

#### **10A NCAC 41A .0405 EXEMPTION FOR CLINICAL STUDIES**

An individual enrolled in a clinical trial of the efficacy of a new vaccine preparation or dosage schedule shall be exempted from those requirements of 10A NCAC 41A .0401 and .0402 which conflict with the trial protocol. This exemption shall only apply to individuals who:

- (1) participate in a clinical trial whose protocol is approved by the State Health Director, and
- (2) fully participate in and complete the clinical trial.

*History Note: Authority G.S. 130A-152(c);  
Eff. October 1, 1983;  
Temporary Amendment Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;  
Amended Eff. March 1, 1988;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. January 9, 2018.*