The University of Tennessee, Memphis
The Health Science Center

HUMAN SUBJECTS IN RESEARCH

Effective Date: October 7, 1997
Revised: March 2000

All research activities involving the use of human subjects by UT Health Science Center faculty, staff or students, or with the use of UT Health Science Center facilities must be reviewed and approved by the UT Memphis Institutional Review Board (IRB) prior to initiation of the work, must be renewed at least annually, and must be conducted in accordance with University policy and procedures, and applicable federal regulations, including HHS regulations published at 45CFR Part 46, revised June 18, 1991, and as may be further revised; and the USFDA regulations published at 21 CFR**,** parts 50 and 56, June 18, 1991, and as may be further revised.

All serious adverse events must be reported immediately to the IRB. All serious adverse events* involving gene therapy must be reported to the IRB**,** the Institutional Biosafety (rDNA) Committee, and appropriate federal agencies in accordance with current federal regulations.

Investigators should note that studies conducted by UT investigators at local hospitals (e.g., VAMC, Baptist, Methodist, LeBonheur, St. Jude) will require approval by the human subjects review boards at the hospitals in addition to the UT Health Science Center IRB.

See also Administrative Policy #2.018 "Assurances of Compliance with Federal Regulations."

See also Research Policy on the use of "Recombinant DNA."

For current information on federal regulations related to human subjects research, visit the NIH website at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

*A "serious adverse event" is defined by, "any expected or unexpected adverse event, related or unrelated to the intervention, occurring at any dose that results in any of the following outcomes: death, a life threatening event, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life threatening, or require hospitalization also may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition." Source: http://www4.od.nih.gov/oba/12-99pro.htm.

For further information, please see the UT Memphis IRB and OHSP websites.