NEW JERSEY STATE DEPARTMENT OF HEALTH
HUMAN RESEARCH ETHICS PROGRAM
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AGREEMENT FOR THE
ETHICAL CONDUCT OF HUMAN SUBJECTS RESEARCH

This Agreement governs human subjects research activities engaged in under the auspices of the New Jersey State Department of Health ("Department"). Pursuant to the Department's Federalwide Assurance (FWA-4020) with the U.S. Department of Health and Human Services, Office for Human Research Protections, the Department becomes engaged in human subjects research when i) Department employees or agents interact or intervene with human research subjects or obtain human research subjects' identifiable private information, or ii) the Department regulates, funds, sponsors or otherwise supports human subjects research through the provision of identifiable private information or the use of Department facilities, premises or property.

The following sections set forth investigators' and research personnel's ethical and legal obligations for the protection of human research subjects. This Agreement will be interpreted and enforced under the laws and jurisdiction of the State of New Jersey. The Department maintains the authority to prohibit, suspend or terminate research projects that breach any part of this Agreement or that pose undue risks to subjects, including the authority to require the return of Department-provided data.

I. OBLIGATIONS TO THE DEPARTMENT

A. I will ensure that research activities I am responsible for are conducted in accordance with the ethical principles set forth in The Belmont Report, Federal, State and local laws and regulations, and relevant Department policies, procedures and guidance. To fulfill this obligation I have read The Belmont Report and the Department's Policy for the Protection of Human Research Subjects.

B. I have completed research ethics training within the past two (2) years that meets Department standards.

C. I will cooperate in good faith with Department decisions, directives, determinations, requirements, site-visits, audits, investigations and inquiries, providing access to all records, documents and data, in all forms concerning this project.

II. OBLIGATIONS TO HUMAN RESEARCH SUBJECTS

A. I will protect human research subjects' rights, welfare and privacy by placing their interests above other considerations, including the goals of the research and my personal and professional interests.

B. I will ensure the fulfillment of my confidentiality obligation, and will not disclose confidential information without prior written consent of the research subject or their legally authorized representative, except as required by law.

C. I acknowledge my confidentiality obligation survives project completion and my right to access the information is limited to the terms of IRB and Departmental approval.

D. If recruiting human research subjects I will obtain assent/consent in a manner that provides sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence.

E. I will only use assent/consent documents and procedures that provide information in an understandable manner, and will ensure that the human research subjects or their legally authorized representative comprehend the information and are making a voluntary decision.

III. OBLIGATIONS TO THE DEPARTMENT'S IRB

A. I will ensure human subjects research activities are conducted in accordance with the IRB's policies, decisions, determinations, directives and requirements, and will not modify research activities or enroll human research subjects prior to IRB review and approval, except when necessary to eliminate apparent immediate harm to research subjects.

B. I will cooperate in good faith with the IRB in fulfillment of its responsibilities for initial and continuing review, record keeping, reporting and certification of research, and will provide requested information in a timely fashion.

C. I will immediately notify the IRB if i) human subjects research is implemented or modified without prior IRB approval; ii) research violates IRB policies, decisions, determinations, directives or requirements; or iii) there is an adverse event to a research subject or an unanticipated problem involving risks to research subjects or others.

D. I will cooperate in good faith with IRB site-visits, audits, investigations and inquiries, providing access to all records, documents and data, in all forms concerning this project. If recruiting human research subjects, I will obtain, document and maintain assent/consent records in accordance with the Federal regulations for the protection of human subjects at 45 CFR Part 46, and as stipulated by the IRB.

IV. CERTIFICATION FOR THE ETHICAL CONDUCT OF HUMAN SUBJECTS RESEARCH

To the extent of my involvement in this human subjects research project, I certify that I understand and accept the above ethical and legal obligations for the protection of human research subjects. I hereby agree in good faith to the terms, conditions and jurisdiction imposed by this Agreement, including fulfilling the standards and requirements set forth in the above-referenced documents so as to protect the rights, welfare and privacy of human research subjects, before all other considerations.

If serving as a principal investigator, I acknowledge that I am primarily responsible for safeguarding the rights, welfare and privacy of each human research subject, and will ensure investigators and research personnel under my direction fulfill the above obligations. If applicable, I will direct and appropriately supervise collaborative research activities performed by extramural investigators and research personnel.

Project Title: _____

Name: _____ Title: _____

Program/Institution: _____

Signature: _____ Date: _____

V. INSTITUTIONAL CERTIFICATION

I certify that the individual listed above is qualified to perform his/her assigned research activities and will be held accountable for complying in good faith with the terms, conditions and jurisdiction imposed by this Agreement, including fulfilling the standards and requirements set forth in the above-referenced documents so as to protect the rights, welfare and privacy of human research subjects, before all other considerations. I further certify that the performance of the human subjects research project is permitted, and that I will in good faith abide by, and enforce, the terms of this Agreement.

Direct Supervisor

Name: _____ Title: _____

Program/Institution: _____

Signature: _____ Date: _____

Human Protections Administrator (HPA) or Signatory Official Designated on Federalwide Assurance*

Name: _____ Title: _____

Program/Institution: _____

Signature: _____ Date: _____

* For Non-Department employees only. If the organization does not have a Federalwide Assurance, this form must be signed by an official who is legally authorized to represent the organization.