

**NEW JERSEY DEPARTMENT OF HEALTH & SENIOR SERVICES
OFFICE OF POLICY
PROTECTION OF HUMAN RESEARCH SUBJECTS**

1. PURPOSE

1.1. To set New Jersey Department of Health & Senior Services ("NJDHSS" or "the Department") policy for the protection of human research subjects pursuant to NJDHSS's Federalwide Assurance (FWA-4020) with the U.S. Department of Health and Human Services. This policy shall be interpreted in good faith and in conformance with applicable New Jersey and Federal laws and regulations, including the Federal regulations for the protection of human subjects at 45 CFR Part 46, Subparts A- D.

1.2. To implement the principles enunciated in the Belmont Report issued by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The Report identified beneficence, justice and respect for persons as the guiding ethical principles for the conduct of biomedical and behavioral research involving human subjects.

2. APPLICABILITY

2.1. This policy and subsequent policies, procedures, forms and guidance shall apply when NJDHSS becomes engaged in human subjects research. NJDHSS becomes engaged in human subjects research when Department employees or agents engage in one or more of the following activities:

- i. Interact or intervene with human research subjects;
- ii. Receive or are awarded a federal grant, contract, or cooperative agreement for non-exempt human subjects research. Receipt of a federal research grant shall be considered engagement in research even where all activities involving human subjects are carried out by employees or agents of another institution,
- iii. Use identifiable private information for human subjects research.

2.2. If NJDHSS is supporting extra-mural human subjects research in a manner limited to one or more of the following but is not otherwise interacting with human research subjects, NJDHSS is not engaged in human subjects research but is still responsible for review of clear violations of the core principles of the Belmont Report and review of data handling and confidentiality protections (see 6.1.10 below.):

- i. Provision of identifiable private information;
- ii. Use of Department facilities, premises or property;
- iii. The facilitation of informed consent.

2.3. If NJDHSS funds human subjects research but is not in receipt of a federal grant, contract, or cooperative agreement for that research or otherwise engaged in human subjects research, NJDHSS is responsible for ensuring that such research is reviewed and approved by an appropriate IRB in compliance with the FWA.

3. AUTHORITY

3.1. Under the authority of the Commissioner, NJDHSS's Office of Policy will implement this policy and maintain oversight authority to monitor for compliance, and implement and oversee corrective actions to address non-compliance.

3.2. The Commissioner serves as the FWA-designated Signatory Official.

3.3. The Director, Office of Policy serves as the FWA-designated Human Protections Administrator.

4. DEFINITIONS

- 4.1. Agent: Agents are non-Department employees who perform on behalf of the NJDHSS Department-designated activities or exercise Department-delegated authority or responsibility.
- 4.2. Assent: Assent means a child's affirmative agreement to participate in research; mere failure to object is not be construed as assent.
- 4.3. Commissioner means the Commissioner, New Jersey Department of Health and Senior Services.
- 4.4. Conflict of Interests: A conflict of interest is any situation in which personal or professional interests may compromise or present the appearance of compromising a person's professional judgment regarding their role in human subjects research.
- i. It is NJDHSS policy that a direct reporting or working relationship represents a conflict of interest in human subjects research matters. As a matter of course indirect reporting or working relationships do not represent a conflict of interest.
- 4.5. Identifiable Private Information: Information that is linked, or could be readily linked, to an individual i) pertaining to behavior that is reasonably expected not to be observed or recorded or ii) that is provided for a specific purpose for which there is a reasonable expectation of privacy.
- 4.6. Informed Consent: The legal and ethical permission given by research subjects (or their legally authorized representative) to be enrolled in research. Informed consent consists of providing information, confirming comprehension and ensuring voluntariness. Informed consent is prospective and affirmative such that "passive consent" and similar procedures are not appropriate.
- 4.7. Investigator: An individual who i) interacts or intervenes with research subjects or has access to research subjects' identifiable private information and ii) makes substantial contributions to the a) project's conception and design, b) acquisition of data or c) analysis and interpretation of data.
- 4.8. NJDHSS shall mean the New Jersey Department of Health and Senior Services.
- 4.9. Publicly Available Data: Data from which research subjects' identifiable private information cannot be ascertained.
- 4.10. Research: A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied..
- 4.11. Research Interaction: Activities involving interpersonal contact or communications between research subjects and investigators or research personnel.
- 4.12. Research Intervention: Procedures or manipulations of research subjects' environment to gather data (e.g., genetic tests).
- 4.13. Research Personnel: An individual who is a non-investigator member of a research team and i) interacts or intervenes with research subjects or ii) has access to research subjects' identifiable private information.

5. OFFICE OF POLICY

The Office of Policy, acting through the Director of Policy and designees, is responsible for coordinating compliance with this policy. The Office of Policy shall:

- 5.1. Develop, implement, oversee and monitor for compliance policies, procedures, forms and guidance related to protection of research subjects.
- 5.2. In consultation with the Commissioner, serve as the primary contact to Federal agencies with human subjects research oversight authority.

5.3. In consultation with the IRB, serve as NJDHSS's primary resource for the protection of human research subjects consistent with NJDHSS's Federalwide Assurance (FWA-4020) with the U.S. Department of Health and Human Services.

5.4. Develop and implement educational programs, projects and initiatives on the protection of research subjects.

5.5. In consultation with the Commissioner, designate personnel to communicate issues with researcher compliance with commitments to the NJDHSS IRB, generally through the designation of research liaisons for individual research proposals as described in Section 7.

5.6. Promptly identify, devise and take appropriate remedial action, in consultation with the IRB as necessary, with respect to:

5.6.1 Research activities that:

- i. May have been implemented or modified without IRB approval,
- ii. May have been conducted in violation of IRB decisions, determinations, directives or requirements,
- iii. May have been conducted in violation of Department policies or procedures,
- iv. May have been conducted in violation of Federal or New Jersey laws, regulations or guidance,
- v. May have led to an unanticipated breach of confidentiality, or
- vi. May have led to unanticipated risks to subjects or others.

5.6.2 A personal or professional interest that may compromise the integrity of the research, or

5.6.3 A suspension or termination of IRB approval.

Such response may at the discretion of the Office of Policy include advice to the Commissioner, Institutional Review Board (IRB), Office of Legal & Regulatory Affairs and appropriate regulatory agencies.

5.7. Provide guidance to Department personnel and to external agencies with agreements to with the Department to utilize the NDHSS IRB regarding human protections issues as they relate to compliance with IRB approvals and the research ethics review process.

5.8. As mandated by NJDHSS's FWA, maintain oversight authority for the protection of human research subjects. Such oversight includes, but may not be limited to, monitoring for compliance and implementing and overseeing corrective actions to address non-compliance based on findings from site-visits, inspections, investigations and audits of human subjects research activities, with access to research investigators, support personnel, research-related records, documents and data, in all forms.

5.9. As mandated by NJDHSS's FWA, in consultation with the Commissioner:

5.9.1 Ensure IRB compliance with obligations under the FWA, New Jersey state law and NJDHSS policy, and take actions necessary to remediate non-compliance.

5.9.2 Prohibit, suspend or terminate research activities, prohibit investigators or support personnel from engaging in research under Department auspices or

5.9.3 Take additional actions as necessary to protect the rights, welfare or privacy of research subjects.

5.10. Make official determinations of non-research, department not engaged in research, non-human subjects research, and exempt human subjects research, including determinations regarding exemptions for requests for de-identified data sets and documentation, and devise and implement procedures therefor. The Office of Policy may, at its discretion, submit any such determination to the IRB for decision.

- 5.11. Make determinations for approval of death certificate requests for research purposes in accordance with New Jersey state law, and devise and implement procedures therefor. The Office of Policy will, in the ordinary course, defer to external IRB where current approvals are in force and confidentiality is maintained, provided that the Principal Investigator shall have submitted copies of such approval and any relevant supporting data to NJDHSS and the Office of Policy.
- 5.12. Advise the responsible Division or program and its designated Research Liaison (as defined in Section 7 below) of all determinations concerning the approval, disapproval, or suspension of research projects.
- 5.13. Establish procedures for the timely administration of all applications and requests for determination, including the imposition of deadlines for responses to requests for data and information, and for unilateral suspension or termination of applications where response has not been forthcoming.
- 5.14. May establish an Advisory Council in order to solicit input and advice from Department Divisions and Programs for the protection of research subjects.
- 5.15. Ensure that the IRB has meeting space and sufficient staff to support the IRB's review and recordkeeping duties.
- 5.16. Review relevant statutes and regulations regarding principles of confidentiality and privacy.

6. INSTITUTIONAL REVIEW BOARD

NJDHSS's IRB of record is responsible for reviewing non-exempt human subjects research to be conducted under the auspices of NJDHSS's FWA or departmental policy. In fulfillment of this mandate the IRB shall:

- 6.1. Develop, implement and oversee policies and procedures in fulfillment of the IRB's role and functions, including:
 - 6.1.1 Directing the HPA to conduct site-visits, investigations and audits of non-exempt human subjects' research with access to investigators, support personnel, research records, documents and data, in all forms; based on findings, develop, implement and oversee corrective actions.
 - 6.1.2 Reviewing all non-exempt research upon initial submission and not less than yearly thereafter, reporting all actions, decisions and determinations to the investigator and the Office of Policy. Research protocols that are determined to be exempt from NJDHSS IRB review need not be reviewed annually, provided that NJDHSS must be notified of any modifications to such research.
 - 6.1.3 Ensuring proposed changes in a research activity are not initiated prior to IRB review and approval, except when necessary to eliminate apparent hazards to research subjects.
 - 6.1.4 Determining which projects require review more often than annually and which projects needs verification from sources other than the investigator that no material changes have occurred since the previous IRB review.
 - 6.1.5 Having the authority to approve, require modification or disapprove human subjects research.
 - 6.1.6 Ensuring the IRB possesses appropriate knowledge of the local research context.
 - 6.1.7 Ensuring that no IRB member participates in the initial or continuing review of human subjects research in which the member has a conflicting interest, except to provide information requested by the IRB.
 - 6.1.8 Promptly reporting to the Office of Policy and appropriate regulatory agencies: i) unanticipated problems involving risks to subjects or others, ii) serious or continuing noncompliance with Federal laws or regulations or IRB requirements or determinations, iii) the

suspension or termination of IRB approval or iv) violations of Department policies or New Jersey laws or regulations.

6.1.9 In accordance with Federal regulations and NJDHSS's FWA i) prohibit, suspend or terminate research activities, ii) disqualify an investigator or support personnel from engaging in research under Department auspices or iii) take additional actions to protect the rights, welfare or privacy of research subjects.

6.1.10 When NJDHSS is not the federal research grantee, and its role is limited to one or more of the following, IRB review will be limited to: violations of the core Belmont Report principles of respect for persons, beneficence and justice; to ensuring that any NJDHSS data supplied shall only be used for the study submitted to the Department's IRB; and to issues of confidentiality and security of individually-identifiable health information:

- i. Releasing to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research;
- ii. Informing prospective subjects about the availability of the research;
- iii. Providing prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) without obtaining subjects' consent for the research or act as representatives of the investigators;
- iv. Providing prospective subjects with information about contacting investigators for information or enrollment; and/or
- v. Seeking or obtain the prospective subjects' permission for investigators to contact them.

6.1.11 Studies shall be considered closed when they are:

- i. No longer engaged in human subjects research, or,
- ii. Are limited to analysis of de-identified data and have destroyed any links between the de-identified data and identifiable personal health information

6.2. Function in compliance with, and only approve research conforming to, The Belmont Report, Department policies and procedures, the Federal regulations for the protection of human subjects at 45 CFR Part 46, Subparts A – D, and New Jersey regulations regarding research involving death certificates at NJAC 8:2A-22 and New Jersey regulations regarding research involving Emergency Medical Services at NJAC 8:41-51.

7. NJDHSS RESEARCH LIAISONS

7.1. Upon receiving an extramural research proposal the responsible Division or Program will, subject to the approval of NJDHSS Office of Policy, assign a Liaison to assist the internal review process and administer the data request on behalf of the Division/Program that maintains the data being requested.

7.2. In fulfillment of this mandate the Liaison will:

7.2.1 Review extramural research proposals and provide the Office of Policy with a recommendation as to whether:

- i. The research is scientifically valid;
- ii. The identifiable private information requested is appropriate for the research; and,
- iii. The request adheres to NJDHSS's and Division/Program's policy on Privacy & Confidentiality.

Such recommendation shall be submitted via the form "Institutional Approval of Extramural Research."

7.2.2 Contact the Principal Investigator to discuss questions or concerns raised during their review, providing the Principal Investigator the opportunity to revise their request as necessary to secure the Liaison's approval.

7.2.3 Comply with NJDHSS's Statement of Policy on Release of Health Data, including releasing data in a secure manner such as using encrypted computer files and protected fax machines.

7.2.4 Administer the data in compliance with the limits of the IRB approval or exemption as determined by the HPA.

7.2.5 Promptly notify the Office of Policy if during the conduct of the research they determine that:

- i. Research activities may have been implemented or modified without IRB approval,
- ii. Research activities may have been conducted in violation of IRB decisions, determinations, directives or requirements,
- iii. Research activities may have been conducted in violation of Department policies or procedures,
- iv. Research activities may have been conducted in violation of Federal or New Jersey laws, regulations or guidance,
- v. Research activities may have led to an unanticipated breach of confidentiality,
- vi. Research activities may have led to unanticipated risks to subjects or others or
- vii. A personal or professional interest may compromise the integrity of the research.

None of the above notification requirements shall be construed as authorizing or requiring research liaisons to conduct an independent investigation of research misconduct on behalf of NJDHSS. This is the responsibility of the Office of Policy as described in Section 5.

8. RESEARCH INVESTIGATORS AND PERSONNEL

Investigators (e.g., principal, sub-, co-, etc.) and research personnel are ethically and legally responsible, to the extent of their involvement, for the design, implementation, performance, recording, analysis and reporting of the research.

8.1. The Principal Investigator is responsible for:

8.1.1 The design, implementation, performance, recording, analysis and reporting of their research, even when these activities are completed by other investigators or research personnel.

8.1.2 Screening investigators and research personnel to ensure they possess the qualifications, skills and competence to perform their assigned research duties, prior to their participation.

8.1.3 Submitting in a timely fashion IRB continuing review applications, correspondence from collaborating sites, protocol deviation reports, study termination reports and other HPA or IRB required information or documentation.

8.1.4 Obtaining IRB approval prior to implementing or modifying human subjects research.

8.1.5 Taking all reasonable precautions to protect research subjects' rights, welfare and privacy.

8.1.6 Promptly notifying HPA and the IRB if during the conduct of the research they determine

- i. Research activities have been implemented or modified without IRB approval,
- ii. Research activities have been conducted in violation of IRB decisions, determinations, directives or requirements,
- iii. Research activities have been conducted in violation of Department policies or procedures, iv) research activities have been conducted in violation of Federal or New Jersey laws, regulations or guidance,

- iv. Confidentiality has been breached,
- v. There has been a serious or unanticipated adverse event to a research subject or vii) a personal or professional consideration may compromise the integrity of the research.

8.1.7 Ensuring investigators and support personnel

- i. Comply with HPA and IRB determinations, requirements, directives and decisions,
- ii. Department policies and procedures,
- iii. Federal and New Jersey laws and regulations,
- iv. Successfully complete NJDHSS-mandated training on the protection of research subjects prior to submitting an IRB application and
- v. Comply with HPA and IRB reviews, site-visits, audits, investigations and inspections, including complete access to investigators, support personnel, records, documents and data, in all forms.

8.2. All personnel engaged in Human Subjects research must have successfully completed an industry-standard program of Human Subjects Research Ethics Training within the past three (3) years and maintain such certification in current good standing for the duration of the research project. NJDHSS will accept certification of completion of the CITI or NIH/CDC courses as satisfying this requirement, and may, at its discretion accept certification from other recognized programs.