Stanford | Environmental Health & Safety
Research Safety

CHARGE TO THE ADMINISTRATIVE PANEL ON BIOSAFETY

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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, the environment, and the 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, but not limited to, those described by the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS), the Occupational Safety & Health Administration (OSHA) , and the

California Division of Occupational Safety and Health. To this end, the Panel shall assist protocol directors in meeting their responsibilities.

All biosafety activities involving the use of Risk Group 2 or higher 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 animal research protocols involving work falling under the purview of the Panel shall be reviewed by the Panel in coordination with the Administrative Panel on Laboratory Animal Care.

All human subject protocols involving gene transfer or gene drives, as defined in the NIH Guidelines, shall be reviewed by the Panel in coordination with the Administrative Panel on Human Subjects in Medical Research.

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
    - Infectious or pathogenic agents classified in the following categories:
        - Risk Group 2, 3, and 4, as classified by the NIH, or
    - Other agents that have the potential for causing disease in otherwise healthy individuals, animals, or plants.

- Biosafety
    - Biosafety is the use of specific practices, safety equipment, and specially designed buildings to ensure that workers, the community, and the environment are protected from infectious agents and toxins and biological hazards.
    - A Biosafety Program will identify biological hazards, measure the level of health-related risks the biological hazards present, and identify ways to reduce the health-related risks associated with the biological hazards.
    - Biocontainment is the use of work practices, safety equipment, and engineering systems to prevent the accidental release of infectious agents and toxins into the environment.
    - Biocontainment controls may include the use of biosafety cabinets, personal protective equipment, air filtration, and other mechanisms.
    - Biocontainment prevents an infectious agent or toxin from reaching laboratory workers and from leaving the lab environment.
- Biosafety Levels
    - Biosafety Levels (BSL) are used to identify the containment measures necessary for work with an infectious or pathogenic agent. Each level of containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling an agent, and are meant to protect the worker, the environment, and the public from the risks of the agent and work.
    - Biosafety Levels 1 through 4 are defined in the Biosafety in Biomedical Laboratories (BMBL) from the CDC.
- Dual Use Research of Concern
    - Per the NIH, biological research is considered 'dual-use' in nature if the methodologies, materials, or results could be used to cause harm. Dual Use Research of Concern (DURC) is a small subset of 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, material, or national security.
- Gene Drives
    - In the context of the NIH Guidelines, defined as a technology whereby a particular heritable element biases inheritance in its favor, resulting in the heritable element becoming more prevalent than predicted by Mendelian laws of inheritance in a population over successive generations
- Gene Transfer
    - Delivery of exogenous genetic material (DNA or RNA or synthetic nucleic acids) into a cell.
- Human Gene Transfer

    - In the context of the NIH Guidelines, these are defined as:
        - Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
        - Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
            - Contain more than 100 nucleotides; or
            - Possess biological properties that enable introduction of stable genetic modifications into the genome (e.g., cis elements involved in integration, gene editing); or
            - Have the potential to replicate in a cell; or
            - Can be translated or transcribed.
- Initiation
    - In the context of the NIH Guidelines, this is defined as the introduction of recombinant or synthetic nucleic acid molecules into organisms, cells, or viruses.
    - The Panel applies this definition also to work with relevant biohazardous agents.
- Recombinant and Synthetic Nucleic Acid Molecules
    - In the context of the NIH Guidelines, these are defined as:
        - (i) Molecules that (a) are constructed by joining nucleic acid molecules and (b) that can replicate in a living cell, i.e., recombinant nucleic acids;
        - (ii) Nucleic acid molecules that are chemically or by other means synthesized or amplified including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
        - (iii) Molecules that result from the replication of those described in (i) or (ii) above.
- Risk Group
    - The Risk Group is a classification that describes the relative hazard posed by infectious or pathogenic agents in the laboratory.
        - Risk Group classification considers the principal hazardous characteristics of the agent, which include its capability to infect and cause disease in a susceptible host, severity of disease, and the availability of preventive measures and effective treatments. It also considers possible routes of transmission of infection in the laboratory, infectious dose, stability in the environment, host range, whether the agent is indigenous or exotic to the local environment, and the genetic characteristics of the agent.
    - Classifications by the NIH are accepted by the Panel as part of the biological risk assessment

        - Classifications by commercial companies are not accepted when they do not align with those determined by the NIH.
        - Classifications can be found on the American Biological Safety Association Risk Group database.
    - The Risk Group to which an agent is assigned is used as the primary, but not the only, consideration in a biological risk assessment to determine the appropriate Biosafety Level in which a worker can handle the agent or toxin. Risk Groups generally correlate with, but do not equate to, Biosafety Level.

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 Risk Group level 2 or higher biohazardous agents must be reviewed and approved by the Panel prior to the initiation. Approval of Biosafety Level 2 protocols may be granted for 3-year periods (provided annual renewal is completed), and approval of Biosafety level 3 protocols may be granted for no more than a one year period 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.

Protocols involving only Biosafety level 1 agents and/or exempt recombinant or synthetic nucleic acids are not reviewed by the Panel. However, any work with human blood, clinical specimens, human tissues/tissue culture, or other potentially infectious materials must still meet the compliance requirements of the OSHA Bloodborne Pathogen Standard.

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

Toxins and Select Agents

Biohazardous agents that produce toxins fall under the purview of the Panel if the agents themselves meet Panel oversight requirements.

Purified toxins do not require Panel 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) of concern. This includes, but is not limited to, toxins or uses included in the Federal Select Agent Program and Select Agent Regulations 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73, the USA Patriot Act of 2001, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential.

Recombinant DNA

Recombinant DNA experiments involving certain Risk Group 1 agents, and all Risk Group 2 and higher agents, require Panel approval before initiation. In addition, Panel approval is required prior to the initiation 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. Biosafety Level 2 Protocols are approved for periods of 3 years; Biosafety Level 3 Protocols are approved for periods of 1 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 initiating work. Protocols are approved for 3-year periods.

Human Gene Transfer

Human Subjects protocols involving gene transfer or use of recombinant biohazardous agents must be reviewed and approved by the Panel prior to initiation. Protocols are approved for 1-year periods.

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

Dual Use Research of Concern

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. All Panel members must agree to abide by the Guidelines for APB Members on Conflicting Interest.

Decisions of the Panel

If an investigator has concerns with respect to procedures or decisions of the Panel, 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 nucleic acid 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 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 EH&S Biosafety and

Biosecurity Program and reports to EH&S Director of Research Safety, who 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.

RESOURCES AND REFERENCES

- Stanford University Research Policy Handbook, Biohazardous Agents and Recombinant DNA
    - https://doresearch.stanford.edu/policies/research-policy-handbook/environmental-health-and-safety/biohazardous-agents-and-recombinant-dna
- National Institutes of Health (NIH) Office of Science Policy (OSP)
    - https://osp.od.nih.gov/
    - NIH Guidelines on Recombinant and Synthetic Nucleic Acids (NIH Guidelines)
        - http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines
- Centers for Disease Control (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL), current edition
    - https://www.cdc.gov/labs/bmbl/?CDC_AAref_Val=https://www.cdc.gov/labs/BMBL.html
- U.S. Department of Health and Human Services (HHS)
    - https://www.hhs.gov/
- Occupational Safety & Health Administration (OSHA)
    - https://www.osha.gov/
    - Biosafety
        - https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/default.aspx
- California Division of Occupational Bloodborne Pathogens Standard (Cal/OSHA)
    - Bloodborne Pathogens Standard
        - https://www.dir.ca.gov/title8/5193.html

    - Aerosol Transmissible Disease Standard
        - https://www.dir.ca.gov/title8/5199.html
- DURC
    - https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab0/
    - https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf
- American Biological Safety Association (ABSA) Risk Group Database
    - https://my.absa.org/Riskgroups
- Stanford University Guidelines on Confidentiality of Administrative Panel Proceedings
    - https://doresearch.stanford.edu/policies/research-policy-handbook/committees-and-panels-support-research/confidentiality
- Federal Select Agent Program
    - https://www.selectagents.gov/index.htm
    - 7 CFR Part 331
        - https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1
    - 9 CFR Part 121
        - https://www.ecfr.gov/current/title-9/chapter-I/subchapter-E/part-121
    - 42 CFR Part 73
        - https://www.ecfr.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1
- USA Patriot Act of 2001
    - https://www.congress.gov/bill/107th-congress/house-bill/3162
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 https://www.congress.gov/bill/107th-congress/house-bill/3448