Approved June 4, 2010

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 18: NEW YORK STATE LAWS RELEVANT TO HUMAN PARTICIPANT RESEARCH

1. Subject of Policy & Procedure

Federal regulations pertaining to human participant research state explicitly that they do not affect state laws which may otherwise be applicable and which provide additional protections for human participants. See 45 CFR § 46.101(f) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101).

This policy addresses New York State laws relating to human participant research activities and their applicability to Cornell University human participant research activities.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell University faculty, staff, or students or by anyone conducting a research activity supported by Cornell University or where Cornell is considered to be engaged in the research.

3. Terms and Definitions

All parties to whom this policy applies should consult the IRB Glossary at http://www.irb.cornell.edu/glossary/

4. New York State Laws Addressing Human Participant Research Issues

4.1. New York State Public Health Law Section 24-A. *Protection of Human Subjects*

New York State addresses research involving human participants in Public Health Law Section 24-A. *Protection of Human Subjects.* New York State expressly exempts federally funded research from compliance with Public Health Law Article 24-A: "The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects." § 2445. As all Cornell research, whether funded or unfunded, is covered under the University's Federalwide Assurance (FWA), the University's Legal Counsel has determined that the provisions of 24-A do not govern the conduct of Cornell human research activities.

4.2. Issues of Informed Consent

Age of Majority: Under the federal Common Rule, "children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under

the applicable law of the jurisdiction in which the research will be conducted" (45 CFR § 46.402). In New York State, a "minor" is defined as a person who is under eighteen (18) years of age (Chapter 14, Domestic Relations Law, Article 1, § 2). New York State does not have an emancipation statute.

Parent: New York State defines "parents" according to the law at issue. The term parent is not defined in Public Health Law 24-A concerning human subjects protection. At a minimum, however, the term parent means father or mother by birth or adoption.

Legal Guardian: Under the federal Common Rule, "guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care" (45 CFR § 46.402(e)). Moreover, "legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research" (45 CFR § 46.102(c)).

In New York State, Legal Guardian is defined as an individual who has obtained legal guardianship through:

1. Surrogate Courts Proceedings Act §17. *Guardians and Custodians*

2. Domestic Relations Law §81. *Appointment of Guardians by Parent*

3. Article Six of the Family Court Act, addressing *Guardianship, Adoption, Custody*

Research Conducted outside New York State: It is the Principal Investigator's responsibility to determine which individuals are considered "children" or "guardians" outside of New York State. The Principal Investigator should incorporate compliance with State Law into the consent process.

HIV Testing: Unless federal law authorizes otherwise, NYS law requires written informed consent to testing for HIV from a test subject with capacity to consent or, if lacking, of a person authorized pursuant to law to consent to health care for such individual (*i.e.*, legally empowered parent or guardian). Public Health Law § 2781(1), see complete consent requirements at (http://public.leginfo.state.ny.us/menugetf.cgi?COMMONQUERY=LAWS).

However, written informed consent is not required "for the purpose of research if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher" (Public Health Law § 2781(6)(b)).