SIMPLIFIED GUIDELINES FOR RECOMBINANT DNA RESEARCH

These condensed guidelines are provided to assist researchers in determining whether or not their research requires Institutional Biosafety Committee (IBC) approval. If so, the researcher should submit a registration form to the IBC. This abstract is not all inclusive and if the researcher is not sure if his/her program needs review, he/she should contact the IBC. Also, see the complete *NIH Guidelines for Research Involving Recombinant DNA Molecules* (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html) for further details.

PLEASE NOTE: Those researchers proposing human gene therapy protocols must submit additional information. Specific points to consider can be found on a separate form available through Research Administration.

Recombinant DNA is defined as: (1) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. (2) DNA molecules that result from the replication of these molecules.

NIH has implemented three major levels of review: (1) Institutional Biosafety Committee (IBC), the local recombinant DNA review board of the university; (2) Office of Recombinant DNA Activities (ORDA), an office within NIH; and (3) Recombinant DNA Advisory Committee (RAC), a national committee that advises the Secretary, Assistant Secretary for Health, and the Director of the NIH on recombinant DNA research.

NIH has defined six classifications for various types of experiments. These classifications define the level of review required and are as follows: (III-A) Experiments that require specific RAC review and NIH/ORDA and IBC approval before initiation of the experiment; (III-B) Experiments that require IBC and NIH/ORDA approval before initiation of the experiment; (III-C) Experiments that require IBC approval and NIH/ORDA registration before initiation; (III-D) Experiments that require IBC approval before initiation; (III-E) Experiments that require IBC notification at the time of initiation of the experiment; (III-F) Experiments that are exempt from the *NIH Guidelines*, but that still require submission to the IBC. Note that it is UTHSC policy that the IBC must make the determination as to whether the experiments can be classified as exempt under the *NIH Guidelines*.

Note: If an experiment falls into sections III-A, III-B, or III-C and one of the other sections, the rules pertaining to sections III-A, -B, or -C will be followed. If an experiment falls into section III-F and into either section III-D or III-E as well, the experiment is considered exempt from the NIH Guidelines.