



DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

**MANDATORY STATE REPORTING
REQUIREMENTS**

2/8/2021

The Duke University Health System must comply with the State of North Carolina mandatory reporting regulations. The Duke University Health System Institutional Review Board (DUHS IRB) requires all Investigators and clinical study staff engaged in research approved by the DUHS IRB to adhere to mandatory reporting requirements specified by State and local law.

A physician or other health professional must report certain conditions/circumstances/diseases to State and local agencies whether they are found in the course of non-research clinical care or as part of a research protocol. This policy relates to research-related findings that present themselves during the conduct of a protocol and must be reported outside of the institution.

The Principal Investigator must also report the event to the IRB only if the condition/circumstance is a serious, unanticipated and study-related adverse consequence of study participation.

Under North Carolina law, any person or institution who has cause to suspect that any juvenile is abused, neglected or dependent, as defined by N.C.G.S. 7B-101, or has died as a result of maltreatment, must report the case of that child to the director of the department of social services in the county where the juvenile resides or is found. This report can be made orally, by telephone, or in writing. The report should include information as is known to the person making it including the name and address of the juvenile; the name and address of the juvenile's parent, guardian, or caretaker; the age of the juvenile; the names and ages of other juveniles in the home; the present whereabouts of the juvenile if not at the home address; the nature and extent of any injury or condition resulting from abuse, neglect, or dependency; and any other information which the person making the report believes might be helpful in establishing the need for protective services or court intervention.

Additionally, all adults must report to law enforcement certain crimes against juveniles such as serious injuries, violent crimes, sex crimes, and misdemeanor child abuse as soon as they become aware of them. The report must be made to law enforcement in the county where the juvenile

resides. The report may be made orally or by telephone. The report shall include information as is known to the person making it, including the name, address, and age of the juvenile; the name and address of the juvenile's parent, guardian, custodian, or caretaker; the name, address, and age of the person who committed the offense against the juvenile; the location where the offense was committed; the names and ages of other juveniles present or in danger; the present whereabouts of the juvenile, if not at the home address; the nature and extent of any injury or condition resulting from the offense or abuse; and any other information which the person making the report believes might be helpful in establishing the need for law enforcement involvement.

[<https://www.ncleg.gov/Sessions/2019/Bills/Senate/PDF/S199v9.pdf>]

North Carolina law also requires the disclosure of specific information, including individually identifiable health information or records (unless prohibited by federal law) such as:

- Known or suspected child abuse or neglect, child dependency, and child deaths believed to be due to maltreatment
- Belief that a disabled adult is in need of protective services
- Belief that an older adult is in need of protective services (known or suspected elder abuse)
- Sexual assault involving a juvenile or disabled adult
- Known or suspected cases or outbreaks of communicable diseases**
- Wounds and injuries caused by firearms
- Illnesses caused by poisoning
- Wounds or injuries caused by knives or other sharp instruments and a physician suspects a criminal act
- Any other wound, injury, or illness wherein a treating physician suspects criminal violence was involved (In North Carolina it is mandatory to report injuries or illnesses in which there is grave bodily harm or grave illness if it appears that the wound or injury resulted from a criminal act of violence. This would include the reporting of domestic violence if the injury gave rise to grave bodily harm.)
- Client-specific information for the central cancer registry
- Symptoms, diseases, conditions, trends in the utilization of health care services, or other health-related information that the State Health Director determines is needed to conduct a public health investigation of a possible terrorist incident.

******For the complete list of reportable diseases and conditions, and their respective reporting timeframes, see 10A NCAC 41A.0101. This list is updated periodically and can be found online at:

<https://epi.dph.ncdhhs.gov/cd/report.html>

Disclosure of Protected Health Information

All DUHS Investigators and staff engaged in human subjects research must comply with regulatory requirements when using or disclosing an individual's protected health information in response to legal, public health, health oversight, law enforcement, and other purposes in which that individual's consent or authorization is not required. Investigators are encouraged to refer to Duke University Health System Policies (*Disclosing Protected Health Information without Patient Authorization or Consent*).

Investigators are required to keep a record of any paper, electronic, or verbal disclosure of individually identifiable health information made in response to health oversight reporting requirements or the legal occurrences as specified above in this policy. Such records should be filed in the research participant's chart.

The DUHS IRB and DUHS Investigators must be cognizant of the requirements associated with Certificates of Confidentiality. Information is available at <https://grants.nih.gov/policy/humansubjects/coc.htm> for options for addressing local reporting requirements in studies for which a Certificate of Confidentiality is granted.

Consent Form Language

When appropriate, the DUHS IRB will require the addition of a statement in the consent form to alert research participants to the possibility that information they disclose, or the results of their medical tests, may have to be reported by law to State/local authorities. For example, additional language in a consent form would be appropriate and necessary when HIV testing or Hepatitis A, B, and/or C testing will occur as a part of a protocol.

References

N.C. Gen. Stat. § 90-21.20 Reporting by Physicians and Hospitals of Wounds, Injuries and Illnesses

10A NCAC 41A.0101 *Reportable Diseases and Conditions*

Duke University Health System Policies titled:

- Recognizing and Reporting Suspected Abuse or Neglect of a Patient
- Wound, Injury, and Illness Reporting Policy
- Disclosing Protected Health Information without Patient Authorization or Consent

https://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_7B/GS_7B-301.html

<https://www.ncleg.gov/Sessions/2019/Bills/Senate/PDF/S199v9.pdf>

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