

The University of Tennessee Health Science Center

RECOMBINANT DNA

Effective Date: October 7, 1997

Revised: Mach 2000

All research activities involving the use of recombinant DNA 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 Biosafety Recombinant DNA Committee prior to initiation of the work, and must be conducted in accordance with University policy and procedures and applicable federal regulations, including regulations published in the Federal Register, Volume 251, No. 88, May 7, 1986, and update din Vol. 55, No. 41, March 1, 1990, and as may be further updated. It is the responsibility of the individual faculty member and department chair to ensure that all projects that require review are submitted to the Committee.

All serious adverse events* involving gene therapy studies in human subjects 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 investigator at the VAMC or other off campus sites may require approval by the rDNA committees at those sites *in addition* to the UT Health Science Center rDNA Committee.

For current NTH Guidelines, visit the NIH web site at <http://www.nih.gov>.

*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 [IBC](#) website.