



**INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH**

**RESPONSIBILITIES OF DIRECTORS OF RESEARCH STUDIES INVOLVING HUMAN SUBJECTS**

University of New Hampshire (UNH) tenure-track faculty, lecturers, senior lecturers, visiting faculty with rank, research faculty with rank, clinical faculty with rank, and permanent staff may serve as directors of research studies (researcher) involving human subjects. Adjunct faculty, courtesy faculty (affiliate, affiliate research, and affiliate clinical), and graduate and undergraduate students must be sponsored by an individual who qualifies to serve as a project director.

- A. Researchers are responsible for complying with
  - I. UNH's Policy on the Use of Human Subjects in Research (<http://usnholpm.unh.edu/UNH/II.Acad/E.htm>),
  - II. UNH's Federalwide Assurance (FWA) (<http://www.unh.edu/osr/compliance/support/ohrp.pdf>), and
  - III. Title 45, Code of Federal Regulations, Part 46: Protection of Human Subjects (45 CFR 46) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).
- B. Researchers are responsible for gaining familiarity with, and adhering to, the ethical principles stated in *The Belmont Report* (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>).
- C. Researchers must submit all proposed research activities involving human subjects to the UNH Institutional Review Board (IRB) for review before commencing. Researchers must not involve human subjects in research activities until the researcher has received written, unconditional approval from the IRB for the study.
- D. Researchers are responsible for protecting the rights and welfare of human subjects in their research studies.
- E. Researchers are responsible for keeping co-researchers and all research staff informed about the nature and goals of the study, and the need to adhere to ethical and responsible practices.
- F. Researchers are responsible for adhering to the IRB-approved protocol and consent process, including providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. The researcher must retain all signed consent documents for at least 3 years after the end of the study.
- G. Researchers must request IRB approval for proposed changes in previously approved human subject research activities before initiating them, except where necessary to eliminate apparent immediate hazards to the subjects.
- H. Researchers are responsible for reporting progress of approved research to the IRB as often as, and in the manner, prescribed by the approving IRB on the basis of risks to subjects. For studies approved at the Expedited and Full Board review levels, this must be no less than once a year (365 days) from the last review date.
- I. Researchers must report to the IRB any injuries or unanticipated problems involving risks to subjects and others within one working day of occurrence.
- J. Researchers will not seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law. However, such activities will not be considered research nor may the data be used in support of research.
- K. Researchers who collaborate with colleagues at other institutions/sites have additional responsibilities. Researchers will advise the IRB, the Office of Sponsored Research, and appropriate officials of other institutions of the intent to engage human subjects in research studies for which the UNH FWA or any related Inter-Institutional Amendment or Non-institutional Investigator Agreement applies. Institutions in the collaboration must possess an OHRP-approved Assurance prior to the involvement of human subjects in a research study.