GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2021

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HOUSE BILL DRH10397-MG-156A

Short Title:	Give Clinical Researchers HIE Network Access.	(Public)
Sponsors:	Representative Insko.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT AUTHORIZING CLINICAL RESEARCHERS TO CONNECT TO THE STATEWIDE HEALTH INFORMATION EXCHANGE NETWORK KNOWN AS NC HEALTHCONNEX IN ORDER TO ACCESS INFORMATION ABOUT CLINICAL INVESTIGATION APPLICANTS AND PARTICIPANTS.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 90-414.4 is amended by adding a new subsection to read:

"(e1) Voluntary Participation by Clinical Researchers. – Any clinical researcher who is conducting or preparing to conduct a clinical investigation approved by an institutional review board may connect to the HIE Network to access protected health information about participants who are enrolled, or applicants who are seeking to enroll, in the clinical investigation, provided that the clinical researcher demonstrates to the satisfaction of the HIE Authority that he or she meets all of the following criteria:

(1) Has obtained a signed release from each applicant or participant authorizing the use or disclosure of protected health information for research purposes, in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, as amended.

(2) Is financially independent from the funding sponsor of the clinical investigation.

(3) Agrees to access the HIE Network on a per-individual basis. A clinical researcher is prohibited from accessing the HIE Network as permitted under this subsection to recruit participants for clinical investigations, to data mine, or to extract multiple patient records.

(4) Agrees to limit the use of each applicant's or participant's protected health information disclosed through the HIE Network to one or more of the following purposes, in a manner that complies with HIPAA and 21 C.F.R. Part 50, as amended:

a. Verifying an applicant's eligibility for a clinical investigation.

b. Protecting the health and safety of a participant while the participant is part of a clinical investigation.

c. Tracking a participant for therapeutic side effects from any test article used in the clinical investigation.

d. Providing continuity of care to a participant during and after the clinical investigation.

As used in this subsection, "clinical researcher" has the same meaning as "investigator" in 21 C.F.R. Part 50, as amended, and the terms "clinical investigation," "institutional review board," "sponsor," and "test article" have the same meanings as in 21 C.F.R. Part 50, as amended."

SECTION 2. This act becomes effective July 1, 2021.