

MEMORANDUM

TO: Members of the IRB Committees
FROM: Office of University Counsel
DATE: April 4, 2018
RE: North Carolina Reporting Requirements

INTRODUCTION

A principal investigator (PI) or other researcher may encounter a participant in a research study or clinical trial who the PI or researcher believes may have a condition that is required to be reported to a state-wide official. Generally, if the participant is within a protected category – based on age or mental or physical condition – or if the condition may threaten the public health, then the researcher will have a duty to report to a designated official in North Carolina. The purpose of this memo is to outline the most commonly occurring situations in which a PI or researcher has a duty to report, and clarify to whom the report must be made. Please note that, in addition to making the required external reports described in this memorandum, the PI or other researcher must also report the event to the IRB *if* the condition or circumstance is reportable as a study-related unanticipated problem involving risks to subjects and others or a study-related adverse event.

REQUIRED REPORTING

1. Dependency, Abuse, or Neglect

a. Children or Minors

If a study participant is less than 18 years of age, and the PI or researcher has cause to suspect that the minor participant is dependent¹, abused² or neglected³ by a parent, guardian, custodian, or caretaker⁴, or that the participant has died as the result of maltreatment from a parent,

¹ “Dependent” is defined as in need of assistance or placement because the child has no parent, guardian, or custodian responsible for the child’s care or supervision or whose parent, guardian, or custodian is unable to provide for the care of supervision and lacks an appropriate alternative child care arrangement. NCGS §7B-101(9).

² “Abused” has a multi-part definition that includes intentional serious physical injury, creation of a substantial risk of serious physical injury or emotional damage, cruel or grossly inappropriate procedures, criminal sex acts, involuntary servitude or human trafficking, and encouragement or approval of acts of delinquency or moral turpitude. NCGS §7B-101(1).

³ “Neglected” is defined as not receiving proper care, supervision, or discipline; abandoned; not provided necessary medical care or remedial care; living in an environment injurious to the child’s welfare; or placed for care or adoption in violation of law. NCGS §7B-101(15).

⁴ “Caretaker” is defined as any person other than a parent, guardian, or custodian who has responsibility for the health and welfare of a juvenile in a residential setting. This definition includes stepparent, foster parents, adult members of the juvenile’s household, adult relatives entrusted with the juvenile’s care, house parents or cottage parents in a residential child care facility or residential educational facility, and any employee or volunteer of a division, institution or school operated by the NC DHHS. The definition also includes any person who has the responsibility for the care of a juvenile in a child care facility. NCGS §7B-101(3).

guardian, custodian, or caretaker, then the PI or researcher must report the case of the participant to the Director of the Department of Social Services in the county where the child resides or is found. **Under the statute, the abuse or neglect must be from a parent, guardian, custodian, or caretaker in order to be reportable.**

The PI or researcher may make the report orally, by telephone, or writing. If the report is made either orally or by telephone, the person making the report must give his/her name, address, and telephone number. The report must include the following items of information as known:

- Name of the child;
- Address of the child;
- Name of the parent, guardian or caretaker;
- Address of the parent, guardian, or caretaker;
- Age of the child;
- Names and ages of other children in the home;
- Present whereabouts of the child if not at the home address;
- Nature and extent of any injury or condition resulting from abuse, neglect, or dependency;
- Any other information which the person making the report believes might be helpful in establishing the need of protective services or court intervention.⁵

Anyone who makes a report as outlined above, who cooperates with the county DSS in a protective services inquiry or investigation, who testifies in any judicial proceeding resulting from a protective services report or investigation, or who otherwise participates in the program authorized by the law is immune from any civil or criminal liability that might otherwise be incurred or imposed for that action, provided that the person was acting in good faith.⁶

b. Disabled Adults

If a PI or researcher has a study participant who is 18 years of age or older, or who is an emancipated minor, and who is also physically or mentally incapacitated due to:

- mental retardation, cerebral palsy, epilepsy or autism,
- organic brain damage caused by advanced age or other physical degeneration in connection therewith, or
- conditions incurred at any age which are the result of accident, organic brain damage, mental or physical illness, or continued consumption or absorption of substances,

and the PI or researcher has reasonable cause to believe that the disabled adult is in need of protective services due to abuse⁷ or neglect⁸ by a caretaker, then the PI or researcher must report such information to the Director of the Department of Social Services in the county where the disabled adult resides or is found.

⁵ NCGS §7B-301.

⁶ NCGS §7B-309.

⁷ “Abuse” is defined as the willful infliction of physical pain, injury, or mental anguish, unreasonable confinement, or the willful deprivation by a caretaker of services which are necessary to maintain mental and physical health. NCGS §108A-101(a).

⁸ “Neglect” refers to a disabled adult who is either living alone and not able to provide for himself the services which are necessary to maintain his mental or physical health or is not receiving services from his caretaker. A person is not receiving services from his caretaker if, among other things and not by way of limitation, he is a resident of one of the State-owned hospitals for the mentally ill, centers for the mentally retarded or North Carolina Special Care Center he is, in the opinion of the professional staff of that hospital or center, mentally incompetent to give his consent to medical treatment, he has no legal guardian or other guardian, and he needs medical treatment. NCGS §108A-101(m).

The report may be made orally or in writing. The report must include:

- Name of the disabled adult;
- Address of the disabled adult;
- Name of the disabled adult's caretaker;
- Address of the disabled adult's caretaker;
- Age of the disabled adult;
- The nature and extent of the disabled adult's injury or condition resulting from abuse or neglect;
- Other pertinent information.⁹

Anyone who makes a report as outlined above, who testifies in any judicial proceeding resulting from a protective services report or investigation, or who participates in a required evaluation is immune from any civil or criminal liability on account of such report or testimony or participation, unless the person acted in bad faith or with a malicious purpose.¹⁰

2. Persons with a Communicable Disease

Apart from the general reporting requirements described already in this memo that apply to any person working on a research study or clinical trial, there are particular reporting requirements applicable to principal investigators or researchers who are licensed physicians. Specifically, a physician licensed to practice medicine who has reason to suspect that a person about whom the physician has been consulted professionally has a communicable disease or communicable condition declared by the Commission for Public Health (Commission) to be reported must report information required by the Commission to the local health director of the county or district in which the physician is consulted.¹¹ Regulations define which diseases and conditions are reportable and specify the time period within which each particular disease must be reported (immediately, 24 hours, or 7 days after the condition is reasonably suspected to exist).¹² For the complete list of reportable diseases and conditions, and their respective reporting timeframes (which is a dynamic list), *see* 10A NCAC 41A.0101. It is important to note that, by statute, HIV infection is a reportable communicable condition.¹³

While not mandatory, a medical facility in which there is a patient reasonably suspected of having a communicable disease or condition declared by the Commission to be reported, may report information specified by the Commission to the local health director of the county or district in which the facility is located.

PIs and researchers confronted with the foregoing communicable disease reporting requirements must also be mindful of the requirements associated with Certificates of Confidentiality (described further at: http://grants.nih.gov/grants/policy/coc/cd_policy.htm), noting the NIH Grants Policy options for addressing local reporting requirements in studies for which a Certificate of Confidentiality has been granted.

⁹ NCGS §108A-102(b).

¹⁰ NCGS §108A-102(c).

¹¹ NCGS § 130A-135. This mandatory reporting requirement also applies to school principals and operators of child care facilities (child care centers, family child care homes, and any other child care arrangement – although not public schools – that provide child care, regardless of the time of day, wherever operated, and whether or not operated for profit). NCGS § 130A-136.

¹² 10A N.C.A.C. 41A .0101. Reportable diseases and conditions can be found online at <http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2041%20-%20epidemiology%20health/subchapter%20a/10a%20ncac%2041a%20.0101.pdf>

¹³ NCGS §130A-135.

3. Injuries caused by suspected criminal violence

Physicians also have an obligation to report injuries caused by suspected criminal violence as soon as practicable to the police authorities in the city where the place of treatment is located.¹⁴ Although this report is typically made by the healthcare facility where the injury is treated, if a physician treats a patient outside of a hospital or other facility, the physician has an individual duty to report:

- Every case of a bullet wound, gunshot wound, powder burn or any other injury appearing to arise from the discharge of a gun or firearm;
- Every case of illness apparently caused by poisoning;
- Every case of wound or injury caused by a knife or sharp or pointed instrument if it appears to the treating physician that a criminal act was involved;
- Every wound, injury or illness in which there is grave bodily harm or grave illness if it appears to the treating physician that a criminal act was involved; and
- Recurrent illness or serious injury to any child under the age of 18 where the illness or injury appears, in the physician's judgment, to be the result of non-accidental trauma.

Any physician making such a report in good faith shall have immunity from liability that might otherwise be incurred as the result of making such report.

4. Diagnosis of cancer or benign brain or central nervous system tumor

Health care providers and health care facilities must submit reports to the central cancer registry of each diagnosis of cancer or benign brain or central nervous system tumors in any person who is screened, diagnosed or treated by the provider or facility.¹⁵ A "provider" includes any person who is licensed or certified to practice a health profession or occupation under the North Carolina laws for Medicine and Allied Health Occupations (including, for example, physicians, dentists, pharmacists, physician assistants, nurses, physical therapists). For purposes of this reporting obligation, "health care facility" is a broad term that expressly includes any facility laboratories or independent pathology laboratories. In the majority of cases, the hospital where a patient is treated typically reports the diagnosis to the central cancer registry. However, laboratories, clinics, and individual professionals that diagnose cancer or benign central nervous system tumors outside a hospital setting are also required to report new cancer cases.¹⁶ Reports must be made within six months after diagnosis in a format prescribed by the registry.

CONCLUSION

Any researcher working on a research study or clinical trial should ensure that he/she is aware of the statewide reporting requirements as they are applicable to the study. This memo is designed to provide a general overview of some of those requirements¹⁷ and to emphasize that if a researcher makes a report based upon reasonable cause then he/she will be protected from liability.

¹⁴ NCGS §90-21.20. If treatment outside city limits, the report is made to the county sheriff.

¹⁵ NCGS §130A-209. The central cancer registry may be found here: <http://www.schs.state.nc.us/units/ccr/>

¹⁶ See, for example, this letter sent to new physicians: <http://www.schs.state.nc.us/units/ccr/documents/New-physician-letter.pdf>

¹⁷ Please note that this memo does not include all health care professional reporting requirements under North Carolina law. Examples of other reporting requirements not detailed in this memo include certain occupational

If you have any additional questions, you should feel free to contact any of the following attorneys in the Office of University Counsel:

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health injuries, NCGS §130A-455; suspicious, unusual or unnatural deaths, NCGS §130A-383; births or fetal deaths occurring outside of a healthcare facility, NCGS §130A-101, 114; health care information that may indicate the existence of a terrorist incident using nuclear, biological or chemical agents, NCGS §130A-476; and death of a migrant worker or worker's dependent, NCGS §130A-418.