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|  | EASTERN CONNECTICUT STATE UNIVERSITY  Office of the Vice President for Academic Affairs  Gelsi-Young Hall, Willimantic, CT 06226  Ph: 860-465-5245 | CUHSR use only:  Protocol # Click or tap here to enter text. |

COMMITTEE ON THE USE OF HUMAN SUBJECTS IN RESEARCH

OHRP IRB00005900 Eastern Connecticut State U IRB #1 Federalwide Assurance FWA00011898

**IRB-1B Genetic Testing Supplemental Form**

Read these important notes before completing this form:

1. There may be periodic updates to this form, so please be sure to use the current version.
2. Please complete this form if the proposed study involves the use of genetic testing.
3. This form must be attached to the IRB-1 protocol application when submitted for initial IRB review. Applications will not be reviewed until they are complete with all the required information and documentation.
4. Do not alter this form/convert it to another format (PDF, etc.). Altered forms will not be reviewed.
   1. Tap in the boxes to check/uncheck your selections.
   2. Use the “Click or tap here to enter text” to enter all information. The boxes will adjust to accommodate however much space you need. Do not bold the text you enter in the text boxes.

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| **Section 1: General Information** |
| **Name of Principal Investigator:** Click or tap here to enter text.  **Department:** Click or tap here to enter text.  **Email:** Click or tap here to enter text.  **Phone:** Click or tap here to enter text.  **Study title:** Click or tap here to enter text.  Does this study use:  **Genetic testing performed for research purposes only?**  Yes  No  If yes, complete section 2.  **Testing for genetic diseases or clinical genetic testing?**  Yes  No  If yes, complete section 3. |

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| **Section 2: Genetic Tests Performed for Research Purposes Only** |
| Genetic tests may be performed on samples for general research purposes only if the individual who provided the sample gave prior written informed consent for use of the sample for general research purposes. There is no requirement to inform subjects of their personal genetic test results, so long as the consent form states that the test is being done solely for research purposes and that the subject’s results will not be provided to the subject or the subject’s physician.  The following elements must be included on the consent form. Please mark the check the boxes below to indicate each appears on the consent form.  1. A general description of the test (see Appendix 1, #1).  2. A statement of the purpose of the test (see Appendix 1, #2).  3. The procedures for collecting and identifying specimens (see Appendix 1, #4).  4. The time period during which the sample will be stored, of if no time limit is specific, a statement that the sample will be stored for as long as deemed useful for research purposes.  5. A description of the policies and procedures to protect subject confidentiality.  6. A statement allowing individuals to consent to future contact for any or all purposes, including the following: research purposes and provision of general information about research findings.  7. A statement explaining the benefits and risks of consenting to future contact.  The following elements must be included on the consent form if they are applicable (see Appendix 2). Please mark the appropriate box.  1. A statement that the sample will be stored and used for future genetic tests.  N/A  Yes, this is on the consent form.  2. A statement indicating where the samples will be retained and the type of future research that will be conducted on the samples, if known.  N/A  Yes, this is on the consent form.  3. A statement of the right to withdraw consent for future use of the sample at any time, and the name of the individual or organization that should be contacted to withdraw consent.  N/A  Yes, this is on the consent form. |

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| **Section 3: Genetic Tests Performed (at least in part) for Genetic Diseases or Clinical Purposes** |
| Elements of consent indicated in Appendix 1 are necessary for genetic testing for diseases or clinical genetic testing (i.e., results of the test will be communicated to the subject or subject’s doctor) and informed consent must be obtained prior to conducting the test. Appendix 1 has more detail on each of the 14 requirements below as well as examples for how to address each on the consent form.  Please mark the check the boxes below to indicate each is on the consent form.  1. A general description of the test.  2. A statement of the purpose of the test.  3. A general description of each specific disease or condition tested for.  4. The procedures for collecting and identifying specimens.  5. A statement that the subject may want to obtain professional genetic counseling before signing consent.  6. Indicate the level of certainty for a positive test result. Note: if genetic results will not be given, check this box for N/A  7. A statement regarding the meaning of a positive test result.  8. Indicate to whom the test results may be disclosed.  9. Indicate whether test results would be disclosed to persons or organizations not named on the consent form.  10. A statement that no tests other than those authorized and the sample will be destroyed.  11. A description of the additional risks of genetic testing research.  12. A description of any additional costs associated with the genetic research.  13. A statement regarding intent to develop a commercial product from specimens obtained.  14. Include a signature of the subject for the genetic test indicated. |

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| **Appendix 1: Consent Requirements Genetic Diseases/Clinical Purposes** | |
| **Required Element** | **Examples of Addressing Element on Consent form** |
| 1. A general description of the test. | The genetic testing being done in this study requires a blood sample from you. The sample will be processed by the study team and sent to a lab where it will be tested. |
| 2. A statement of the purpose of the individual test or tests that will be conducted. | The purpose of this test is to see if you may develop XXX disease in the future (or to see if you have inherited a gene that may increase the likelihood you could develop XXX in the future). |
| 3. A general description of each specific disease or condition tested for. | We are gathering genetic material or DNA to test for XXX, to learn more about who may be at risk for developing XXX and how severe their disability may be. [If applicable: We may also try and collect specimens from related family members, to see how XXX is transmitted in families.]  *Note: Focus first on the subject, informing him/her that we are testing his/her blood for the genetic disease/condition. Address the relative later, if applicable.* |
| 4. Describe the procedures for collecting and identifying specimens for the genetic test (specifically what biological specimen will be required, how it will be collected, and how much). | Explain how the sample will be collected (e.g., blood draw, cheek swab), how much will be collected, and how the sample will be identified for purposes of this research study and future use, if applicable. |
| 5. A statement that the subject may want to obtain professional genetic counseling before signing consent. | You may want genetic counseling before signing this consent.  If you do not understand what a genetic test is and wish to receive professional genetic counseling prior to signing this consent form, please let us know. |
| 6. Indicate the level of certainty that a positive test result for the specific disease/condition being tested serves as a predictor of such disease/condition for the subject.  *Note: If genetic results will not be given to the individual or his/her physician, or the level of certainty of the test result is unknown, disregard this requirement.* | If a mutation is found in your XXX gene, at present, we believe this means that you are at an increased risk (X% higher) of developing XXX compared to people in the general population who do not have this gene. |
| 7. A statement regarding the meaning of a positive test result (i.e., an indication that the subject may be predisposed to or have the specific disease/condition tested for and may wish to consider further independent testing, consult their physician or pursue genetic counseling.) | If there is a positive test result, this means that you may develop, or that you may have XXX disease/condition that we are testing for in this study. You may want to undergo further independent testing, consult with your doctor, or receive professional genetic counseling. |
| 8. Indicate to whom the test results may be disclosed (including the subject, study doctor, or category of persons or organizations).  *Note: Subjects should retain the right not to receive information about test results that reveals genetic status. Any disclosure of genetic information should be accompanied by appropriate counseling by trained genetic counselors.* | The research testing results will be reported back to you and made available to your study doctor.  Note: Unless return of testing results is necessary to conduct the study, the subject must indicate agreement (yes/no) to return of results to entities noted, such as, “The testing results on my sample may be returned to my study doctor.”  OR (if results not returned)  The meaning of these research testing results is not known, so we will not make these results available to you or your doctor. |
| 9. Indicate whether genetic test results would be disclosed to persons or organizations not named in the consent form. | If we want to share the results of your genetic tests with other people or groups not listed in this form, we will ask for your consent to do so first.  OR  We may combine your results with those from other research subjects in a way that your sample cannot be individually identified or linked to you personally. If we do this, we may share the combined results with other researchers. |
| 10. A statement that no tests other than those authorized and the sample will be destroyed at the end of the testing process (or not more than 60 days after the sample was taken), unless subject expressly authorizes a longer period of retention. | We will do the tests only for our own research. The specimen will be destroyed at the end of the testing process for this study.  OR  The samples will be destroyed not more than XX days after the sample was taken. |
| 11. Description of the additional risks for genetic testing research. In addition to the physical risk of obtaining the sample, include any potential financial, psychological and social risks of disclosure of the test results, as applicable.  *Note: A statement regarding GINA is required for inclusion on the consent.* | Additional risks when conducting genetic testing may include effects of the knowledge of being a carrier of a disease gene that might affect your life course, employability or insurability (see #12 below regarding option to pay out of pocket for test), or family relationships.  Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. |
| 12. Describe any additional costs associated with the genetic research. | You will need to pay for the costs of genetic counseling if you seek care outside of that provided by the study counselor.  You may pay for the cost of the genetic test out of pocket rather than filing an insurance claim. |
| 13. A statement regarding intent to develop a commercial product from the specimens obtained in this study. | If there is a commercial product developed as a result of the research testing done in this study, you [will/will not] be paid for the use of your sample. |
| 14. Include signature of the subject for the genetic test indicated, or the signature of the legally authorized representative for subjects with decisional impairment to consent for themselves; date of signature. | Included on consent signature page. |

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| **Appendix 2: Consent Requirements for Future Contact/Stored for Future Tests** | |
| The elements described below should be included in the consent form if subjects may be contacted in the future regarding testing not specified within the study consent, or if samples will be collected and stored for purposes of future genetic testing. | |
| **Required Element** | **Examples of Addressing Element on Consent form** |
| 1. If samples will be stored and used for tests other than those for which specific consent has been obtained, provide a description of those activities and provision for subject to opt in.  Note: Samples may be used for tests other than those for which specific consent was obtained, for research purposes, pursuant to a research protocol approved by an IRB, provided the individuals who provided the samples gave prior written informed consent for the use of their sample for general research purposes and didn’t specify time limits or other factors that would restrict use of the sample for the test,  **and,**  • The samples have been permanently stripped of identifying information, **OR**  • A coding system has been established to protect the identity of the individual who provided the samples, and an IRB has reviewed and approved the procedures for the coding system.  *Inform the subject whether his/her sample may be used for tests other than those for which specific consent has been obtained. This can be done in two ways: 1) future, unspecified research may be conducted on de-identified samples, or 2) the subject may be re-contacted so he/she may re-consent to the use of his/her sample for research.* | More tests may be conducted on your sample if you agree to let the investigators keep your sample for future research use. No future genetic testing will be done on your identified sample without your consent.  *If optional retention for future testing is being requested, use the following language:*  “My coded sample may be kept indefinitely, and may be made available to other scientists studying disease XXX.”  Checkboxes at the signature page (“I do/do not agree that my specimen[s] can be kept [for specified period of time or indefinitely] and can only be used for future genetic testing as described above. I understand that all future research will be done with the approval of an institutional review board, and that my sample will be coded to protect my identity. Due to the investigational nature of the research to be conducted with my sample, I will not be informed of any individual test results.”  *If subject will be contacted to consent to future research, use the following language:*  “If we need more information or testing not described in this consent form, we may ask you to take part in a continuation of this study or a new study. When we contact you, we will tell you about the study and ask you to sign and date a new consent form.” |
| 2. If samples will be stored for future testing, indicate where the samples will be retained. Also describe the type of future research that be conducted on the samples, if known. | The blood sample [without your name] will be sent to a repository in XXX for future research.  Your DNA and other health information will be stored at XXX for future research. |
| 3. A statement regarding right to withdraw the subject’s sample. | If you decide that you don’t want us to keep your sample, let us know and we will destroy it. However, if identifiers were removed from your sample before it was provided to other investigators, it may not be possible for us to stop future research with your sample.  **OR**  Your sample may have already been distributed to other researchers before you asked us to destroy it, so we may not be able to retrieve it and stop future research. |