

Human Research Protections Program (HRPP)

Institutional Roles and Responsibilities

Ethical Principles that the MCG HRPP Follows

Medical College of Georgia (MCG) Human Research Protection Program (HRPP) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the institution. In the review and conduct of research, MCG is guided by the ethical principles regarding all research (including exempt) involving humans as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, often referred to as the Belmont Report, (National Commissions for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979):

- Respect for persons is applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations.
- Beneficence is applied so that possible benefits are maximized and possible risks are minimized to the persons involved.
- Justice is evidenced in the equitable selection of subjects.

Additionally, to honor its commitment to the Charlie Norwood VA Medical Center (VAMC), the institution abides by the Department of Veterans Affairs policies for human research protection, including the regulations at 38 CFR 16, and the Veterans Health Administration (VHA) Handbook 1200.5. The actions of MCG will also conform to all other applicable federal, state, and local laws and regulations.

All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

Engagement in Research

The institutions are engaged in research when the planned project meets the DHHS definition or the FDA definition of research as stated earlier.

Federalwide Assurance

Each of the five components of the HRPP holds a Federalwide Assurance (FWA) from the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP). This FWA is an agreement between DHHS and our research community to review and approve federally funded research involving human subjects in accordance with the ethical principles outlined in the Belmont Report and the DHHS regulations 45 CFR Part 46. Each component of the MCG HRPP has elected to extend DHHS OHRP's authority to all human subjects' research conducted to include the principles of the Belmont Report and the Common Rule to be applied to all research

reviewed and approved at MCG. These are available on our web site at <http://www.mcg.edu/research/ohrp/irb/hac/fwa.asp>