

North Carolina State Laws Governing Clinical Research

SOP 6.3 - Public Records request

Some of this documentation may be subject to public access under the North Carolina Public Records Act. The Office of University Counsel should be consulted when a public records request is received.

SOP 26.3 - Lotteries, raffles and door prizes

Occasionally, investigators who are not in a position to offer equal compensation to each research subject propose to substitute a drawing as an incentive. For example, an investigator with only \$200 to compensate 100 subjects might propose a drawing for two \$100 prizes rather than paying each subject \$2.00. University research projects may not include distribution of prizes to the research subjects via chances purchased by the human subjects or obtained by them in exchange for something of value (e.g., money, human tissues or blood samples). The terms used for these purchased chance distributions include "lottery" and "raffle." The prohibition is pursuant to State law and University policy.

A prize distributed by chance where the chance is obtained merely by attendance at an event (sometimes called a "door prize") and not by the payment of any fee, donation or other consideration is not prohibited by law or University policy.

Regardless of the terminology used, University research should generally not include distribution of incentives to human subjects by chance. This method may represent coercion or undue influence if the incentive is sufficiently valuable. Additionally, the distribution of incentives via chance represents an unequal distribution of the incentive and may be unfair to subjects who will ultimately receive nothing. Generally, rather than conducting a drawing, researchers should provide equitable incentives to each subject, even if such a practice diminishes the value of the incentive. However, use of incentives structured as described above for "door prizes" may be considered by the IRB on a case-by-case basis for research studies of minimal risk and brief duration if the proposed incentives do not have potential for coercion or undue influence and clearly are not distributed in exchange for valuable consideration such as blood or tissue samples or significant time and effort in research participation. The IRB should consult with the Office of University Counsel prior to approval of any incentive distributed by chance.

If such an incentive is approved for a given study, consent form language describing the incentive should avoid terms like "lottery" or "raffle." Acceptable terminology might include a reference to a "drawing based on chance in which each subject has equal odds of receiving [the incentive]."

SOP 26.4 - Collection of Social Security Numbers for Research Purposes

There are occasions within the research setting when an investigator either needs to or is required to collect the social security number (SSN) of a subject. Most often, the SSN is collected as required by law, to comply with Internal Revenue Service (IRS) reporting requirements. Less often, the SSN may be collected as a unique identifier to help match research datasets.

During the 2005 legislative session, the General Assembly enacted the North Carolina Identity Theft Protection Act. The Act imposes new restrictions upon the collection and segregation of

SSNs and upon the disclosure and security of SSNs and other personal identifying information (PII).

Collection of the SSN may NOT be approved for:

- 1) Use as an identifier when other means of unique identification would suffice.
- 2) Labeling of stored biological specimens.
- 3) Convenience.
- 4) An identifier to facilitate future contact with subjects.

SOP 28.9.1 - Special issues in consent involving older children

Principal investigators are required to seek the consent of a child's parent or guardian before enrolling a child in a study and beginning treatment and/or conducting research. North Carolina statutes do not address consent for research; however, IRBs and investigators should be aware that under North Carolina state law, a child can consent to medical treatment when he/she is emancipated or when the services are for the prevention, diagnosis, and treatment of (i) venereal disease and other diseases reportable under North Carolina law (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional disturbance.

In certain cases, limited to those described below, the assent of children may, by itself, represent informed consent. Most children, however, must assent in tandem with parental permission. The special circumstances, which will be reviewed on a case-by-case basis by the IRB, include:

- Minors emancipated via court petition (In North Carolina, emancipated minors must be at least 16 years of age and must petition the courts for emancipation. Pregnancy or parenthood does not automatically emancipate a minor (See Appendix L). For children who are pregnant, assent and permission will be obtained in accordance with the regulations;
- University students under the age of 18;
- Minors who are legally married;
- Minors serving in the armed forces of the United States; or
- International subjects (investigators and IRBs should consider local laws and customs in evaluating the majority status of international subjects)

It is sufficient for researchers to use a verbal statement to confirm a child is indeed emancipated. A confirmation of such a claim can be done in a similar way to the verification of individuals who claim to be married or over the age of 18. For example, a researcher, keeping in mind that under North Carolina law a child is not eligible to be emancipated by a court until he or she is 16 years or older, could ask the child his/her age and how long he/she has been emancipated. This age restriction does not apply to married children, who are considered emancipated by virtue of being married regardless of age. A researcher could also simply ask about the process the child went through to get emancipated (i.e., see if the child talks about going to court). Investigators and IRBs should consult with the Office of University Counsel if there are questions regarding legal issues related to guardianship and/or the age for consent.

SOP 28.11.2 - Who can act as a legally authorized representative (LAR) for a decisionally impaired research subject in North Carolina?

As is the case for most states, North Carolina does not have State legal statutes that specifically address research enrollment. In accordance with federal regulations and guidance from the OHRP, UNC-Chapel Hill has established that the informed consent laws applicable to clinical

care in North Carolina (North Carolina General Statute 90-21.13) will be followed to determine who would be considered an acceptable LAR for purposes of providing surrogate consent for decisionally impaired subjects in studies conducted in North Carolina. Although the statute is specific to medical care, it may reasonably be applied to research participation as well. In the case of an adult subject who lacks the capacity to consent, the LAR of the subject will be determined by taking the following individuals in this order of priority:

(1) A **court-appointed legal guardian** (except to the extent any appointed health care agent has authority, unless the health care agent's authority has been suspended by a court order) is a court appointed guardian granted "general" guardianship or "guardian of the person" may provide surrogate consent for all activities of the individual; therefore, this guardian may provide surrogate consent for research participation of the individual.

(2) A **health care power of attorney (HCPOA)** is a health care agent pursuant to the execution of health care power of attorney document. A HCPOA document (to the extent of authority granted) grants the agent power to make health care decisions for the individual following a physician's determination that the individual lacks adequate capacity to make her/his own health care decisions. Therefore, if such a physician determination has been made, the agent under an HCPOA may provide surrogate consent for research participation, to the extent this does not contradict the written HCPOA.

(3) A **durable general power of attorney** grants the agent whatever authority is specified in the power of attorney document and is referred to as an attorney-in fact. Where the power of attorney includes a specific provision stating that it shall survive any period of incapacity or mental incompetence of the principal it is considered a durable power of attorney, and the person holding power of attorney may provide surrogate consent for research participation unless the research participation includes an activity expressly excluded from the power of attorney. NOTE that a general power of attorney is only valid when registered with the register of deeds in either the county named in the power of attorney or the county in which the principal resides. Before relying on the decision of a person holding a general power of attorney, investigators should require proof that the power of attorney has been registered and should examine the document to ensure that it expressly survives any period of incapacity or mental incompetence of the principal. For assistance with these determinations, please contact the Office of University Counsel.

Where there is both a valid **HCPOA** and a valid **general power of attorney**, the person holding the **HCPOA** has priority over the person holding the general power of attorney in making decisions regarding participation in human subjects research.

(4) In the event that there is neither a court appointed guardian nor an agent under a durable general power of attorney or HCPOA, surrogate consent for research may be given, as long as there is no evidence to the contrary, by the **other individuals listed below**, in order of priority. When surrogate consent will be sought from one of these individuals, in the absence of a legal designation, their authority would be no broader (and may be more limited) than that of a duly appointed health care agent:

- (4a) The subject's spouse;
- (4b) A majority of the subject's reasonably available parents and adult children;
- (4c) A majority of the subject's reasonably available adult siblings; or

(4d) Another individual with an established relationship with the subject who is acting in good faith on behalf of the subject and can reliably convey the subject's wishes.

To determine the authorized representative, refer to UNC Health Care System Policy ADMIN 0019, Authorized Representatives of Patients. If there is any doubt as to which individual is the legally appropriate authorized representative for the subject, the Office of University Counsel must be contacted.

NOTE: In the case of designations (1), (2) or (3) above, the investigator should obtain a copy of the court order, HCPOA, or durable power of attorney and should maintain the copy with the research records as documentation of the authority of the surrogate decision maker.

SOP 30.14 - Research involving potentially addictive substances

With respect to cigarettes and alcoholic beverages, IRBs and researchers should be aware that under North Carolina state law these substances may not be distributed to or used by minors.

SOP 35.3.6 - Emancipation

According to North Carolina Law, emancipation alters the legal status of a minor, rendering the minor an adult for all intents and purposes. In order to petition for emancipation, a minor must be at least 16 years of age, and must have resided in the same county in North Carolina for six months immediately preceding the court filing of the petition. The effect of a final decree of emancipation is that the child —has the same right to make contracts and conveyances, to sue and to be sued, and to transact business as if they were an adult.¶ (NCGS §7B-3507)

An emancipated minor may consent to any medical treatment, dental and health services for himself/herself. An emancipated minor may also consent to any medical treatment, dental and health services for his/her child. (NCGS §90-21.5(b)). It should be noted that solely becoming a parent is not enough for a minor to establish his/her ability to give consent for non-emergency treatment for the child. The new parent must petition for emancipation before that right is clearly established under North Carolina law. (See Appendix L)

Age of Majority Exceptions:

A. Medical Conditions

A minor can give consent to a physician licensed to practice in North Carolina for medical treatment or care in limited circumstances. Specifically, a minor can consent when the services are for the prevention, diagnosis and treatment of (i) venereal disease and other diseases reportable under North Carolina law (See Appendix); (ii) pregnancy, (iii) abuse of controlled substances or alcohol, and (iv) emotional disturbance.

As the above exceptions show, a minor is generally able to give consent only when not allowing him/her to do so -- or requiring parental or guardian consent -- would cause worse harm than allowing treatment (i.e., through the spread of communicable disease or through endangerment of others because of the minor's condition). In such contexts, exceptions to the general rule requiring parental consent to non-emergency medical treatment have been created.

B. Age of Majority and Informed Consent

Under North Carolina law, a minor is defined as “any person who has not reached the age of 18 years.” Minors are “subject to the supervision and control” of their parents¹ and, by definition, do not have the ability to enter into contracts or to consent to medical care for themselves. Since parents are responsible for their children’s medical care, “they usually have the legal right to control the care – arranging for it, consenting to it or not, and paying for it.” It is our understanding that a minor who is also a parent has the same rights to control the medical care received by his or her child as a parent who has reached the age of majority.

C. Marriage or Military Service

Apart from the formal emancipation process, there are two other methods by which a minor may alter his/her legal status. First, a minor who is legally married will be treated as an adult. Second, a minor who is serving in the armed forces of the United States will be treated as an adult.

References:

NCGS § 7B-301

NCGS § 7B-309

NCGS § 14-309.15

NCGS § 48A-2

NCGS § 7B-3400

NCGS § 90-21.5(a)

NCGS § 7B-3507

NCGS § 90-21.5(b)

NCGS § 108A-102(b)

NCGS § 108A-102(c)

Reportable Diseases and Conditions (10A NCAC 41A .0101)

NC Identity Theft Protection Act of 2005