1  Mandatory Reporting

While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, North Carolina law mandates that certain persons who suspect child or elder abuse or neglect report this as outlined below.

The UNC-Chapel Hill policy requires the solicitation of informed consent from all adult research subjects and, where appropriate, assent from children involved as research subjects, in addition to the permission of their parents. In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of abuse or neglect.

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 those situations in which a PI or researcher has a duty to report, and clarify to whom the report must be made.

1.1  Required Reporting

1.1.1  Dependency, Abuse, or Neglect Regarding 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 dependent, abused or neglected by a parent, guardian,

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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 "Abuse" 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, 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).
custodian, or caretaker⁴, or that the participant has died as the result of maltreatment from a parent, 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

1.1.2 Disabled Adults

If a PI or researcher has a study participant who is 18 years of age or over 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,

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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).

⁵ NCGS §7B-301.

⁶ NCGS §7B-309.
• and the PI or researcher has reasonable cause to believe that the disabled adult is in need of protective services due to abuse\textsuperscript{7} or neglect\textsuperscript{8} 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.

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.\textsuperscript{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.\textsuperscript{10}

1.1.3 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\textsuperscript{11} or communicable condition\textsuperscript{12} declared by the Commission for Health Services (Commission) to be reported, must report information required by the Commission to the local health director of

\textsuperscript{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).

\textsuperscript{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).

\textsuperscript{9} NCGS §108A-102(b).

\textsuperscript{10} NCGS §108A-102(c).

\textsuperscript{11} “Communicable disease” is defined as an illness due to an infectious agent or its toxic products which is transmitted directly or indirectly to a person from an infected person or animal through the agency of an intermediate animal, host or vector, or through the inanimate environment. NCGS §130A-133(1).

\textsuperscript{12} “Communicable condition” is defined as the state of being infected with a communicable agent but without symptoms. NCGS §130A-133(5).
the county or district in which the physician is consulted.\textsuperscript{13} Reportable conditions can be found online at \url{http://epi.publichealth.nc.gov/cd/}. The site lists more than sixty conditions. It is important to note that, by statute, HIV infection is a reportable communicable condition.\textsuperscript{14}

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.

1.2 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 those requirements and to emphasize that if a researcher makes a report based upon reasonable cause then he/she will be protected from liability.

If you have any additional questions, you should feel free to contact the Office of University Counsel.

Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process.

\textsuperscript{13} This mandatory reporting requirement also applies to 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).

\textsuperscript{14} NCGS §130A-135.