

**10A NCAC 15 .0363 PROVISIONS FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS**

(a) A licensee may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

(b) If the research is conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy for the Protection of Human Research Subjects (Federal Policy), the licensee shall, before conducting research:

- (1) Obtain review and approval of the research from an "Institutional Review Board" as defined and prescribed in the Federal Policy; and
- (2) Obtain "informed consent" as defined and described in the Federal Policy, from the human research subject.

(c) If the research will not be conducted, funded, supported, or regulated by a Federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

- (1) Obtain review and approval of the research from an "Institutional Review Board" as defined and described in the Federal Policy; and
- (2) Obtain "informed consent," as described in the Federal Policy, from the human research subject.

(d) Nothing in this Rule relieves licensees from complying with the other requirements in this Chapter or with any other applicable Rules and Laws in the State of North Carolina.

*History Note: Authority G.S. 104E-7; 104E-10(b); 104E-12;  
Eff. November 1, 2007;  
Transferred and Recodified from 15A NCAC 11 .0363 Eff. February 1, 2015.*