1. **Purpose**
   1.1. Outline the additional protections required by the State of New York for individuals participating in research involving genetic testing.
   
   1.2. Establish additional requirements and processes when conducting research involving gene transfer such that the necessary institutional protections are in place for the safety of researchers and subjects.

2. **Scope**
   This policy applies to any employee or agent of the University of Rochester proposing and conducting human subject research involving genetic testing or gene transfer.

3. **Definitions**
   3.1. *Biological Sample* – Any material part or discharge of the human body known to contain DNA, such as tissue specimen, blood or urine.

   3.2. *Genetic Test* – 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 disorder in the individual or the individual’s offspring (e.g., tests for breast cancer, prostate cancer, Huntington disease, sickle cell anemia).

   3.2.1. A genetic test does not include the following:
   
   • Tests performed on a person with symptoms of the disease or disorder under study;
   • Tests performed for the purpose of answering a research question, where the ultimate purpose of performing the test is not to identify a genetic variation (e.g., comparing efficiency of one diagnostic test to another).
   • 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.

   3.2.2. Under this law, the RSRB does not consider genetic testing to include studies of gene expression.

   3.3. *Genetic Predisposition* – The presence of a variation in the composition of the genes of an individual or an individual’s family member that is scientifically or medically identifiable, and that is determined to be associated with an increased statistical risk of being expressed as either a physical or mental disease or disorder in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder.
3.4. **Recombinant Nucleic Acid** – Molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell.

3.5. **Synthetic Nucleic Acid** – Nucleic acid molecules that are chemically (or by other means) synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.

4. **References**
   4.1. State of New York’s Civil Rights Law Section 79-l; NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
   4.2. Policy 506 Data and Safety Monitoring; Policy 801 Reporting Research Events; Guideline for Internal Review of Human Gene Transfer Research; RSRB Elements of Consent for Genetic Testing Research

5. **Responsibilities**
   5.1. The RSRB is responsible for determining whether the research meets criteria for genetic testing or gene transfer.
   5.1.1. The RSRB will review all studies determined to involve gene transfer at a convened meeting.

6. **Requirements for Research Involving Genetic Testing**
   6.1. Investigators will follow the additional regulations under New York State’s (NYS) Civil Rights Law, Section 79-l, when proposing and conducting research involving genetic testing.
   6.1.1. If any results of the genetic test will be communicated to the subject or the subject’s doctor, then the test is considered in part for a clinical purpose. Therefore, all elements of consent required under NYS Civil Rights Law, Section 79-l, must be incorporated into the research consent as outlined in the RSRB Elements of Consent for Genetic Testing Research. In addition, these elements should be addressed in the research protocol.
   6.1.2. Investigators will ensure that genetic tests conducted, at least in part, for clinical purposes, are performed in a Clinical Laboratory Improvement Amendments (CLIA) certified lab.

7. **Requirements for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Human Gene Transfer Protocols)**
   7.1. All research involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from such molecules, into human research subjects (i.e., human gene transfer protocols) must be conducted in accordance with the National
Institute of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules as well as the Institutional Biosafety Committee (IBC) procedures, regardless of funding source.

7.2. All human gene transfer protocols must include a data and safety monitoring plan in compliance with the RSRB Policy for Data and Safety Monitoring Plans, as well as the NIH and FDA requirements, as applicable.

7.3. Only the RSRB, and not any other independent IRB (e.g. WIRB), may review human gene transfer protocols.
   7.3.1. All gene transfer protocols will be reviewed by a convened board in accordance with applicable federal regulations and guidelines.
   7.3.2. The RSRB will conduct continuing review of all gene transfer protocols every six months.

7.4. All human gene transfer protocols will be reviewed according to the Guideline for Internal Review of Human Gene Transfer Research and will need to receive institutional approval before an application can be formally submitted for funding.

7.5. No research subject may be enrolled into a human gene transfer protocol until the following criteria have been met:
   7.5.1. Recombinant DNA Advisory Committee (RAC) review process has been completed;
   7.5.2. IBC approval has been obtained;
   7.5.3. RSRB approval has been obtained; and,
   7.5.4. Additional regulatory authorization(s) have been obtained, as applicable.

7.6. In addition to the responsibilities in Policy 901 Investigator Responsibilities, the following apply when conducting human gene transfer research:
   7.6.1. Investigators will document appropriate staff training regarding protocol requirements as well as safe laboratory practices;
   7.6.2. Investigators will follow good manufacturing practices;
   7.6.3. Investigators will report research events in accordance with Policy 801 Reporting Research Events, as well as any additional requirements of the NIH as applicable.
Research Subjects Review Board

Research Involving Genetic Testing and Gene Transfer

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Originator/Authors:
Emily Flagg, Senior Regulatory Specialist

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Approved By:

Kelley A. O'Donoghue
Director, OHSIP

Tiffany L. Gomniel
Director, RSRB

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10/10/2014 Date

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