

Guidance in Bold Text

Rule: 3701:1-66-17 Effective: 12/20/2019

General Administration for Medical Radiation-Generating Equipment

This rule provides standards for self-referral screening and medical research. Notwithstanding paragraph (B) of rule 3701:1-66-02 of the Administrative Code:

Self-referral screening and medical research are exempt from the discrete authorization (ordering) requirement by a license practitioner to expose individuals for a radiologic procedure provided they meet the requirements of this rule.

- (A) Any person proposing to conduct a self-referral screening program using radiation-generating equipment shall not initiate such a program without prior approval by the department. When requesting such approval, that person shall submit information on a form prescribed by the department. If any information submitted to the department becomes invalid or not current, the department shall be immediately notified in writing.

No self-referral screening program shall be operated without approval by the Ohio Department of Health (ODH). The request for ODH approval of a self-referral screening program must be made on, and include the information on, the designated ODH form. If there are any changes to the information provided to the ODH for approval of the self-referral screening program, the facility (person) shall notify the ODH of those changes in writing.

- (B) No person shall use radiation-generating equipment to conduct research on human beings unless the research has been approved by an institutional review board (IRB) as required by, Title 45, CFR, Part 46 (as effective on the effective date of this rule and Title 21, CFR, Part 56 (as effective on the effective date of this rule).

Any research using radiation-generating equipment on human beings must be approved by an Institutional Review Board (IRB) as required by:

Title 45, CFR Part 46: U.S. Department of Health and Human Services (HHS) Protection of Human Subjects, and

Title 21, CFR Part 56: Institutional Review Boards.

- (C) Nothing in this rule relieves registrants from complying with the other requirements of this chapter.

Registrants with self-referral screening and research programs must comply with all other requirements of this Ohio Administrative Code Chapter.