

## SYSTEM REGULATION

### 15.99.01 Use of Human Participants in Research

*August 24, 2001*

#### 1. ADMINISTRATIVE REQUIREMENTS

- 1.1 Research on human participants at each System component shall comply with the ethical principles and standards of the Belmont Report, April 18, 1979, and with the Code of Federal Regulations, 45 CFR 46. Procedures for safeguarding the rights of individuals shall be consistent regardless of sources of funding.
- 1.2 Each component that is involved with research on human participants shall develop an Institutional Review Board (IRB) or enter into a Memorandum of Understanding with another System component with a registered IRB. Each IRB shall meet the requirements set out in the federal regulations and register with the Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. All research on human participants, whether funded or unfunded, must be approved by the component's IRB before the initiation of the research project.
- 1.3 Each component that conducts research involving the use of human participants shall submit a Federalwide Assurance of Protection for Human Subjects (FWA) form to OHRP. Requirements for the FWA and sample forms, as well as controlling documents (such as the Belmont Report, 45 CFR 46, etc.), may be obtained from the official website of OHRP. <http://www.hhs.gov/ohrp/>
- 1.4 Each component that uses human participants shall develop guidelines and protocol procedures for use of human participants in research. A specific protocol shall be developed for each project. Each protocol shall be approved by the component's IRB for human participants before the initiation of the research project.

#### 2. GENERAL GUIDELINES

- 2.1 Principal investigators and department heads (or equivalent) are responsible for ensuring that all research involving human participants (including protocols which may be exempt, as defined in the federal regulations) is submitted to their respective IRB for review and approval.
- 2.2 Principal investigators shall submit continuing reviews to their respective IRBs, as directed by the IRB, but not less than annually.

2.3 For research projects involving more than one component, all respective IRBs must approve the protocol, unless there is:

- A. a joint review arrangement;
- B. reliance upon the review of another qualified IRB; or
- C. similar arrangements for avoiding duplication of effort.

If the research involves federal funding and A, B or C is utilized, the review process must be approved by OHRP or the funding agency.

2.4 Each component shall establish a rule or procedure for carrying out this regulation.

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HISTORY: Last Version: November 1, 1985 (APRM D.7)

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