

CHARGE TO THE ADMINISTRATIVE PANEL ON BIOSAFETY

(Revised July 2008)

GENERAL CHARGE

The Administrative Panel on Biosafety reviews all University research and teaching activities involving the use of biohazardous agents and recombinant DNA molecules that require approval ("biosafety activities"), as defined below. Through these reviews, the Panel ensures that the activities described in the previous sentence and the related facilities are in compliance with applicable University policies and external regulations.

The Panel advises the University and recommends policies to guide investigators and the Department of Environmental Health & Safety (EH&S) in carrying out the University's Biosafety Program in the acquisition, use, training, transfer, storage, disposal, and emergency response procedures for all biosafety activities. The Panel's objective shall be to ensure that such activities meet standards of good practices consistent with safety of personnel and the general public in ways that best facilitate relevant research or teaching activities of the University.

The Panel is responsible for reviewing all University projects conducted by Stanford faculty, staff, students and/or visiting scientists which involve biosafety activities at Stanford facilities. In addition, the Panel may be asked by the University administration to review research protocols on behalf of other institutions with which Stanford has formal affiliation agreements. Under Stanford's current "Institutional Biosafety Committee" agreement with the Veterans Affairs Palo Alto Health Care System (VAPAHCS), the Panel shall review all biosafety protocols from Stanford researchers located at the VAPAHCS and from VAPAHCS researchers not otherwise affiliated with Stanford University.

The Panel shall function so as to discharge the University's obligations placed upon the Panel by current governmental requirements, including those described in the NIH Guidelines, the Centers for Disease Control and Prevention (CDC) Guidelines, and Occupational Health & Safety Administration (OSHA) Regulations. To this end, the Panel shall assist protocol directors in meeting their responsibilities.

All biosafety activities involving the use of Class 2 or 3 agents OR non-exempt recombinant DNA molecules as defined by the National Institutes of Health (NIH) shall be reviewed by the Panel regardless of the source of funding for the project. The Panel may approve research protocols with or without modifications, or withhold approval of all or any portion of a protocol. The Panel may delegate review and approval of protocols that meet specific requirements to a voting member of the panel. This subset of protocols must be agreed upon by the full Panel and approved by the Dean of Research.

All human subjects' protocols involving gene transfer or gene therapy, as defined in the NIH Recombinant DNA Research Guidelines, shall be reviewed by the Panel in coordination with the Administrative Panel on Human Subjects in Medical Research. (See Review Process for Biosafety and Human Subjects Gene Transfer or Gene Therapy Experiments.)

The Panel shall assess suspected or alleged violations of protocols, external regulations, or University policies which involve biosafety activities. Activities in which serious or continuing violations occur may be suspended by the Panel or the Institutional Biosafety Officer. In such cases, the Panel will immediately notify the affected investigator(s), the relevant school dean, the Vice Provost and Dean of Research, appropriate University officers, and others as required by University policies and external regulations.

Upon request, the Panel shall review and comment on proposed external regulations dealing with biosafety. When appropriate, the Panel will formulate draft policies and procedures for approval by the appropriate University bodies and promulgation by the Vice Provost and Dean of Research.

DEFINITIONS

Biohazardous Agents:

- A. Infectious/pathogenic agents classified in the following categories: Class 2, 3, and 4 bacterial, fungal, parasitic, viral, rickettsial or chlamydial agents or,
- B. Other agents that have the potential for causing disease in healthy individuals, animals, or plants.

Recombinant DNA Molecules:

- A. Molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or,
- B. DNA molecules that result from the replication of those described in "A" above.

Gene Transfer

Delivery of exogenous genetic material (DNA or RNA) to somatic cells for the purpose of modifying those cells.

GUIDELINES

All biosafety protocols shall be available for review by any member of the Panel. The Panel shall maintain records of research protocol reviews, minutes of meetings, including records of attendance and Panel deliberations. The activities of this Panel are subject to the Guidelines on Confidentiality of Administrative Panel Proceedings.

The following guidelines are established to aid the Panel in the exercise of its responsibilities:

Biohazardous Agents

Protocols involving Class 2 and Class 3 biohazardous agents must be reviewed and approved by the Panel prior to the initiation of use of agent. Approval of Class 3 agents may be granted for no more than one year after review at a convened meeting of a quorum of the Panel (i.e., a majority of the voting members) with the affirmative vote of a majority of those present. Class 2 protocols are approved for 3 years

Protocols involving Class 1 agents that do not involve recombinant DNA, are not reviewed by the Panel.

Research using Class 4 agents is not currently being carried out at Stanford.

Toxins

The routine use of most toxins will not require APB review and approval. However, the Panel will notify the Department of Environmental Health and Safety (EH&S) if any experiments involve the isolation and production of certain toxins (from live biological organisms) that are listed in the CDC Standard, Select Agent Regulation (42 CFR 73).

Recombinant DNA

Recombinant DNA experiments involving certain Class 1 agents and all Class 2 and Class 3 agents require Panel approval before initiation. In addition, Panel approval is required prior to the commencement of any proposed recombinant DNA project that involves pathogenic agents, human subjects, live animals, plants, and/or planned release of recombinant DNA organisms into the environment.

Gene Transfer

Human Subjects protocols involving gene transfer or gene therapy must be reviewed and approved by the Panel prior to initiation of protocol. Approval may be granted for no more than one year after review at a convened meeting. RAC review occurs before final Panel approval in order to inform that Panel of the RAC's recommendations before the Biosafety Panel makes its final determination.

Experiments classified as "Exempt" in the *NIH Guidelines* do not require Panel review.

Conflict of Interest

In accordance with the NIH Guidelines, no member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

APPEALS

In cases of dispute with respect to procedures or decisions of the Panel, appeals may be made to the Vice Provost and Dean of Research for mediation.

MEMBERSHIP

The Panel is appointed by the Vice Provost and Dean of Research and shall be made up of at least five members with expertise in general issues of laboratory biosafety, use of infectious materials, and recombinant DNA technology. Individuals on the Panel include faculty and staff, one student nominated by the ASSU Committee on Nominations who is either an upperclassman or preferably a graduate student with previous biosafety experience, two members from the local community not otherwise affiliated with the University, and any others who may be invited to serve when their expertise is required.

Voting ex officio members shall include representatives of the: Department of Environmental Health & Safety (Biosafety Officer) and Department of Comparative Medicine (a veterinarian). Non-voting ex officio members shall include representatives of the: Department of Environmental Health & Safety (Associate Vice Provost), Office of Vice Provost and Dean of Research and Office of General Counsel (consultation basis).

The term of membership on the Panel is a 12-month renewable period beginning October 1 through September 30.

REPORTING OBLIGATIONS

The Panel reports to the Vice Provost and Dean of Research. The Biosafety Officer is the institutional official responsible for the day-to-day operation of the biosafety program and reports to the Associate Vice-Provost for Environmental Health and Safety.

PANEL MEETINGS

The Panel shall meet as necessary to conduct its business but no less than bi-monthly. The Chair shall submit an annual report of Panel activities and deliberations to the President by October 1st of the following year.

STAFF SUPPORT

EH&S and the Office of the Vice Provost and Dean of Research shall provide the necessary staffing and administrative assistance. EH&S shall provide technical expertise and advice as necessary for the Panel to fulfill its duties.