



August 2015

Charter Statement for the Institutional Review Boards

- (1) There shall exist Committees at UNC-Chapel Hill which shall serve as IRBs in accordance with 45 CFR 46, 21 CFR 50 and 56, and other federal regulations. New IRBs shall be created or existing IRBs abolished from time to time as necessary to provide expert and timely review and oversight of the human research protection program at the University. Each IRB shall be registered as a separate and distinct IRB with the federal Office for Human Research Protections (OHRP).
- (2) The IRBs shall be guided by and act in a manner consistent with the ethical principles contained in the **"Belmont Report."** The IRBs shall also be guided by relevant published ethical and professional standards of the various disciplines and professions represented among the faculty who conduct research with human participants.
- (3) **The IRBs shall receive all protocols** in which the use of human subjects in research is proposed, regardless of the source of funding for such protocols. **Each IRB shall review and have the authority to approve, require modifications to secure approval or, disapprove research conducted by the University; to suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected harm to participants; and to observe or have a third party observe the consent process and the conduct of the research.** Each IRB shall exercise these authorities as it deems appropriate, consistent with the various federal regulations and University policies that govern its work. ***No research with human subjects shall take place at the University of North Carolina at Chapel Hill without the prior approval of an IRB.***
- (4) **The judgments of the IRBs shall be final.** There shall be no appeal of substantive decisions of the IRBs to any other authority. Appeal on procedural matters may be heard by the University Institutional Official who shall have the authority to require an IRB to reconsider a protocol if there is reason to believe the IRB did not follow its established procedures or acted in violation of federal regulations or University policy.
- (5) It is University policy that no University protocol is subject to ongoing review and approval by more than one University IRB. Any IRB may enter into agreements with any other IRB at the University to allow protocols to be reviewed by the IRB with greatest expertise in the subject matter of the protocol or with the greatest facility to oversee the resulting research.
- (6) With the approval of the University Institutional Official for Human Subjects, ***any IRB may enter into agreements with other institutions to serve as the IRB of record for some or all of the human subject protocols originating within such other institutions.*** With the approval of the University Institutional Official for Human Subjects, any IRB may enter into agreements with other institutions to allow an IRB at another institution to serve as the IRB of record for a project conducted collaboratively between the University and the other institution, ***so long as the other institution has a valid federal wide assurance of compliance and the other IRB is registered with OHRP.***
- (7) The IRBs shall provide standard procedures for investigators to follow and standard forms for investigators to use in applying for approval of protocols to any of the IRBs and shall adopt and publish

Standard Operating Procedures, consistent with applicable federal regulations and University policies, to govern their activities.

Mission Statement for the Human Research Protection Program

The University of North Carolina at Chapel Hill (UNC-Chapel Hill) is committed to expanding and disseminating knowledge for the benefit of the people of North Carolina and the world. An important part of that commitment to knowledge is research of the highest quality on all aspects of the health and behavior of people, and such research is only possible through the participation of humans as research subjects.

Human subjects are partners and participants in research and a precious resource to the University. ***At UNC-Chapel Hill, human subjects' research is a privilege, not a right.*** Consistent with that philosophy, it is the mission of the UNC-Chapel Hill Human Research Protection Program to provide that:

1. the rights and welfare of human subjects are paramount in the research process;
2. the highest standards of ethical conduct are employed in all human subjects research;
3. research investigators are properly trained in the ethical and regulatory aspects of research with human subjects;
4. research investigators deal honestly and fairly with human subjects, informing them fully of procedures to be followed, and the risks and benefits of participating in research; and
5. research using human subjects at UNC-Chapel Hill conforms with all applicable local, state and federal laws and regulations and the officially adopted policies of the University.