

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Research Subjects Review Board</b>		<b>Effective Date: 12/03/2019</b>
	<b>Research Involving Genetic Testing and Gene Transfer</b>		<b>Policy 608</b>
			<b>Version: 2.1</b>

## POLICY

### 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 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).
  - 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.
  - 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.

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3.4. *Recombinant Nucleic Acid* – Molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell, or a molecule that results from this replication.

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, or a molecule that results from this replication.

3.6. *Human Gene Transfer* - The deliberate transfer into human research subjects of either:

- Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
- Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
  - Contain more than 100 nucleotides;
  - Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration);
  - Have the potential to replicate in a cell;
  - Can be translated or transcribed.

#### 4. References

- 4.1. State of New York’s Civil Rights Law Section 79-1;  
NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- 4.2. [Policy 503 Ancillary Committee Reviews](#);  
[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. Investigators are responsible for determining whether the research activities meet the criteria for genetic testing or gene transfer and indicating in the IRB review system whether ancillary review by Institutional Biosafety Committee is required according to *Policy 503 Ancillary Committee Reviews*.

- When the RSRB is the Reviewing IRB, or when conducting institutional review as the Relying IRB, the RSRB may also determine whether the research meets criteria for genetic testing or gene transfer during the review process.

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## 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 79-1, when proposing and conducting research involving genetic testing.

- 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 79-1, 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.
- 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 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 UR 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 *RSRB Policy 506 Data and Safety Monitoring*, as well as the NIH and FDA requirements, as applicable.

7.3. When the RSRB is the Reviewing IRB, all gene transfer protocols will be reviewed by a convened board in accordance with applicable federal regulations and guidelines. 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*.

7.5. No research subject may be enrolled into a human gene transfer protocol until the following criteria have been met:

- IBC approval has been obtained;
- IRB approval has been obtained; and,
- 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 and the RSRB is the Reviewing IRB:

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- Investigators will document appropriate staff training regarding protocol requirements, as well as safe laboratory practices;
- Investigators will follow good manufacturing practices;
- Investigators will report research events in accordance with *Policy 801 Reporting Research Events*, as well as any additional requirements of the NIH as applicable.

7.7. Human gene transfer conducted under an FDA regulated individual patient expanded access IND, including for emergency use, is not research subject to the NIH Guidelines and thus does not need to be submitted to an IBC for review and approval.

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**Appendices:**

None

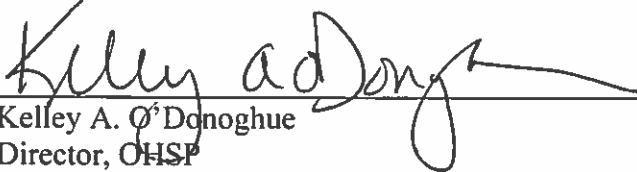
**Revision History:**

05/2017: Add hyperlinks, updates due to revised NIH guideline for RAC review, Sect 7.3 removed regarding requirement for RSRB to review gene transfer protocols, updates for single IRB review.  
12/2019: Revise definitions and policy to be consistent with updated NIH Guidelines, remove RAC, and update signatories.

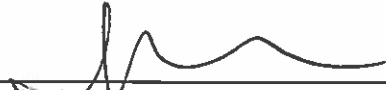
**Supersedes Date:**

05/08/2017

**Approved By:**

  
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Kelley A. O'Donoghue  
Director, OHSP

12/4/2019  
Date

  
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Executive Director, RSRB

12/4/2019  
Date