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| **Version History** | **Date** | **Revision** |
| R00 | 3/5/15 | Original issue |
| R01 | 11/16/23 | Annual review, updated logo, added revision table |

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| The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving genetic testing when the research takes place in New York State. This worksheet is to be used. It does not need to be completed or retained. | |
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| 1. Research Involving Genetic Testing (§79-L.1(a)) (Check if “Yes”. If Yes, Informed Consent Requirements in sections 3 and/or 4 are required.) | |
|  | Does the activity involve a genetic test [[1]](#footnote-1)on a biological sample[[2]](#footnote-2) taken from an individual? |
| **If “No” for section 1 then the research does not involve genetic testing on an individual and requirements do not apply.** | |
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| 2 General Requirements (Check if “Yes”. All items must be “Yes” or “N/A”. ) | |
|  | If the research is on samples from a deceased individual, then consent is sought from the next of kin. **N/A** |
|  | No person who lawfully possesses information derived from a genetic test on a biological sample from an individual shall incorporate such information into the records of a nonconsenting individual who may be genetically related to the tested individual; nor shall any inferences be drawn, used, or communicated regarding the possible genetic status of the nonconsenting individual. **N/A** |
|  | Additional genetic testing may be performed on a given sample without additional consent of the person tested only when such testing is necessary and required to demonstrate the integrity of the sample tested or to resolve the analysis of a test with a previously indeterminate result. **N/A** |
|  | The protocol indicates procedures for when consent to storage of the tissue sample is withdrawn (at any time). These procedures include the entity storing the sample promptly destroying the sample or portions thereof that have not already been used for research purposes. **N/A** |
|  | Family members of an individual who provided a stored tissue sample will NOT be contacted for clinical, research, or other purposes without consent from the individual who provided the tissue sample with respect to the specific family members who will be contacted and the specific purpose of the contact. **N/A** |
|  | Information about an individual derived from genetic tests performed on stored human tissue or information linking an individual with specific results of genetic tests will NOT be released to any organization or person without the explicit written consent of the individual who donated the stored tissue to release of the information for the purposes set forth in the written consent document. **N/A** |
|  | DNA samples will be stored for no more than ten years in the absence of genetic testing, if authorized in writing by the subject. If genetic testing will be performed on the stored samples or samples will be stored for more than 10 years, informed consent will be obtained. **N/A** |
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| 1. Informed Consent Requirements for Prospective Genetic Testing (Check if “Yes”. All items must be “Yes” or “N/A”. ) The consent form must be dated and signed and must include: | |
|  | A general description of the test. |
|  | A statement of the purpose of the test. |
|  | A statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent. |
|  | A statement that a positive test result is an indication that the individual may be predisposed[[3]](#footnote-3) 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. **N/A (The protocol doesn’t permit such degree of specificity):** |
|  | A general description of each specific disease or condition being tested. **N/A** (**The protocol doesn’t permit such degree of specificity):** |
|  | A description of the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease. **N/A (**No level of certainty has been established): |
|  | The name of the person or categories of persons or organizations to whom the test results may be disclosed. |
|  | 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. |
|  | 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 an individual. |
|  | A general description of possible incidental findings, whether such findings will be disclosed, the process for disclosing them, and how the participants can opt out of receiving certain types of findings. |
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| 1. Informed Consent Requirements for Human Tissue Stored for General Research Purposes[[4]](#footnote-4) (Check if “Yes”. All items must be “Yes” or “N/A”. ) The consent form includes: | |
|  | A statement that the sample will be used for future genetic tests. |
|  | 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. |
|  | A description of the policies and procedures to protect patient confidentiality. |
|  | 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. |
|  | A statement allowing individuals to consent to future contact for any or all purposes, including the following:  Research purposes.  Provision of general information about research findings.  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. |
|  | A statement explaining the benefits and risks of consenting to future contact |
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| 5 For Modifications to Approved Research (All must be “Yes”.) | |
|  | The protocol describes the process for obtaining consent of subjects when further disclosure of genetic test results to persons or organizations not named on the informed consent form is requested. **N/A** |
|  | Any further disclosure of genetic test results to persons or organizations not named on the informed consent shall require the further informed consent of the subject of the test. **N/A (**research meets the waiver criteria in sections 8 and/or 9)**:** |
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| Waivers of Informed Consent for Genetic Testing (Research must fall into one of the categories below in order to qualify for a waiver of informed consent) | |
| 1. Research Involving Genetic Testing per (§79-L.4(a)) (Check if “Yes”. If “No” research does not qualify for this waiver.) | |
|  | Does the activity involve anonymous samples for research or statistical purposes, pursuant to a research protocol approved by an institutional review board which assures the anonymity of the sources of the samples? |
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| 1. Research Involving Genetic Testing per (§79-L.4(b)) (Check if “Yes”. If “No” research does not qualify for this waiver) | |
|  | Does the activity involve genetic tests performed pursuant to an order of a court of competent jurisdiction? |
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| 1. Research Involving Genetic Testing per (§79-L.4(c)) (Check if “Yes”. If “No” research does not qualify for this waiver) | |
|  | Does the activity involve disclosure of results of genetic tests performed pursuant to an order of a court of competent jurisdiction? |
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| 1. Research Involving Genetic Testing per(§79-L.9(a)) (Check if “Yes” or “N/A”. If “No” research does not qualify for this waiver) | |
|  | Does the activity involve samples being used for tests other than those for which specific consent has been obtained, for general research purposes and pursuant to a research protocol approved by an institutional review board? |
|  | Have the individuals who provided the samples given prior written informed consent for the use of their sample for general research purposes and did not specify time limits or other factors that would restrict use of the sample for the test? |
|  | Maintaining subject confidentiality:  Have the samples been permanently stripped of identifying information? **OR:**  Has a coding system been established to protect the identity of the individuals who provided the samples, and an institutional review board has reviewed and approved the procedures for the coding system? |

1. “genetic test” means 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 the individual’s offspring; it also includes DNA profile analysis. ­“Genetic test­” does not include any test of blood or other medically prescribed test in routine use that is associated with a genetic variation, unless conducted purposely to identify such genetic variation. [↑](#footnote-ref-1)
2. “biological sample” means any material part of the human body or of discharge there from known to contain DNA, including but not limited to tissue specimen, blood or urine. [↑](#footnote-ref-2)
3. “genetic predisposition” or “predisposed” 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. [↑](#footnote-ref-3)
4. In order to use human tissue for genetic testing that was collected for general research purposes, the original consent must have included the items in section 4. The IRB can also recommend the requirements in this section are included in prospective studies collecting tissue for undisclosed future research. [↑](#footnote-ref-4)