1. LLUAHSC acknowledges its responsibilities for protecting the rights and welfare of human subjects in research as guided by the ethical principles set forth in the Report of the National Commission for the Protection of Human Subjects and Biomedical and Behavioral Research, entitled “Ethical Principles and Guidance for the Protection of Human Subjects of Research” (the “Belmont Report”). In summary, these principles are:

1.1 Respect for persons – recognition of the personal dignity and autonomy of individuals and special protections for those persons with diminished autonomy.

1.2 Beneficence – Obligation to protect persons from harm by maximizing potential benefits and minimizing possible harm.

1.3 Justice – Fairness in distribution of research benefits and burdens.

2. LLUAHSC shall grant the authority of developing and maintaining a Human Research Participant Protection (HRPP) program, with appropriate policies, procedures, and adequate resources, to the Vice President for Research Affairs.

3. LLUAHSC shall maintain a Federal Wide Assurance (FWA) for the Protection of Human Subjects with the Office for Human Research Protections (OHRP).

4. LLUAHSC shall comply with the following: for federal regulations, (the “Common Rule”), 45 CFR 46 and its subparts A, B, C and D; for Food and Drug Administration (FDA)-regulated studies, 21 CFR Parts 50 and 56; and for applicable clinical studies, the International Council of Harmonization on Guidance and Good Clinical Practice (ICH-GCP) Part E6; as well as state and local laws and regulations.

5. LLUAHSC, by action of the President and Board of Trustees, shall establish an Institutional Review Board (IRB) to review human subject research that is conducted at or supported by LLUAHSC.

Approved: LLUAHSC Board of Trustees - December 10, 2008

_________________________________________  ________________
Vice President, Research Affairs  Date

_________________________________________  ________________
President  Date

_________________________________________  ________________
Corporate Secretary  Date