Allina Health

System-wide Policy: **Use of Biohazardous Materials**
Reference #: SYS-ADMIN-RA-003

Origination Date: December 2015
Next Review Date: August 2021
Effective Date: August 2018

Approval Date: August 2018
Approved By: Research Oversight Committee Chair

System-Wide Policy Ownership Group: Research Administration

System Policy Information Resource: Director, Research Compliance

Stakeholder Groups
Compliance Department
Research Directors/ Managing Scientist Roundtable

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital, West Health; Orthopedic Institute Surgery Center at COC; Allina Health Group; Allina Health Home Care Services; All other business units	Research Administration	All persons performing research at Allina Health

POLICY STATEMENT

Allina Health is committed to minimizing the risks to patients, research subjects, investigators, researchers, staff, the community and the environment while using recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins during research activities, or while storing such materials, at Allina Health.

Allina Health has adopted this policy to ensure compliance with relevant laws and regulations pertaining to the receipt, use, storage, transfer, or disposal of biohazardous materials, including without limitation the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("NIH Guidelines"). Since laboratory work involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins may include other chemical and radiological hazards, this policy should be used in conjunction with any other pertinent Allina Health policies, guidelines, and manuals.

(See definitions section for defined terms)

Section 1: General; IBC Review

All Allina Health Research shall adhere to the NIH Guidelines and all applicable laws, regulations, and Allina Health policies.

All Allina Health Research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins shall be reviewed by the Institutional Biosafety Committee ("IBC"), regardless of funding source. The IBC shall oversee the assessment of facilities, procedures, and practices of research personnel to assure compliance with the NIH Guidelines and other pertinent guidelines and regulations. The IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence with the appropriate regulations, guidelines, and Allina Health policies.

Investigators must abide by the decisions of the IBC.

The Institutional Official (or designee) may waive the requirements for IBC review for Allina Health Research involving biohazardous materials, agents and toxins so long as appropriate protections are in place to assure compliance with the NIH Guidelines and other pertinent guidelines and regulations.

Section 2: Scope

This policy applies to all research involving recombinant or synthetic nucleic acid molecules or biohazardous materials, agents and toxins that:

- are sponsored by Allina Health;
- conducted by Allina Health personnel;
- conducted at or using Allina Health property and/or facilities; or
- require the receipt, storage, use, or disposal of such materials at an Allina Health facility.

Section 3: Acceptable Biosafety Levels

Research involving recombinant or synthetic nucleic acid molecules and/or biohazardous materials, agents and/or toxins that exceed biosafety level 2 are not permitted to be conducted in an Allina Health facility.

It is the responsibility of the investigator to conduct an initial risk assessment to determine the appropriate level of perceived risk and biological and physical containment level prior to possessing or using biohazardous materials, consistent with the BMBL. The IBC will make the final decision as to the level of risk and appropriate biological and physical containment levels for biohazardous materials subject to IBC review and approval.

Section 4: Reportable Incidents and Violations

Incidents involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agent and toxins that may pose a safety risk must be immediately reported to the IRB, the IBC (if applicable research is overseen by the IBC), and Employee Occupational Health (EOH). Examples of reportable incidents include but are not limited to any overt exposure, such as a needle stick, splash, contamination due to equipment failure, and incidents involving improper disposal of recombinant or synthetic nucleic acid molecules. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals. Questions regarding reportable incidents should be directed to EOH at (612)-262-4490.

Failure by research personnel to follow federal and institutional regulations, guidelines, policies, and/or procedures may also require reporting to the appropriate institutional, local, state and/or federal agencies.

Section 5: Select Agents and Select Agent Toxins

Select Agents and Select Agent Toxins are biological agents and Select Agent toxins that are deemed to pose a threat to public, animal or plant health, or animal or plant products that have not been excluded or exempted from federal regulatory control. The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) have identified those Select Agents and Select Agent Toxins (“listed Select Agent or Toxin”) that are subject to registration and regulatory oversight.

No Select Agents or Select Agent Toxins are permitted to be used or stored at an Allina Health facility, unless approved in advance by the Vice President of Research Administration and the Institutional Official.

Section 6: Inspection

All Allina Health facilities in which biohazardous materials are received, used, stored, transferred, or disposed of are subject to internal and external inspection.

Section 7: Training

Training is required of Principal Investigators and research personnel performing research involving recombinant or synthetic nucleic acid molecules and biohazardous materials, agents and toxins, as determined by Allina Health and/or the IBC. It is the Principal Investigator's responsibility to ensure that all research personnel have completed the required training prior to submitting the protocol to the IBC for review.

DEFINITIONS:

Biohazardous materials, agents, and toxins: Infectious biological or synthetic agents, biologically derived materials and toxins that present a risk or potential risk to the health of humans, animals, or plants either directly through exposure or infection or indirectly through damage to the environment. Categories of potentially infectious biological materials including the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses, prions).
- All human and nonhuman primate blood, blood products, tissues, and certain bodily fluids (use of human blood and body fluid for clinical diagnostic and treatment purposes is excluded)
- Cultured cells and potentially infectious agents these cells may contain
- Infected animals and animal tissues.

BMBL: *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) is a publication of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) that contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is considered the standard for biosafety.

Institutional Official: the senior executive with oversight of the Allina Health research program.

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

Recombinant or Synthetic Nucleic Acids: (i) molecules that (a) are constructed by joining nucleic acid molecules and (b) that can replicate in 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 by 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.

PROCEDURES: Not applicable.
PROTOCOL: Not applicable.
FORMS: Not applicable.
ALGORITHM: Not applicable.
ADDENDUM: Not applicable.
FAQs: Not applicable.

REFERENCES:
CITI Program

Related Regulation and Laws: N/A

Alternate Search Terms:
Institutional Biosafety Committee, IBC, Biohazard, biohazardous materials, recombinant or synthetic nucleic acid molecules, r/sNA, toxins, research

Related Policies:

Name of Policy	Content ID	Business Unit where Originated
N/A		

Policies Replacing:

Name of Policy	Content ID	Business Unit where Originated
N/A		