4731.4401 PROTECTION OF HUMAN RESEARCH SUBJECTS.

A. A licensee may conduct research involving human research subjects only if the licensee uses radioactive materials specified in the license and for the uses authorized in the license.

B. If the research is conducted, funded, supported, or regulated by a federal agency that has implemented Code of Federal Regulations, title 45, part 46, subpart A, the federal policy for the protection of human subjects, the licensee must, before conducting research:

(1) obtain review and approval of the research from an institutional review board according to Code of Federal Regulations, title 45, section 46.111; and

(2) obtain informed consent from the human research subject according to Code of Federal Regulations, title 45, section 46.116.

C. If the research will not be conducted, funded, supported, or regulated by a federal agency that has implemented the federal policy, the licensee must, 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 according to Code of Federal Regulations, title 45, section 46.111; and

(2) obtain informed consent from the human research subject according to Code of Federal Regulations, title 45, section 46.116.

D. Nothing in this part relieves licensees from complying with other parts of this chapter.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755*

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