New Jersey State Law: Research Guidance

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Research with Genetic Information [N.J.S.A. C.10:5-45-48]
Genetic information, as defined by the Genetic Information Nondiscrimination Act (GINA) refers to information about:
a) an individual’s genetic tests,
b) the genetic tests of family members of an individual, and
c) the manifestation of a disease or disorder in family members of an individual.

Genetic test is defined as any analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

New Jersey State law outlines restrictions related to the collection, retention, and sharing of genetic information. Likewise, it outlines restrictions related to the collection and retention of genetic samples. These restrictions are outlined below. Moreover, NJ state law also outlines requirements for notifying individuals of their genetic results.
Collection of Genetic Information and Samples

- Expressed informed consent from research participants (or their LAR) is required to obtain *identifiable* genetic information or samples.
- A waiver of informed consent may be granted if the genetic information or samples are *completely de-identified*.

Retention / Storage of Genetic Information and Samples

- Expressed informed consent from research participants (or their LAR) is required to retain (store) *identifiable* genetic information or samples.
- DNA samples must be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless otherwise stated in the informed consent.
- A waiver of informed consent may be granted if the retained genetic information or samples are *completely de-identified*.

Participants retain the right to inspect, correct, and obtain their genetic information from their records unless they agree otherwise via informed consent.

Sharing / Disclosures of Genetic Information

Researchers may not disclose the identity of a participant upon whom a genetic test has been performed or disclose their genetic information unless the participant authorizes this via informed consent. This also applies to any subsequent disclosures on the part of recipients.

Informing Participants of Genetic Testing / Results

Participants must be notified that genetic testing was conducted unless the participant agrees otherwise via informed consent. Participants must be notified by individuals receiving genetic test records, results or findings that the records, results or findings were received unless the participant agrees otherwise via informed consent.

“Medical Research” with Cognitively Impaired Adults [NJSA 26:14-3-5]

Cognitively impaired adults are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals may be considered decisionally impaired or have limited decision-making ability because they are under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, are terminally ill, or have severely disabling physical handicaps.

Participants are unable to consent for themselves if they are unable to voluntarily reason, understand, and appreciate the nature and consequences of proposed health research interventions, including their diagnosis and prognosis, the burdens, benefits, and risks of, and alternatives to, any such research, and to reach an informed decision.
State law surrounding clinical research involving cognitively impaired individuals within New Jersey requires the following:

1. Determinations of capacity to provide consent must be made by an attending physician with no connection to the proposed research.
2. A subject’s objection to a determination of incapacity or dissent to the proposed research intervention shall be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity.
3. Consent discussions must involve a witness and the consent form must include a witness signature line.
4. A person who provides surrogate consent may not receive financial compensation for providing consent.

In addition to the above, the IRB must determine the following for greater than minimal risk research:

1. With a prospect of direct benefit
   - the risk is justified by the anticipated benefit to the subject;
   - the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches; and
   - If a currently recognized treatment exists, the subject or his guardian or authorized representative, as applicable, shall be presented with the choice of the recognized treatment and the research protocol.

2. Without a prospect of direct benefit, but of vital importance to the vulnerable population.
   - The study is likely to yield generalizable knowledge about the subject's disorder or condition;
   - By its very nature cannot be conducted without the participation of decisionally incapacitated persons as subjects; and
   - Involves no more than a minor increase over minimal risk.

Surrogate Consent
Individuals who may qualify as authorized representatives to provide surrogate consent are detailed in IRB SOP Section IC 705 SURROGATE CONSENT.

New Jersey law differs from Pennsylvania state law in the following ways:
1. Excludes “An adult who has knowledge of how the patient would make decisions” as an individual who may qualify as an authorized representative to provide surrogate consent, which is permitted by PA state law.
2. When there are two or more people in a class of LARs and at least one disagrees about research participation, the researcher has not obtained informed consent. For
example, if a cognitively impaired participant has three children and one objects to research participant, the research may not occur with the participant. However, under PA law, majority rules.

“Experimental Research” with Mental Health In-Patients [N.J.S.A. 30:4-24.2]
NJ state law requires express written informed consent for participation of any inpatient being treated for mental illness or mental health concerns in “experimental research.” A copy of the consent must be placed in the patient's treatment record. Thus, NJ state law precludes a waiver of informed consent with this patient population for any research deemed “experimental.” The IRB may issue an alteration of informed consent, with appropriate rationale provided by the study team, if the criteria are met.

The “experimental research” must be “directly related to the goals of the patient’s treatment program.”

If the patients may lack capacity or be incompetent, the study team must consult with the Office of General Counsel.

Mental Health Records [N.J.A.C. 10:37-6.1]
NJ state law precludes a waiver of informed consent for the use of identifiable mental health record information. To collect identifiable mental health record information, prospective consent and HIPAA authorization must be obtained.

A waiver of informed consent may be granted by the IRB if the information is collected/recorded in a de-identified manner, with no link to any identifiers. The IRB may issue an alteration of informed consent, with appropriate rationale provided by the study team, if the criteria are met.

Research that obtains and uses human embryonic stem cells, human embryonic germ cells and human adult stem cells, including somatic cell nuclear transplantation is permitted by NJ state law, if reviewed by the IRB.

Embryonic or cadaveric fetal tissue may be donated for research purposes. However, NJ state law precludes a waiver of informed consent under these circumstances. It is required that an individual donating remaining embryos for research purposes be presented with this option and provide written consent for the donation, including somatic cell nuclear transplantation.

Prospective Research Involving Drug Trials or Invasive Procedures Conducted in the Context of Advanced Life Support
Services, Mobile Intensive Care Units, Specialty Care Transport Services, or Air Medical Services [N.J.A.C. 8:41-5.1]

NJ State Law requires that any “prospective research activity involving drug trials or invasive procedures” conducted in the context of Advanced Life Support Services, Mobile Intensive Care Units (MICU), Specialty Care Transport Services, or Air Medical Services undergo review by the NJ State Office of Emergency Medical Services (OEMS) MICU Advisory Council. Please contact ems@doh.nj.gov for more information on this process.

Research of this type within the state of NJ will be referred to the Office of General Counsel prior to IRB review. The IRB will withhold IRB approval until approval from the Commissioner through OEMS MICU Advisory Council is received.

Research with Children [N.J.S.A. 9:17B-3; 9:17a-1]

Under New Jersey law, persons under the age of eighteen (18) generally meet this definition of “children”, with the exceptions noted below. As a result, permission of the child’s parent(s) or legal guardian(s) must generally be obtained prior to the participation child’s participation in the research.

The following exceptions to the general rule apply, where a person under the age of 18 does not meet the federal definition of “child” and may provide legally effective consent to participate in research if either:

1. The research involves the provision of medical care or treatment, (including care or treatment deemed to be experimental) and the person:
   • is married, or
   • is or has been pregnant.

2. The person is an emancipated minor. If an emancipated minor provides consent for himself or herself, the court order should be copied and included in the research records with the consent document.

Prisoner Research within the State of NJ [N.J.A.C. 10A:1-10.1-10.6]

NJ state law states that no experimentation shall be conducted involving the use of inmates or employees of the New Jersey Department of Corrections. However, this prohibition does not preclude individual treatment of an inmate based on need for a specific medical procedure that is not generally available.

Research with prisoners within the state of NJ that is not precluded by state law requires review and approval by the New Jersey Department of Corrections Departmental Research Review Board (DRRB). For more information please contact the NJ DOC: https://www.state.nj.us/corrections/pages/index.shtml. The IRB recommends researchers consult with the Office of General Counsel for research protocols involving prisoners in New Jersey.
Consent Requirements
Participation in research requires an inmate’s express written informed consent. An inmate should not be required or coerced to participate in research activities. Refusal by an inmate to participate in research should not constitute a reason for imposing penalties upon the inmate.

Likewise, inmate records are considered confidential, and release of these records requires the inmate’s written informed consent. Hence, NJ state law precludes a waiver of consent for the inclusion of NJ prisoners in research as well as for the release of their records.

The form must be signed by all of the following:
1. The inmate:
2. A witness and/or legal representative when deemed necessary; and
3. The principal researcher.

Compensation / Gifts
NJ state law bans compensation of any kind to an inmate for participating in research. Gifts may be allowed after approval by the Commissioner, Department of Corrections.

Publication / Dissemination
State law requires that, prior to publication or any dissemination, the investigator must make the research findings or results available to the correctional facility Administrator, community program supervisor, or operational unit supervisor and the Commissioner, New Jersey Department of Corrections, for review and comments.