



Policy on Research Involving Recombinant or Synthetic Nucleic Acid Molecules (DNA/RNA)

Overview

Whitworth University is responsible for ensuring that all research involving recombinant or synthetic nucleic acid molecules conducted at or sponsored by Whitworth University is conducted in compliance with National Institutes of Health (NIH) [Guidelines](#). According to the NIH, the purpose of the Guidelines is to “detail safety practices and containment procedures for basic and clinical research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic nucleic acid molecules.” Whitworth’s responsibilities include but are not limited to establishing and maintaining a compliant Institutional Biosafety Committee (IBC), including annual registration of committee members, ensuring adequate expertise and training, and establishing procedures that the IBC follows with regard to review and approval of applications and compliance with federal regulations.

Definitions

Recombinant and Synthetic Nucleic Acids:

In the context of this policy and the *NIH Guidelines*, recombinant and synthetic nucleic acid molecules 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.

Policy and Responsibilities

No employee or student may conduct research involving recombinant or synthetic nucleic acid molecules, infectious agents, and/or transfer vectors at Whitworth University without first demonstrating compliance with applicable requirements and obtaining approval from the IBC. This also applies to research involving recombinant or synthetic nucleic acid molecules that is sponsored by Whitworth, but may take place off-campus. Participation in research at other

institutions by Whitworth faculty or research staff is expected to be approved by that institution's IBC.

The Principal Investigator (PI) is responsible to submit the initial research protocol and any subsequent changes to the IBC. The Principal Investigator is responsible to ensure that the research does not deviate from the approved protocol and to ensure that everyone working on the project has been thoroughly trained on applicable biosafety practices and procedures. The PI is responsible to report all exposures, accidents and injuries to the IBC so they can be reported to NIH.

The Whitworth University Institutional Biosafety Committee (IBC) shall oversee research involving recombinant and synthetic nucleic acid molecules, as defined above and in the [NIH Guidelines](#) performed at Whitworth in order to protect the health and safety of employees, students and the public regarding such research. The IBC shall review all research proposals involving the use of recombinant or synthetic nucleic acid molecules, infectious agents, and/or associated transfer vectors to assure compliance with all NIH guidelines and general biosafety best practices. Note that the NIH Guidelines allow certain experiments to begin simultaneous with IBC proposal submission. Certain other experiments are exempt from NIH regulations and therefore IBC approval. Please consult the NIH Guidelines for more information. The IBC has established practices, procedures and protocols to insure compliance with all governmental and institutional regulations, including but not limited to the NIH Guidelines. The IBC requires that research protocols incorporate all NIH stipulations and requirements and that research designs contain reasonable safeguards necessary to protect research personnel, the public and the environment. The IBC shall annually review all active research projects. All decisions of the IBC concerning research, recommended practices, procedures and protocols shall be reported to the Dean of the CAS and/or Provost for implementation.

Institutional Biosafety Committee Composition

The President of the University shall appoint all members of the IBC. The IBC is required to have at least five members, two of which must be external to Whitworth and represent the interests of the surrounding community. According to NIH Guidelines, external committee members are to have no other connection to the University except as members of the IBC. A quorum shall be no less than five members. Appointments shall be for a term of three years, with the option to be reappointed for subsequent terms. The IBC meets at least twice per year.

Whitworth Prohibited Research

There are certain types of research that are currently prohibited at Whitworth University. These types of research are prohibited for a variety of reasons including extreme risk, insufficient facilities or equipment and the necessity of additional regulatory oversight. Should there be a desire to conduct research of this nature in the future the necessary oversight mechanisms would need to be developed and proper equipment installed.

Prohibited research:

- i) Recombinant or synthetic DNA research that the NIH defines as a “Major Action”. This type of research involves the deliberate transfer of a drug resistance trait to a microorganism when such resistance could compromise the ability to control the disease agent in humans, veterinary medicine, or agriculture. This includes any research involving “Schedule A” organisms which are “Dual Use Research of Concern”. These organisms can be used for legitimate and benevolent research, but can also be used to cause deliberate harm. Major action research would have to be approved by the Director of the NIH and the RAC (Recombinant DNA Advisory Committee of the Department of Health and Human Services). Click [here](#) for more information.
- ii) Experiments that involve the cloning of toxin molecules that are lethal to vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. For example, botulinum toxins, tetanus toxin, diphtheria toxin and *Shigella dysenteriae*. Such experiments would require approval from the NIH Office of Science Policy.
- iii) Research involving “Select Agents” or DNA from Select Agents. Click [here](#) for more information. This list is dynamic in nature, but in general, are things that have the potential to cause significant harm.
- iv) Research involving the transfer of nucleic acid molecules into humans. This type of research would require outside approval from the RAC as well as inside approval from the University’s IBC and IRB. This prohibition applies to any research with human subjects in which a Whitworth investigator is a collaborator, including work conducted outside of Whitworth University.

Workflow

1. The Principal Investigator determines the applicability of IBC review, completes and submits an application for recombinant DNA research.
2. If genetic material will be acquired from an external, non-commercial source then a Material Transfer Agreement must be completed and submitted to the IBC.
3. The IBC will review the application and determine whether the research is approved, approved upon condition of certain revisions, or denied. The IBC will forward all decisions to the Dean or their designee.
4. Once approved, the PI is required to provide training to all laboratory personnel that will work on the project and provide documentation of such training to the IBC.
5. Annually, the IBC will send a renewal form to the PIs in charge of all active projects. The PI is to complete this form and return it to the IBC in a timely fashion.

Suspension Protocol

1. The IBC receives notification of concern about an ongoing, approved research project.
2. The IBC will investigate and determine if there is any violation of NIH Guidelines or other federal regulations.

3. If a violation is found the IBC may vote to suspend the approval of a project. Such a vote must be at a meeting where a quorum is present.
4. If an approval is suspended, the IBC Chairperson notifies the Dean of the College of Arts and Science (CAS)/Provost or their designee in writing, including a description of the suspension rationale.
5. The Dean/Provost or their designee will notify the PI, the appropriate Program Director or Department Chair and the IACUC Chairperson (if live vertebrate animals are involved), as well as the Provost's office in writing.
6. In consultation with the IBC, the Dean/Provost or designee shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to the NIH Office for Biotechnology Activities (within 30 days) in accordance with NIH policy of reporting serious adverse events <http://www.osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/incident-reporting>
7. In cases where the IBC cannot be assembled in a timely fashion, the Dean/Provost or their designee, in consultation with the IBC Chairperson, is empowered to act on the IBC's behalf. They may immediately suspend any activity that is not, in the Dean's (or Provost's) judgment, being conducted in accordance with applicable governmental and institutional regulations and policies including, without limitation, provisions of the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines").
8. A suspended activity may be reinstated only after approval by a majority of the quorum present at a meeting of the IBC.

IBC Coordination with Other Committees

The IBC shall function independently of, but in coordination with other institutional committees. The IBC may approve, approve with conditions/modifications, or disapprove all research activities that fall within its jurisdiction as specified by both governmental and institutional policies. Approval by the IBC in and of itself shall not constitute approval for full implementation if a protocol is subject to review by other Whitworth research review bodies. In turn, no institutional officials or committees may fully approve the conduct of research that requires IBC approval. Similarly, the IBC will not approve protocols that have been disapproved by other committees and other committees agree not to approve protocols that have been disapproved by the IBC.

Any research involving live vertebrate animals and recombinant or synthetic nucleic acid molecules shall be reviewed and approved by both the IBC and the Institutional Animal Care and Use Committee (IACUC). This includes any research using animals in which a Whitworth investigator is a collaborator, including work conducted outside of Whitworth University.

Institutional Biosafety Policy
Schedule A: Prohibited Organisms and Toxins

- Botulinum neurotoxin
- Avian influenza virus
- Bacillus anthracis
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus,
- Yersinia pestis