

Charge To The Administrative Panel On Biosafety

(Revised Sept. 2022)

GENERAL CHARGE

The Administrative Panel on Biosafety reviews all University research and teaching activities involving the use of biohazardous agents, recombinant DNA molecules and synthetic nucleic acid 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 is also responsible for review of biological agents as they relate to Biosecurity, identifying risks associated with the potential misuse of information, technologies, or products that may be generated.

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 & Biosecurity 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 has a similar arrangement with the SLAC National Accelerator Laboratory.

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 for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Centers for Disease Control and Prevention (CDC) Guidelines, the U.S. Department of Health and Human Services (HHS), 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 Biosafety Level 2 or 3 agents AND/OR non-exempt recombinant DNA AND/OR synthetic nucleic acid molecules, as defined by the National Institutes of Health (NIH), AND/OR agents identified as Dual Use Research of Concern 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 subject protocols involving gene transfer, as defined in the NIH Guidelines, shall be reviewed by the Panel in coordination with the Administrative Panel on Human Subjects in Medical

Research (see

https://doresearch.stanford.edu/policies/research-policy-handbook/environmental-health-and-safety/biohazardous-agents-and-recombinant-dna).

The Panel shall assess suspected or alleged violations of protocols, external regulations, or University policies which involve biosafety or biosecurity 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: Biosafety level 2, 3, and 4, 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.

Synthetic Nucleic Acid Molecules:

- A. Can replicate or generate nucleic acids that can replicate in a living cell, or
- B. Are designed to integrate into DNA, or
- C. Produce a toxin with a LD50<100ng/kg body weight.

Synthetic nucleic acids that are deliberately transferred into one or more human subjects and:

- A. Are >100 nucleotides, or
- B. Can integrate into the genome, or
- C. Can replicate in a cell, or



D. Can be transcribed or translated.

Gene Transfer:

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

Dual Use Research of Concern:

A subset of research, as defined by the Federal government, that has the greatest potential for generating information that could be readily misused to threaten public health and national security has been termed "dual use research of concern" or DURC.

GUIDELINES

All biosafety protocols shall be available for review by any member of the Panel. The Panel shall maintain records of research protocol reviews and 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 Biosafety level 2 and 3 biohazardous agents must be reviewed and approved by the Panel prior to the initiation of use of agent. Approval of Biosafety level 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. Biosafety level 2 protocols are approved for 3 years.

Protocols involving Biosafety level 1 agents and/or do not involve recombinant DNA are not reviewed by the Panel.

Research using Biosafety level 4 agents are not currently being carried out at Stanford.

Toxins and Select Agents

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 U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) USA PATRIOT Act and Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the select agent regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

Recombinant DNA



Recombinant DNA experiments involving certain Risk Group 1 agents and <u>all</u> Risk Group 2 and 3 agents require Panel approval before initiation. In addition, Panel approval is required prior to the commencement of any proposed recombinant DNA project which involves pathogenic agents, human subjects, live animals, plants, and/or planned release of recombinant DNA organisms into the environment. Protocols involving RG2 Agents are approved for 3 year, RG3 for one year.

Synthetic Nucleic Acid Molecules

Any work using synthetic nucleic acid molecules that are deemed by the NIH to be non-exempt from the NIH Guidelines must have APB approval prior to commencing work. Protocols are approved for 3 years.

Gene Transfer

Human Subjects protocols involving gene transfer 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.

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

<u>Dual Use Research of Concern</u>

Potential DURC must be reviewed by the Panel prior to initiation of work. All Federal requirements must be met prior to and for the duration of work. Approval may be granted for no more than one year after review at a convened meeting. The appropriate Federal agency must approve the work and risk mitigation plan prior to final Panel approval.

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.

Decisions of the APB

If an investigator has concerns with respect to procedures or decisions of the IBC, the investigator may discuss his/her concerns with the Vice Provost and Dean of Research. Neither the Vice Provost and Dean of Research, nor the Provost, nor any other Stanford official or committee may approve a protocol that has not been approved by the decision of the Panel, nor apply undue pressure on the Panel to reverse a decision.

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 or their representative), 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 on 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 Vice Provost and Dean of Research.

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.

References

http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

http://www.dir.ca.gov/title8/5193.html

http://www.dir.ca.gov/title8/5199.html

http://www.selectagents.gov/

http://www.selectagents.gov/Regulations.html

http://www.justice.gov/archive/ll/highlights.htm

http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf