



Compliance Note

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Recombinant DNA Materials

HSD-BSC-001

This information is for your use and as a way of providing consistent information. This information is based on current UCHSC Policy, and/or Federal, State or Local regulatory requirements.

Research Involving Recombinant DNA (rDNA) Materials

Institutions receiving funds from NIH must comply with federal regulations governing the use of recombinant DNA (rDNA) materials. Compliance includes conforming to various environmental, public health and worker safety requirements for basic and clinical research with these materials. NIH has issued [Guidelines for Research Involving Recombinant DNA Molecules](#). The Guidelines can be viewed or downloaded in their entirety on the web:

The NIH definition of rDNA covers:

1. recombinant deoxyribonucleic acid (DNA) molecules, and
2. organisms and viruses containing recombinant DNA molecules.
3. those molecules constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules capable of replicating in a living cell;
4. those molecules that result from the replication of those described above and
5. those synthetic DNA molecules likely to yield a potentially harmful polynucleotide or polypeptide (or protein) toxic or pharmacologically active

The UCHSC has established an [Institutional Biosafety Committee \(IBC\)](#) and a Biosafety Office to oversee the safe use and handling of rDNA materials. The Biosafety Office, in conjunction with the IBC reviews all proposals that anticipate use of rDNA materials and issues Biosafety Authorizations with recommendations on the biosafety levels, containment and training requirements for the research proposals. To apply for a biosafety authorization you must complete and submit UCHSC forms, which are available from the Biosafety Office or on our website: <http://www.uchsc.edu/safety/Forms/BSForms.htm>

UCHSC has also established specific policies and procedures for use of recombinant DNA in clinical trials involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human research participants (Human Gene Transfer). Such studies require concurrent review by the IBC and COMIRB. The complete policy is also on our web page.

If you have any questions regarding research involving rDNA materials, contact the Biosafety Office of the Department of Environmental Health and Safety, 303-724-0235.