DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

STATE LAW TERMS AND PRINCIPLES APPLICABLE TO HUMAN SUBJECTS RESEARCH

11/20/2023

Certain aspects of the federal laws and regulations relating to human subjects research recognize the applicability of State law definitions of certain terms.

Accordingly, the IRB periodically must apply such definitions to its assessment of a protocol or proposal. The following provides guidance relative to State law provisions applicable to human subjects research.

1) LEGALLY AUTHORIZED REPRESENTATIVE

Federal regulations that govern research involving human subjects define a legally authorized representative (LAR) as 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. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. [45 CFR 46.102(i) and 21 CFR 50.3(l)]

North Carolina case law has established that consent for therapeutic clinical research may be provided by the same individuals as are entitled to consent to medical treatment generally. In accordance with North Carolina law and DUHS policy regarding informed consent for medical treatment, the order of authority to provide consent as an LAR on behalf of another adult for participation in clinical research is as follows:

- Court-approved guardian
- Health care agent
- Spouse
- Adult son and/or daughter
- Parent
- Adult brother and/or sister
- Uncle and/or aunt
- Other adult kin

In addition to requiring that LAR consent be provided according to the above hierarchy, approval of a proposal for LAR consent in research that is not clearly therapeutic in nature will require demonstration of the fact that a) the research involves no more than minimal risk to the participant; b) the research can only be performed through the enrollment of participants whose consent must be provided by an LAR; and c) the LAR has confirmed through IRB-approved language in the consent form that they have no conflict of interest in acting on behalf of the participant.

The IRB must initially approve the use of a legally authorized representative for adult participants in a particular research protocol during a convened meeting of the IRB. Subsequent approval at the time of periodic continuing review may occur using the expedited procedure under Category 9 of the Office for Human Research Protections' "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure".

2) CHILD

For the purpose of applying DHHS regulations (45 CFR 46 Subpart D) and FDA regulations (21 CFR 50 Subpart D), 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.

North Carolina law defines individuals less than 18 years of age to be minors (and thus children as defined in federal regulation), and Subpart D applies to such individuals unless:

A. The individual is married.
B. The individual has been declared by a court order to be emancipated.

DUHS applies the regulations of 45 CFR 46 Subpart D and 21 CFR 50 Subpart D to all individuals defined as minors as described above.

There are four medical conditions described in North Carolina law for which a minor may seek medical care for the prevention, diagnosis or treatment of the medical condition, and thus give informed consent for this medical care. These medical conditions are:

1. Venereal disease and other reportable diseases;
2. Pregnancy;
3. Abuse of a controlled substance or alcohol;
4. Emotional disturbance.

It is the policy of the DUHS IRB not to approve a child's involvement in research directed at any of these four medical conditions without the permission of the child's parents or consent of the guardian and the child's assent (when applicable).

3) GUARDIAN

Under DHHS regulations "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)]. Under FDA regulations "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research [21 CFR 50.3(s)]. A guardian may grant permission for a child to participate in research.

Under North Carolina law, a guardian of a child must be appointed by a court under Article 6 of Chapter 35A-1220 of the North Carolina General Statutes.

4) RESEARCH OCCURRING IN OTHER JURISDICTIONS AND CONDUCTED BY DUHS INVESTIGATORS

Research conducted by a DUHS investigator and subject to DUHS IRB approval may occur in a jurisdiction other than North Carolina. When the research involves:

a) informed consent for a person's participation from an individual other than the participant;
b) a child as a research participant;
c) a guardian asked to provide permission for the child's participation; the DUHS IRB shall consult with the Office of Counsel to ensure that such other jurisdiction's laws relating to definitions of "legally authorized representative," "child," and "guardian," as applicable, are properly applied to the conduct of such research. Such consultation shall not be required if an IRB other than the DUHS IRB is responsible for reviewing the activity occurring in such other jurisdiction (i.e., if the DUHS IRB's review relates to a multi-center trial coordinated by DUHS but subject to separate review by local IRBs as to activities occurring in such local areas).

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