University Policy 50

Research Involving Recombinant or Synthetic DNA Molecules

Initially approved: August 15, 1994

Revised: March 9, 2020

Policy Topic: Research and Sponsored Activities

Administering Office: Office of Research Administration

**I. POLICY STATEMENT**

WCU faculty, staff, or students involved in Recombinant or Synthetic DNA (r/s DNA) molecules research are required to follow established guidelines issued by the National Institute of Health (NIH). The Guidelines for Research Involving Recombinant or Synthetic DNA Molecules (NIH Guidelines) are published in the Federal Register and are available at the NIH Office for Science Policy website ([osp.od.nih.gov](file:///C%3A%5CUsers%5Cjcarson.WCU%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CINetCache%5CContent.Outlook%5CTW0S75AI%5Cosp.od.nih.gov)).

**II. DEFINITIONS**

**Biosafety Levels (BLs)**: BLs are categories for biocontainment precautions, based on levels of hazard, not to be confused with Risk Groups.

1. BL1 work involving minimal or no known hazard to laboratory personnel and the environment.
2. BL2 work involving agents of moderate potential hazard to personnel and the environment, requiring a type II biosafety cabinet for containment.
3. BL3 work involving indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation.
4. BL4 work involving viruses that cause severe to fatal disease in humans, that are easily transmissible by aerosols or contact entry, and for which vaccines or other treatments are not available

**Recombinant and Synthetic Nucleic Acid Molecules**:

1. Molecules that a) are constructed by joining nucleic molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2. 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
3. Molecules that result from the replication of those described in (i) or (ii) above.

**Risk Groups (RGs):** NIH categorizes experiments which involve r/s DNA into four RGs on the basis of hazard, according to their relative pathogenicity for healthy adult humans.

1. RG1 agents are not associated with disease in healthy adult humans
2. RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
3. RG3 agents are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available
4. RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

**III. ROLES AND RESPONSIBILITIES**

1. Institutional Biosafety Committee (IBC): The IBC is responsible for reviewing and recommending policies and procedures with the goal of ensuring safe use of r/s DNA in research and compliance with guidelines established by the NIH and Centers for Disease Control (CDC). The IBC is responsible for the review, approval, and oversight of activities with r/s DNA conducted at or sponsored by the University, regardless of source of funding.

The IBC shall consist of faculty, staff and community members with experience and expertise in r/s DNA technology and biosafety and physical containment. The composition of the membership of the IBC shall meet all membership requirements in the NIH guidelines. A chairperson will be appointed by the Chief Research Officer of the Office of Research Administration. Committee members are appointed for a term of three years and may be reappointed to additional three year terms without limitation. The WCU Laboratory Safety Officer and Research Compliance Officer are permanent members of the IBC.

1. Office of Research Administration (ORA) and the Research Compliance Officer (RCO): The ORA and RCO provide administrative support to the IBC, maintain appropriate records, and receive all Request for Review Forms for research involving r/s DNA.
2. Office of Safety and Risk Management and Safety Officer: The Office of Safety and Risk Management registers all pathogens and labs, and maintains a biological inventory of all pathogens on campus. All biohazardous agents used in research and teaching laboratories on campus must be registered with this office. The role of the Safety Officer is to assure the use of biohazardous agents conform to university policy and applicable government regulation, to conduct periodic inspection of biological laboratories, and provide biosafety training. The Safety Officer provides an annual report to the IBC of agents on campus.
3. Principal Investigator (PI): The PI is responsible for full compliance with NIH Guidelines in the conduct of r/s DNA research and must register all pathogens and labs with the Safety Office. The PI shall conduct the initial risk assessment required by NIH Guidelines § 11-A-3. The PI shall complete and submit a Request to Review research protocol Form, and shall ensure that r/s DNA research activities subject to the NIH Guidelines are initiated or modified only after that research or proposed modification has been reviewed and approved by the IBC. The PI is responsible for training laboratory staff and students in the practices and techniques required to maintain safety and in the procedures for handling accidents.

**IV. PROTOCOL REVIEW AND APPEAL**

1. Review of New Protocol

The PI must conduct the initial risk assessment based on the RG of an agent, and shall submit a protocol application to the Research Compliance Officer (RCO) in the Office of Research Administration. Research requiring biosafety level 3 or 4 containment is prohibited at WCU as there are no suitable facilities. The RCO will convene the IBC to conduct review of new applications and protocol modifications at least biannually, at which quorum is required. No member of the IBC may participate in the review of an application in which the committee member has a conflicting interest, except to provide information if requested. Specialists may be invited to meetings to assist in review of issues beyond or in addition to the expertise available to the IBC.

IBC review of new protocol applications will include:

1. independent assessment of the containment levels required by the NIH Guidelines for the proposed research;
2. assessment of the facilities, procedures, practices, and training and expertise of personnel involved in r/s DNA research;
3. implementing appropriate measures with the goal of ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines; and
4. implementing appropriate measures with the goal of ensuring that the research does not involve human subjects in gene transfer trials as the IBC will not approve this research at this time.

The NIH Guidelines require that the IBC perform continuing review of all ongoing activities with r/s DNA approved by the IBC. It is the PI’s responsibility to initiate the request for continuation, which must include a summary of the protocol and a status report on the progress to date. The continuing review of activities with recombinant DNA will be conducted in the same manner as the initial review of the protocol.

1. Appeal of IBC Determination

The IBC does not have to approve any protocol. The PI will be notified in the event a protocol is not approved by the IBC. Upon notification, the PI may modify and resubmit the protocol. All notifications will be handled by the Office of Research Administration.

The IBC may terminate or suspend research determined not compliant with NIH guidelines and WCU IBC requirements. The PI may appeal an IBC determination of suspension, disapproval, or termination by sending a letter to the Chief Research Officer (CRO) in the Office of Research Administration. The CRO shall request to convene the IBC for a hearing. The hearing will allow relevant discussion, documentation, and witnesses on behalf of the investigator. The IBC will vote to sustain or change its original recommendation.

Should the IBC determine that either unethical behavior or research misconduct occurred, the Chairperson will initiate action as outlined in WCU Policy 56, Ethics in Research.

**V. POLICY REVIEW**

This policy shall be reviewed and revised as necessary every two (2) years.

**VI. RELATED POLICIES AND RESOURCES**

[Request for Review Form](https://www.wcu.edu/WebFiles/IBC_Application_FINAL_2019.docx)

[Request for Modification or Continuing Review](https://www.wcu.edu/WebFiles/IBC_Annual_Renewal_Modification_FINAL.docx)

[NIH Citation Table](https://www.wcu.edu/WebFiles/IBC_NIH_Section_Citations_TABLE.pdf)

[Training Checklist](https://www.wcu.edu/WebFiles/IBC_Training_Documentation_Checklist_FINAL.docx)