

Office/Contact: Division of Research and Economic Development

Source: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*)

Link: <https://osp.od.nih.gov/biotechnology/nih-guidelines/>

Associated Forms: IBC Registration Form: <https://sdsubc.questionpro.com/>

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## **SOUTH DAKOTA STATE UNIVERSITY Policy and Procedure Manual**

**SUBJECT:** Institutional Biosafety

**NUMBER:** 8:5

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### **1. Purpose**

The science of creating and using recombinant DNA (rDNA) has been evolving over several decades. However, the scientific community and the public continue to have concerns over human genetic engineering, genetically modified foods, and the release of genetically modified organisms into the ecosystem. The purpose of this policy is to outline the guidelines associated with research using rDNA and other biohazardous materials at the University.

### **2. Definitions**

- a. Recombinant DNA (rDNA): (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.
- b. NIH: National Institutes of Health
- c. OBA: Office of Biotechnology Activities

### **3. Policy**

- a. All University personnel conducting research in the following areas are required to complete the *IBC Registration Form* and submit it to the University's Institutional Biosafety Committee (IBC) for review either prior to or upon initiation of research, in accordance with the [\*NIH Guidelines\*](#).
  - i. Recombinant or synthetic nucleic acid molecules
  - ii. Genetically modified organisms
  - iii. Pathogens/infectious agents (human, animal, or plant)
  - iv. Select/Biological Agents and Toxins (CDC and USDA)
  - v. Any other activity that falls under the NIH Guidelines
- b. To assure the public that safety concerns are being addressed, and to ensure uniform application across all activities, all research conducted at the University, regardless of funding source and including any organizations using University facilities, shall fall under this policy.

- c. All research in the areas identified above (3.a) conducted at or sponsored by the University when the University receives funding from the NIH for conducting such research should be done in compliance with the *NIH Guidelines*. When the University is not receiving NIH funds for such work, the institution will maintain voluntary compliance as outlined in Section IV-D-1 of the *NIH Guidelines*.
- d. The *NIH Guidelines* call for the establishment of an IBC to oversee research activity using rDNA and other biohazardous materials. The University's IBC will follow the rules and regulations as set forth in the *NIH Guidelines*. Some of the responsibilities of the University's IBC include:
  - i. Reviewing rDNA research and research using hazardous biological materials conducted at or sponsored by the University to ensure compliance with the *NIH Guidelines*;
  - ii. Notifying the Dual Use Research of Concern (DURC) Institutional Review Entity (IRE) of any IBC Registration in which the research involves one or more of the DURC Agents identified in University Policy 8:11, or other research protocol the IBC believes the IRE should review;
  - iii. Notifying the Principal Investigator of the results of the IBC's review and approval;
  - iv. Setting containment levels;
  - v. Adopting emergency plans covering accidental spills and personnel contamination resulting from rDNA research;
  - vi. Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate IO and NIH/OBA within thirty (30) days, unless the IBC determines that a report has already been filed by the Principal Investigator; and
  - vii. Performing such other functions as may be delegated to the IBC.
- e. The University's Research Integrity and Compliance Officer (RICO) serves as the Institutional Official (IO) of the IBC. The IO shall help identify and, upon consultation with others, appoint individuals to the IBC. The IO is responsible for seeing that the University is in full institutional compliance with the NIH, filing annual updates and other reports. The IO shall maintain registration with the NIH and review, recommend and report any disciplinary actions taken as a result of non-compliance. The RICO provides overall administration, coordinates IBC activities with other compliance activities and committees, monitors federal and state regulations, and drafts revised policies and procedures to remain in compliance with regulations.
- f. The Principal Investigator (PI) is the “first line of defense” in all research. The PI is responsible for ensuring the conduct of covered research is compliant with the *NIH Guidelines*. At the University, PI status is limited to individuals serving as post-doctoral associates or higher. PIs shall be adequately trained in good microbiological techniques. Specific responsibilities include the following:
  - i. To ensure research that requires IBC approval prior to initiation is not conducted until having been approved by the IBC and having met all other requirements of

the *NIH Guidelines*;

- ii. To determine whether experiments are covered under Section III-E of *the NIH Guidelines* and to ensure the appropriate procedures are followed;
  - iii. To report any new information bearing on the *NIH Guidelines* to the IBC;
  - iv. To adhere to the University's IBC approved emergency plans for handling accidental spills and personnel contamination;
  - v. To comply with shipping requirements for rDNA molecules (as outlined in Appendix H of the *NIH Guidelines*);
  - vi. To ensure that all participating personnel have completed the appropriate biosafety training;
  - vii. To follow approved research protocols and receive IBC approval for any changes prior to implementing the changes;
  - viii. To immediately file a report of any unanticipated problems or serious adverse events;
  - ix. To report annually on the progress of the research; and
  - x. To file all necessary project extensions.
- g. In keeping with the *NIH Guidelines*, the University's IBC shall consist of no fewer than five (5) individuals, including a Biological Safety Officer, Animal Expert, Plant Expert, and two (2) individuals not affiliated with the University, except for their service on the University's IBC, who represent the interest of the surrounding community with respect to health and protection of the environment. Other members of the University's IBC are *Ex Officio* and shall include the Chair and the RICO.
- i. The Biological Safety Officer conducts periodic inspections to ensure that laboratory standards are rigorously followed; develops emergency plans for handling accidental spills and personnel contamination; investigates laboratory accidents involving rDNA research; provides advice on laboratory security; and provides technical advice to the PI and IBC on research safety procedures.
  - ii. The Vice President for Research, or designee, serves as the IBC Chair. The Chair shall convene and preside over meetings, perform initial review and approve protocols as exempt, and make initial determinations of protocols to concur that it is proper to initiate experiments upon registration, as outlined in Section III-E of the *NIH Guidelines*. The Chair is responsible for ensuring that all members of the IBC are appropriately trained.
  - iii. The Division of Research and Economic Development shall provide for administrative assistance to the IBC for purposes of scheduling meetings, taking minutes, and assisting in maintaining records for the IBC. These records shall include a current roster and curriculum vitae of all IBC members, files of all projects, and records of all correspondence between the PI and IBC Chair or members. Files shall be destroyed three (3) years after the close or completion of the project.

- h. The University's IBC members shall be appointed to three (3) year terms. Terms will be staggered in order to maintain continuity, and members may be reappointed to additional terms as needed if they are willing to continue service.
- i. The University's IBC shall meet as necessary to conduct business. A quorum, which shall consist of a simple majority (greater than 50% of the IBC) will be required to conduct business. *Ex officio* members cannot be counted toward a quorum. Meetings will be announced in advance and announced to the public so that members of the general public may attend if they desire. The minutes of the meeting shall follow *NIH Guidelines* and shall be made available to the public. The level of discussion included in the minutes shall include sufficient detail for members of the general public to ascertain the nature of the discussion and the conclusions reached.
- j. At a minimum, IBC review (per *NIH Guidelines*), will consist of:
  - i. Independent assessment of the containment levels required by the *NIH Guidelines*;
  - ii. Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in the research;
  - iii. Ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*; and
  - iv. Any other factors affecting the safety of the PI, University faculty and staff, and the general public. Any other review criteria required by the *NIH Guidelines*, although not enumerated, shall also apply to research at the University.
- k. Levels of review and approval will be exempt, approved, approved with minor modifications, resubmit, or disapproved. The *NIH Guidelines* have several other levels of review, such as those requiring NIH approval. Although these other levels of review are not presented in this policy, and research requiring those levels of review is generally not performed at the University, all are applicable to research at the University.
- l. A protocol under review by the IBC shall be deemed approved if accepted by a majority of those voting members present at the IBC meeting. The IBC may condition approval subject to modifications to the protocol. These modifications may be provided electronically or in writing, and the IBC Chair shall determine if the modifications follow IBC requirements. In addition, the IBC may ask that a protocol be resubmitted, requiring substantial changes before approval. When appropriate, the IBC may disapprove a protocol. The IO may review IBC decisions, impose additional modifications or disapprove research activity approved by the IBC. The IO, or any other official, cannot approve research that the IBC has disapproved.
- m. Research projects will be approved for three (3) years, subject to annual review. PIs shall be required to submit an annual report on the status of the project (not yet started, ongoing, temporarily stopped, or completed). The IBC may determine that more frequent review is appropriate or may perform random audits of any project or facility.
- n. Although not a requirement, it is recommended that exempt research be brought to the University's IBC to verify that it is exempt under *NIH Guidelines*. The IBC Chair may make the determination that the protocol is exempt or should be reviewed under other containment levels and may call on other IBC members or consultants to provide

additional review when needed.

- o. In accordance with the *NIH Guidelines*, no member of the University's 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 (Section IV-B-2-a-(4)).
  - p. The IBC, through the Chair, may seek the advice of experts in other disciplines to review protocols on an ad hoc basis as necessary. These individuals shall not have voting privileges.
  - q. The University may serve as a point of review of rDNA research for other organizations within the State of South Dakota. These unaffiliated organizations will first sign a memorandum of understanding agreeing to abide by the decisions of the University's IBC. A fee may apply. After review, the University may accept decisions from other institutions' IBCs operating in accordance with the *NIH Guidelines*.
  - r. When a researcher is found to be in noncompliance with *NIH Guidelines* and any other federal, state or University regulations, the IBC may recommend disciplinary action to be taken. Such actions may include, but are not limited to, the suspension of research activities until all appropriate administrative activities have been corrected or completed; re-inspection to substantiate the facility/laboratory is subsequently in compliance; and the referral of the noncompliance issues to the Department Chair, Dean, IO, and the appropriate federal oversight agency, when appropriate. The University President, upon consultation with other officials as necessary, shall have final authority as to disciplinary action.
4. Responsible Administrator

The Vice President for Research and Economic Development, successor, or designee is responsible for the annual and ad hoc review of this policy. The University President is responsible for approval of modifications to this policy.

SOURCE: Approved by President on 09/16/2014. Revised; Approved by President on 02/15/2021.