HSC OP: 73.05, Research Involving Hazardous Chemical and Biological Materials, and Recombinant or Synthetic Nucleic Acid Molecules

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to provide a framework for compliance with federal, state, and local rules, regulations, and laws regarding hazardous chemicals, biological materials, and recombinant or synthetic nucleic acid molecules.

REVIEW: This HSC OP will be reviewed on June 1 each odd-numbered year (ONY) by the Director of Safety Services and the Assistant Vice President for Research Integrity, with recommendations for revisions forwarded to the Senior Vice President for Research (SVPR) by June 15.

POLICY/PROCEDURE:

1. Compliance with federal, state, and local rules, regulations, and laws.

TTUHSC adopts and continues its policy that all research involving hazardous chemicals and biological materials conducted or sponsored by TTUHSC shall be conducted in accordance with federal, state, and local rules, regulations, and laws. In addition, all research involving recombinant or synthetic nucleic acid molecules conducted at TTUHSC shall also adhere to federal, state, and local rules, regulations, and laws, including the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) published in 2013, and all subsequent revisions.

2. Compliance policy.

In furtherance of that policy, TTUHSC directs as follows.

a. Establishment of IBC. TTUHSC shall establish an Institutional Biosafety Committee (IBC) whose members shall be appointed by the Senior Vice President for Research.

   Membership on the IBC shall consist of a minimum of five TTUHSC faculty members with attempts to include representation from each TTUHSC school and campus whose faculty conduct basic laboratory research. Attempts will be made to include non-faculty representatives from the Office(s) of Safety Services from each TTUHSC campus where basic laboratory research is conducted. The TTUHSC Biological Safety Officer (BSO) shall also be a voting member.

   The purpose of the IBC is to provide oversight of all research involving biologically hazardous and chemically hazardous materials (excluding recombinant or synthetic nucleic acid molecules (addressed in 2b below) at TTUHSC campuses and facilities used by TTUHSC faculty and/or contractors.

b. Establishment of RDBC. TTUHSC shall establish a Recombinant DNA Biosafety Committee (RDBC) whose members shall be appointed by the SVPR.

   The RDBC shall consist of at least one individual with expertise in each of the following areas: animal containment principles, genetics, micro-organisms, recombinant or synthetic nucleic acid molecule technology, biological safety and/or physical containment; at least one member representing the laboratory technical staff; two committee members
who are not affiliated with TTUHSC (including family members) who represent the
interests of the West Texas area with respect to health and protection of the environment;
and the TTUHSC Biological Safety Officer. The purpose of the RDBC is to provide
oversight of all research utilizing recombinant DNA at all TTUHSC campuses and
facilities in accordance with the NIH Guidelines. A single RDBC shall serve all TTUHSC
campuses and facilities used by TTUHSC faculty and/or contractors.

Note that the NIH Guidelines refer to this type of Committee as an Institutional Biosafety
Committee (IBC); however, TTUHSC has chosen to establish a committee separate from
the IBC and to name it the Recombinant DNA Biosafety Committee for oversight of the
use of and/or research involving recombinant or synthetic nucleic acid molecules.

c. **Appointment of BSO.** The Director of Safety Services shall appoint a Biological Safety
Officer (BSO) who shall also serve as a member of both the IBC and the RDBC.

d. **Responsibilities of the IBC and RDBC.** The IBC and the RDBC shall be responsible for
monitoring TTUHSC compliance with applicable federal, state, and local rules,
regulations, and laws with regard to research involving biologically and chemically
hazardous materials (IBC) and Recombinant or Synthetic Nucleic Acid Molecules
(RDBC). In conjunction with the Department of Safety Services, the committees shall
monitor and review all TTUHSC research and research facilities utilizing biologically
hazardous materials or toxins and recombinant or synthetic nucleic acid molecules in
accordance with established policies and procedures.

e. **Authorities of the IBC and RDBC.** The IBC and the RDBC are authorized to inspect
research facilities, obtain information relating to laboratory practices and procedures, and
take such actions as are in their judgment necessary to insure compliance with the NIH
Guidelines, applicable federal, state, and local rules, regulations, and laws, and
established policies and procedures, including the suspension of research in the event of
a violation of policy or procedure which may create a safety hazard.

f. **Responsibilities of the Senior Vice President for Research.** The SVPR shall be
responsible for the implementation of this policy through the provision of necessary
resources, and the establishment of appropriate policies and procedures. The Assistant
Vice President for Research Integrity (or designee) will respond to initiatives from the
SVPR concerning the goals of this operating procedure.

g. Both the Institutional Biosafety Committee and the Recombinant DNA Biosafety
Committee are considered “Medical Committees” as defined under Texas Health &
Safety Code chapter 161, and/or other applicable state and federal statutes. All
documents generated by, submitted to, or created for purposes of fulfilling IBC or RDBC
duties are considered confidential and privileged as “medical committee documents”.