UTHSC Institutional Biosafety Committee - Charter

I. Introduction:

The following are excerpts from the "Biosafety in Microbiological and Biomedical Laboratories (BMBL) Manual, Fifth Edition, 2007.

The *NIH Guidelines*, initially published in 1976 by the Office of Biotechnology Activities (OBA), were the first documents to formulate the concept of an Institutional Biosafety Committee (IBC) as the responsible entity for biosafety issues stemming from recombinant DNA research. The *Guidelines* are revised on an ongoing basis in response to scientific and policy developments and describe the membership, procedures, and functions of an IBC. The *Guidelines* also outline federally mandated responsibilities for an IBC, as well as the roles and responsibilities of various entities affiliated with recombinant DNA research, including institutions, investigators, and the NIH. The institution is ultimately responsible for the effectiveness of the IBC, and may define additional roles and responsibilities for the IBC apart from those specified in the *Guidelines*.

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.

Excerpts from the "NIH Guidelines, 2002".

The *NIH Guidelines* are intended to assist the institution, the IBC, the Biological Safety Officer (BSO), and Principal Investigators in determining safeguards that should be implemented during research activities involving recombinant DNA. The *NIH Guidelines* will never be complete or final since all conceivable experiments involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the institution and those associated with it to adhere to the intent of the NIH Guidelines as well as to their specifics. **Each institution that receives NIH funding (and the IBC acting on its behalf) is responsible for ensuring that all recombinant DNA research conducted at or sponsored by that institution is carried out in compliance with the *NIH Guidelines*.**

II. Responsibilities and Policies of the IBC:

UTHSC utilizes the *NIH Guideline*s and information in the most recent *BMBL* to establish institutional policies that govern research activities involving recombinant DNA and other biological materials. UTHSC has established an IBC whose responsibilities are not restricted solely to recombinant DNA, but that also include biological materials that have biohazard potential. This includes both infectious and non-infectious biohazardous materials.

A. Responsibilities:

The responsibilities of the IBC are applicable to all activities involving recombinant DNA and biohazardous materials if:

1. The research is sponsored by UTHSC, or;
2. The research is conducted by, or under the direction of, any employee or agent of UTHSC in connection with his or her institutional responsibilities, or;

3. The research is conducted by, or under the direction of, any employee or agent of UTHSC using any property or facility of UTHSC.

B. Policies:

1. All research utilizing recombinant DNA (rDNA), including those considered exempt under the *NIH Guidelines*, will be reviewed and approved by the UTHSC IBC.
2. The IBC has the responsibility and authority to review, approve, disapprove, or require changes to proposed research utilizing recombinant DNA to ensure compliance with the *NIH Guidelines*.
3. No IBC member may be involved in the review or approval of a registration in which he/she is engaged, has a direct financial interest, or serves in a supervisory role for the PI of the registration, except to provide requested information similar to other investigators.
4. The IBC shall meet monthly, or at the call of the Chair or any other member of the IBC, and the meeting shall be open to the public except when proprietary information is discussed, or when matters involving restricted information, such as Select Agent location and quantities, are discussed. Any public comments will be incorporated into the minutes of the next scheduled monthly IBC meeting.
5. To conduct business a quorum consisting of 50% plus 1 members of the IBC must be present. Action on IBC registrations (e.g. approval, revision, etc) requires a face-to-face meeting of the IBC. Email votes, absentee ballots, etc are not allowed.
6. Sub-committees of the IBC may be formed to address specific issues for which additional expertise is required. The composition of the sub-committee will include at least three members of the IBC, one of which will be the IBO. The other members shall be nominated by the IBC Chair in consultation with the Sr. Associate Vice Chancellor for Research.
7. UTHSC will maintain documentation of IBC activities as prescribed by the *NIH Guidelines*. All approved IBC meeting minutes, or other documents requested by OBA, must be maintained on file, and made available to the public in accordance with Section IV-B-2-(a)-7 of the *NIH Guidelines* if requested.
8. The IBC looks to UTHSC to provide both meeting space for the IBC and sufficient staff to support the review and record keeping duties of the IBC.
9. UTHSC encourages and promotes constructive communication among the research administrators, department heads, research investigators, the IBC, the IBO and other institutional officials as a means of maintaining a high level of awareness regarding the *NIH Guidelines*.
10. The IBC shall maintain strong liaisons with the UTHSC Institutional Review Board for the Protection of Human Subjects (IRB) and the Institutional Animal Care & Use Committee (IACUC).

11. The IBC shall function through the Office of Research Compliance with regard to project registration, document preparation, educational efforts, materials, and compliance with biosafety regulations and guidelines.
12. UTHSC will exercise appropriate oversight to ensure that its practices and procedures designed for research involving rDNA are being effectively applied and are in compliance with the requirements of the *NIH Guidelines* and this policy.
13. UTHSC will comply with the requirements set forth in the *NIH Guidelines* regarding cooperative research projects. When research covered by this policy is conducted at, or in cooperation with, another entity all provisions of this policy remain in effect for that research. UTHSC may accept, for the purpose of meeting the IBC review requirements, the review of an IBC established under another policy of compliance with NIH. Such acceptance must be in writing, approved and signed by the appropriate individual from the UTHSC Office of Research Compliance and approved and signed by the responsible officials of each of the other cooperating institutions.
14. Copies of this Charter will be available to all UTHSC faculty through the Office of Research Compliance and the Chairperson of the IBC.
15. Research covered by this policy will fall into one of the following categories:
    i. rDNA: (i.) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; (ii.) molecules that replicate as a result of the above;
    ii. Research considered exempt will be reviewed by the IBO and the Chair of the IBC, and approved by the Chair of the IBC. All other categories will be approved by the full IBC;
    iii. BSL-2 (Biosafety Level-2): Agents or materials that are associated with diseases or conditions that are rarely serious and for which preventive/therapeutic interventions are often available;
    iv. BSL-3: Agents or materials that are associated with serious/lethal human consequences for which preventive/therapeutic interventions may be available (high individual risk, but low community risk);
    v. BSL-3 Select Agents: Select agents are biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal or plant products. The IBC will be responsible for initial review of inactivation protocols for all BSL-3 select agents as required by the Centers for Disease Control. Annual reviews of approved inactivation protocols will be performed by the UTHSC RBL Executive Committee;
    vi. Studies that fall under the Dual Use Research of Concern (DURC) classification: DURC studies include all life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly

misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. As such, the IBC will serve at the Institutional Review Entity (IRE).

1. The IBC/IRE will not make recommendations as to whether the research should be conducted, or whether the results or other work products should be published. Rather, the committee will draft a statement elaborating the potential dual use implications of the work. This statement will be forwarded, after review and concurrence of the Deputy Director for Intramural Research (DDIR), with any manuscript or abstract to the editor of the journal or meeting organizer to which the work will be submitted for publication.
2. The IBC/IRE will also assist the PI in performing a risk assessment and risk mitigation plan for the DURC.

16. In instances where biological samples are used for research purposes that have the potential for containing blood-borne pathogens (e.g. use of human or non-human primate materials), but that otherwise do not involve intentional infection with replicating pathogens, infections with viral vectors, or that contain rDNA, the IBC may allow "designated member review" of the associated protocol to ensure proper biosafety precautions are described. Designated members are the IBC Chair, IBO and a member with the appropriate expertise, if necessary. Following review, the IBC will be provided a summary and given a recommendation by the reviewers.
17. Public comments regarding the IBC, its workings, or institutional research activities involving recombinant DNA and other biological materials may be made in three ways; either in person to the IBC Chair, by calling the Office of Research Compliance, or by sending a message via compliance@uthsc.edu. The latter is accessible only by the Associate Vice Chancellor for Research (AVC) who is also the contact person for interactions with OBA. The AVC will review all comments and forward substantive comments to OBA.

III. IBC membership:

IBC members will be appointed in accordance with the current UTHSC appointment policies, which include appointment for renewable three-year terms.

A. IBC composition.

In accordance with the *NIH Guidelines*, the UTHSC IBC must be comprised of:

1. No fewer than five members so selected that they collectively have experience and expertise in rDNA technology and the capability to assess the safety of rDNA research and to identify any potential risk to public health or the environment.

2. At least two members who are not affiliated with the institution (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment.
3. At least one scientist with expertise in animal containment principles.
4. In addition, when the institution conducts research at BSL-3, or performs large scale (greater than 10 liters) production of materials containing rDNA, or large scale production of some infectious agents, a Biological Safety Officer (a.k.a. UTHSC IBO) is mandatory and shall be a member of the IBC.

IV. Review and Amendments:

The Charter will be reviewed annually; however, amendments or revisions to the Charter may be proposed at any meeting of the IBC. Changes to the Charter require approval by a majority vote of the IBC.