also state
- a. Whether or not participants will be informed of the results of genetic tests, and if so, whether and how counseling will be performed.
 - b. If genetic tests may reveal other information unrelated to the study. For example, in cases where parents and children are both tested, the test may disclose the possibility that the father is not the biological parent. Although these types of information will not be disclosed, the participant must be informed about the potential findings.
9. Genetic research utilizing identified, stored human tissue for general research purposes as defined under section I. E. of this policy, the consent language must comply with NY CLS 79-9(e) as listed below. See Appendix 'B' attached to this policy for template language.
- a. A statement that the sample will be used for future genetic tests;
 - b. The time period during which the tissue will be stored, or if no time limit is specified, a statement that the tissue will be stored for as long as deemed useful for research purposes;
 - c. A description of the policies and procedures to protect patient confidentiality;
 - d. A statement of the right to withdraw consent to use of the tissue for future use at any time and the name of the organization that should be contacted to withdraw consent;
 - e. A statement allowing individuals to consent to future contact for any or all purposes, including the following: (i) research purposes; (ii) provision of general information about research findings; and (iii) information about the test on their sample that may benefit them or their family members in relation to their choices regarding preventive or clinical care; and
 - f. A statement explaining the benefits and risks of consenting to future contact for the purposes set forth in subparagraph 'e.' of this paragraph. In no event shall information about specific test results on stored human tissue donated for general research purposes be disclosed to an individual without obtaining informed consent.

IV. POLICY FOR USE OF HUMAN EMBRYOS AND HUMAN EMBRYONIC STEM CELLS FOR RESEARCH (Policy pending.)

V. PAYMENT FOR SPECIMENS

Specimens may not be sold. However, it is permissible to charge a reasonable processing fee, subject to institutional approval by the Executive Dean of Albert Einstein College of Medicine or designee, and/or the Director of the Research and Sponsored Programs of Montefiore Medical Center, and other institutions that may be involved.

VI. SAMPLE INFORMED CONSENT LANGUAGE AND TEMPLATE

A. Sample Genetic Research (See Appendix A).

- B. Future Use of Specimens For Potential Human Research Template (See Appendix B (identified specimens) and Appendix C (de-identified specimens)).

VII. MATERIAL TRANSFER AGREEMENT (MTA)

A. YU Employees

1. Specimens Sent to Another Entity

YU employees should refer to the AECOM Office of Biotechnology website at <http://www.aecom.yu.edu/biotechnology/> for an appropriate MTA when sending materials to another entity (academic institution, non-profit, federal agency, or commercial company). Refer to Section II. to determine if the research protocol requires CCI/IRB review.

2. Specimen Received from Another Entity

YU employees must contact the AECOM Office of Biotechnology at 430-3357 to sign an incoming MTA if they will be receiving materials from another entity (academic institution, non-profit, federal agency, or commercial company). Before requesting the signature from the Office of Biotechnology, CCI must review the protocol. Refer to Section II.

3. An MTA is not required when specimens are sent to or received from another entity (academic institution, non-profit, federal agency, or commercial company) having a contract with the institution that addresses the exchange of material.

- B. MMC employees are required to contact the Director of the Office of Research and sponsored Programs for an appropriate MTA at 718 920-4151 Ex. 230 if they will be receiving or sending materials to or from another entity (academic institution, non-profit, federal agency, or commercial company).
- C. NBHN employees are required to contact the Research Director for an appropriate MTA at 718-918-7070 if they will be sending materials to another institution.

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Approved by JCC 11.06

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APPENDIX 'A'
Sample Template Including Instructions for Genetic Research

NY State Law and CCI/IRB definition of Genetic Test: New York Civil Rights Law Section 79-1 defines a genetic test as:

- a. "Any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or individual's offspring; such term shall also include DNA profile analysis. 'Genetic test' shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation. The CCI/IRB also includes any measurement of certain metabolites associated with heritable diseases as a genetic test.
- b. "Genetic Predisposition shall mean the presence of a variation in the composition of the genes of an individual or an individual's family member which is scientifically or medically identifiable and which is determined to be associated with an increased statistical risk of being expressed as either a physical or mental disease or disability in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder."

CONSENT REQUIREMENTS:

- I. NYS Law requires the following information be included in the consent:
 - A. PURPOSE (Why are we doing this research)
 - i. Include –
 - a. A simple explanation of the general description of each specific disease or condition tested for.
 - b. A statement that tests conducted under this research study may reveal genetic information.
 - B. GENETIC COUNSELING INFORMATION:
 - i. A statement that the individual may wish to obtain professional genetic counseling prior to signing the informed consent.
SAMPLE: You may wish to obtain professional genetic counseling prior to signing the informed consent. A genetic counselor is a person qualified to provide information about what the results of this type of test may mean to you and your family. You or your insurance company will be responsible for the cost of these services.
 - ii. The level of certainty that a positive test result for that disease or condition serves as a predictor of such disease. If no level of certainty has been established, this subparagraph may be disregarded.
SAMPLE WHEN TEST SERVES AS A PREDICTOR: If the test is positive, it means that there is a ____% chance you might have you may wish to talk with your doctor, go for another blood test or speak to a genetic counselor. If no level of certainty has been established, this subparagraph may be disregarded.
 - C. PROCEDURES (How will the test be done?)
Provide detailed information specific to your study.
SAMPLE: We will obtain 10 ml of blood from your arm by a needle stick when you come to This will only be done one time.

D. ADDITIONAL TESTS ON YOUR SAMPLE

Include a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent.

SAMPLE: No other tests other than those explained under this study will be done on your sample. The sample will be destroyed at the end of the research study.

Alternatively, include the CCI Future Use consent language. See Appendix B (identified) or Appendix C (de-identified).

E. WHO CAN CONSENT

The individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual must sign. An authorized person is a health care proxy legal guardian.

II. CCI/IRB Policy requires the following information be included in the consent: (CCI/IRB policy requirements and are in addition to the NYS Law requirement.)

A. Whether or not participants will be informed of the results of genetic tests, and if so, whether and how counseling will be performed.

SAMPLE: Since the significance of these tests are not known for you, we will not disclose the results of the genetic testing. No formal counseling will be provided under the research study. If you request, you will be referred to a genetic counselor. You or your insurance carrier will be responsible for the genetic counselor's fee.

OR

You will be told the results of the genetic tests and formal counseling will be provided under the research study at no cost to you.

B. If genetic tests may reveal other information unrelated to the study. For example, in cases where parents and children are both tested, the test may disclose the possibility that the father is not the biological parent. Although these types of information will not be disclosed, the participant must be informed about the potential findings.

SAMPLE: Genetic tests may reveal medical information that is not related to this research study. For example, in cases where parents and children are both tested, the test may disclose the possibility that the father is not the biological parent. This information will not be revealed to you and will remain confidential.

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APPENDIX 'B'

NOTE: This template is required when obtaining specimens for future research that will be identified (linked back to the original donor).

See Appendix 'C' if the specimens will be de-identified.

USE OF IDENTIFIED SPECIMENS FOR FUTURE RESEARCH:

In addition to the research you are consenting to under this research study, Dr. _____ or other researchers at this or other institutions may wish to study the samples in future research, including genetic analysis. These samples, taken from your body, would be able to be linked back to you. Information about you may be shared with other researchers who will keep the information confidential. However, it is possible that information about you may become known to people other than the researchers.

At this time, the researcher does not know what the future studies will be. Your specimens may also be submitted to a tissue/cell/DNA bank. The specimens may be kept for a long time and may exceed 50 years. You have the right to withdraw consent to use of the tissue for future use at any time by contacting the supervisor of the study named on the first page of the consent or the CCI office at 718-430-2253. Unused specimens will be destroyed.

In some research using human blood or tissue, the specimens and their parts may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests or treatments.

Your specimens may be used for future research, even though the purpose of the future research is not known at this time.

**PARTICIPANT:
PLEASE INDICATE YOUR CHOICE BY
INITIALING ONE (1) OF THE FOLLOWING
OPTIONS**

I consent to have my specimens used for

APPENDIX 'C'

NOTE: This template is required when obtaining specimens for future research that will be de-identified (not linked back to the original donor).

When uncertain, use the Appendix 'B' template.

USE OF DE-IDENTIFIED SPECIMENS FOR FUTURE RESEARCH:

In addition to the research you are consenting to under this research study, Dr. _____ or other researchers at this or other institutions may wish to study the samples in future research, including genetic analysis. These samples, taken from your body, would NOT be linked back to you. No one will know your name or protected health information.

At this time, the researcher does not know what the future studies will be. Your specimens may also be submitted to a tissue/cell/DNA bank. The specimens may be kept for a long time and may exceed 50 years.

In some research using human blood or tissue, the specimens and their parts may enable researchers to develop medical tests or treatments that have commercial value. You will not receive any money that may result from any such commercial tests or treatments.

Your specimens may be used for future research, even though the purpose of the future research is not known at this time.

**PARTICIPANT:
PLEASE INDICATE YOUR CHOICE BY
INITIALING ONE (1) OF THE FOLLOWING
OPTIONS**

I consent to have my specimens used for future research studies.

I consent to have my specimens used for future research studies only for the study of _____.

I do NOT consent to have my specimens used for future research studies. (The specimens will be destroyed at the end of the study.)

future research studies.

I consent to have my specimens used for future research studies only for the study of _____.

I do NOT consent to have my specimens used for future research studies. The specimens will be destroyed at the end of the study.

**PARTICIPANT:
FOR FUTURE CONTACT, PLEASE INITIAL
YOUR CHOICES BELOW**

I consent to be contacted in the future to learn about:

New research protocols that I may wish to join.

General information about research findings.

Information about the test on my sample that may benefit me or my family members in relation to choices regarding preventive or clinical care.

I DO NOT AGREE TO BE CONTACTED IN THE FUTURE, EVEN IF THE RESULTS MAY BE IMPORTANT TO MY HEALTH OR MY FAMILY'S HEALTH.

Dated: 6.01
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