

Official Memorandum of Action MOA-02/10

RESEARCH POLICIES COUNCIL

Name of Council/Committee

11 APRIL 2002

Date of Meeting

RECOMMENDATION: (Attach copies of relevant documents)

Immediate upon final approval  
Implementation Date

The Research Policies Council recommends approval of the attached Microbiological Safety and Security Policy. (The Microbiological Safety and Security Procedures are attached for informational purposes only.)

Jan Means 20 June 2002  
Jan Means, Council Chair Date

☒ Approve ☐ Hold for Faculty Senate Review ☐ Return to Council/Committee

Route to Council(s): (1) \_\_\_\_\_ (2) \_\_\_\_\_  
Comments: \_\_\_\_\_

Approved by the Faculty Senate, in assembly, at its regular meeting on 7 November 2002.

W. Louie 6 December 2002  
Faculty Senate President Date

☒ Approve ☐ Disapprove ☐ Other Action \_\_\_\_\_  
Comments: \_\_\_\_\_

Jack Friedman 1-13-03  
Vice President for Research Date

Donal M. Litynski 21 JUL 03  
Provost and Vice President for Academic Affairs Date

☒ Approve ☐ Disapprove ☐ Other Action \_\_\_\_\_  
Comments: \_\_\_\_\_

Judith L. Bailey 7/23/03  
President Date

☐ Approve ☐ Disapprove ☐ Other Action \_\_\_\_\_  
Comments: \_\_\_\_\_

\_\_\_\_\_  
Chair, Board of Trustees Date



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# WESTERN MICHIGAN UNIVERSITY

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## **Microbiological Safety and Security Policy**

Approved by the Research Policies Council  
of the Faculty Senate  
11 April 2002

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## I. Purpose

To ensure that all teaching, research, and clinical activities involving the use of potentially hazardous microbial agents and/or their products are conducted in a safe and secure environment at Western Michigan University (WMU).

|              |  |
|--------------|--|
| <b>NOTE:</b> | <ol style="list-style-type: none"><li>1. Recombinant DNA – Recombinant DNA biosafety is under the auspices of the Recombinant DNA Biosafety Committee (RDBC).</li><li>2. Animal care and use – Animal care and use is under the auspices of the Institutional Animal Care and Use Committee.</li><li>3. Occupational exposure to blood-borne pathogens – Blood-borne pathogens exposure control is under the auspices of the Division of Environmental Health and Safety.</li><li>4. Copies of this policy, procedures, and related materials are located in the Office of the Vice President For Research</li></ol> |
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## II. Requirements

### A. General

WMU recognizes biosafety and biosecurity as two distinct but integrated arms of an effective microbiological safety program.

1. This policy applies to all individuals involved in the use and/or storage of potentially hazardous microbial agents and/or their products.
2. The vice president for research shall be responsible for the implementation of this policy.
3. WMU has adopted the biosafety procedures and guidelines described in the Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) *Biosafety in Microbiological and Biomedical Laboratories 4<sup>th</sup> ed.* (BMBL) published by the U.S. Government Printing Office, May 1999, and all future amendments to ensure the safe use, storage, transport, and security of all microbial agents.
4. Procedures, both broad-based (University level) and lab-specific, shall be developed and enacted in order to effectuate and enforce this policy, and shall be amended as needed to best accomplish the purpose of this policy.
5. The Biosafety Coordinating Committee (BCC) may formulate and recommend to the vice president for research additional controls as

deemed necessary to ensure the safety of the staff, students, and the public at large.

6. This policy requires adherence to the procedures and guidelines established and/or approved for the safe use, storage and transport of and the security of microbial agents. This includes, but is not limited to, the 4<sup>th</sup> edition of the BMBL and all future amendments, WMU microbiological safety procedures, and lab-specific procedures.
7. This policy requires all individuals involved in the use and/or storage of potentially hazardous microbial agents and/or their products cooperate and assist in any investigation of alleged noncompliance with the rules, regulations, procedures, and policies that govern the use or security of microbial agents.

B. Biosafety

1. WMU expressly prohibits the use and/or storage of Class 4 Agents as listed in the National Institutes of Health's guidelines, unless a Biosafety Level 4 facility is constructed.
2. No work may be conducted with restricted animal pathogens as listed in Appendix D to the BMBL, which are strictly prohibited by law, or by the United States Department of Agriculture.

C. Biosecurity

1. The standards and guidelines set forth in Appendix F, "Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories," to the BMBL constitute the requirements and actions necessary to ensure the security of both the users and the agents.
2. The Department of Public Safety is to handle suspicious letters, packages, or other material. This is to be done by in such a manner that keeps the material out of all University research, clinical, and/or teaching facilities and isolated from the general public.

### III. Sanctions for Non-Compliance

In the event an individual fails to comply with the rules, regulations, procedures, and policies that govern the use or security of microbial agents, the University will take the recourse deemed appropriate, including but not limited to, meetings to resolve and prevent recurrence of issues, suspension or termination of research and/or teaching privileges, and/or actions under the policy for research misconduct.



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WESTERN MICHIGAN UNIVERSITY

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**Microbiological  
Safety and Security  
Procedures**

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## I. Purpose

To establish the roles and responsibilities to ensure compliance with Western Michigan University's microbiological safety and security policy. These procedures may also be collectively referred to as "University Procedures."

## II. Definitions and Abbreviations

### A. Definitions

|                            |   |
|----------------------------|---|
| Laboratory Director        | Any person in charge of a laboratory and/or supervising students, WMU employees, researchers, or visitors engaged in potentially hazardous microbiological activities.                        |
| Class 1 Agent              | A microorganism that requires a BSL-1 facility as recommended in the BMBL.  |
| Class 2 Agent              | A microorganism that requires a BSL-2 facility as recommended in the BMBL.  |
| Class 3 Agent              | A microorganism that requires a BSL-3 facility as recommended in the BMBL.  |
| Class 4 Agent              | A microorganism that requires a BSL-4 facility as recommended in the BMBL.  |
| Microbial Agent            | Any potentially pathogenic microorganism and/or its products.   |
| Principal Investigator     | Synonymous with laboratory director under the microbiological safety and security policy.   |
| Researcher                 | An employee, student, visiting scientist, or contractor engaged in work covered by the microbiological safety and security policy.  |
| Restricted Animal Pathogen | A microorganism or toxin listed in Appendix D to the BMBL.  |
| Select Agent               | A microorganism or toxin listed in Appendix A to 42 CFR 72.6.   |
| Student                    | A person working toward and/or receiving WMU academic credit who is engaged in work covered by the microbiological safety and security policy.  |
| Support Staff              | WMU employees or contract staff performing custodial, maintenance, or other support activities.   |
| Visiting Scientist         | Any person who requires access to a BSL-1, 2, 3, or 4 facility, who is engaged in work covered by the microbiological safety and security policy, and is not a WMU employee and/or a student. |
| Visitor                    | Any person who requires access to a BSL-1, 2, 3, or 4 facility and who is not engaged in work covered by the microbiological safety and security policy.                                      |



## B. Abbreviations

|       |  |
|-------|--|
| BCC   | Biosafety Coordinating Committee   |
| BMBL  | <i>Biosafety in Microbiological and Biomedical Laboratories 4<sup>th</sup> ed.</i> published by the U.S. Government Printing Office, May 1999 and subsequent amendments. |
| BSC   | Biosafety Cabinet  |
| BSL-# | Biosafety Level - # can be 1, 2, 3, or 4   |
| BSO   | Biosafety Officer  |
| CDC   | Centers for Disease Control and Prevention   |
| DPS   | Department of Public Safety  |
| NIH   | National Institutes of Health  |
| USDA  | United States Department of Agriculture  |
| WMU   | Western Michigan University  |

## III. Responsibilities

### A. Vice President For Research

The vice president for research is responsible for ensuring that all work utilizing microbial agents is conducted in full conformity with the WMU microbiological safety and security policy and for overseeing compliance with the WMU microbiological safety and security policy and procedures.

Duties and responsibilities shall include, but are not limited to, the following:

1. Ensure compliance with the rules, regulations, and procedures governing the use, storage, transportation, and security of microbial agents.
2. Take prompt and decisive action when dealing with individuals who fail to comply with the rules, regulations, and procedures governing the use, storage, transportation, or security of microbial agents.
3. Maintain an active Biosafety Coordinating Committee.
4. Request that all construction projects for facilities designed for the use of microbial agents include the necessary resources to ensure their safe use and security.
5. Require the laboratory directors to provide the necessary resources to safely and securely operate their facilities designed for the use of microbial agents.
6. Provide adequate resources for the dissemination of information on microbiological safety procedures and practices.

7. Provide resources necessary for vaccinations, the collection and safe storage of serum samples, and maintenance of required documentation.
8. Delegate the resources and the authority to conduct oversight of the day-to-day compliance with the rules, regulations, and procedures governing the use, storage, transportation, and security of microbial agents.

B. Biosafety Coordinating Committee

The Biosafety Coordinating Committee (BCC) advises the vice president for research on matters of biosafety and biosecurity. Additionally, the BCC provides guidance and assistance to all WMU employees, researchers, students, and visitors involved in the development and implementation of procedures and practices used to ensure compliance with the rules and regulations governing the use and security of microbial agents.

1. Duties and responsibilities shall include, but are not limited to, the following:
  - a. Provide oversight of microbiological safety program in conjunction with the biosafety officer and/or other staff designated by the vice president for research.
  - b. Review any significant biosafety trends, problems, violations of or allegations of violations of the BMBL or directives, and any investigative findings and recommendations relating to biosafety and/or biosecurity events.
  - c. Coordinate the integration of microbiological laboratory-specific emergency plans with WMU's critical incident plan.
  - d. Provide input into the development or enhancement of procedures and protocols presented by the laboratory directors, including laboratory-specific emergency plans.
  - e. Review the annual microbial agent inventory as presented by the biosafety officer.
  - f. Disseminate information associated with the use of microbial agents, such as changes in rules, regulations, procedures, or policies that govern their use, storage, transportation, or security.
  - g. Recommend to the vice president for research actions needed to bring operations into compliance with all federal, state, and local rules, regulations, procedures, or policies.
  - h. Perform such other functions as may be delegated to it by the vice

president for research, NIH, CDC and/or the USDA.

- i. Recommend to the vice president for research the temporary or permanent suspension of any activity conducted with microbial agents which is deemed to pose a significant danger to health, safety, or security.
2. Biosafety Coordinating Committee Chair:
    - a. Duties and responsibilities shall include, but are not limited to, the following:
      - i. Schedule the BCC meetings.
      - ii. Establish and distribute the agenda and minutes for all full committee meetings.
      - iii. Provide any subcommittee its charge and grant it the authority to conduct business.
3. Appointments to the Committee
    - a. Members of the Biosafety Coordinating Committee shall be appointed by the vice president for research for staggered, renewable, three-year terms. Staggered term appointments provide continuity of the committee's work. Each appointment will correspond with the fiscal year (July 1 through June 30).
    - b. The vice president for research shall appoint the chair from the BCC membership. The chair's appointment shall be for a three-year period. The chair must have a minimum of two years' experience in microbiological procedures and techniques.
    - c. The composition of the committee shall include:
      - i. Biosafety Coordinating Committee chair
      - ii. Associate vice president for research (ex officio)
      - iii. Biosafety officer (ex officio)
      - iv. Research compliance coordinator, Office of the Vice President for Research
      - v. Appointed members should represent each of the following units:
        - Department of Biological Sciences
        - Department of Chemistry
        - Department of Public Safety

- Sindecuse Health Center
- vi. A member from the community who is not affiliated with WMU.
- d. BCC meetings
  - i. The BCC shall meet regularly at least once every six months.
  - ii. Whenever an incident occurs or a new threat is identified, the BCC shall meet for an immediate review of safety policies, procedures, and practices in order to identify and implement necessary changes to the policies, procedures, or practices.
  - iii. Members are required to attend the meetings and may not delegate attendance to another individual.
  - iv. Full committee meeting minutes should be forwarded to the appropriate administrators of units using or storing microbial agents covered by this policy.
- e. Recourse for failure to carry out BCC member duties and responsibilities
  - i. The vice president for research may remove a member of the committee who does not fulfill his/her obligations.

C. Biosafety Officer

The biosafety officer (BSO) is responsible for the development and maintenance of the WMU microbiological safety program. The vice president for research designates the BSO. The BSO shall have unrestricted access to all buildings and areas where microbial agents covered by this policy are used and/or stored.

Duties and responsibilities shall include, but are not limited to, the following:

1. Assist in the day-to-day compliance with the rules, regulations, and procedures governing the use, storage, transportation, and security of microbial agents.
2. Serve as a liaison between WMU and regulatory agencies on matters pertaining to microbiological safety or security.
3. Direct the microbiological safety program.
4. Advise the Biosafety Coordinating Committee, laboratory directors, supervisors, and workers as necessary on biosafety issues and compliance questions.

5. Conduct or participate in investigations of any significant accidents and illnesses related to the use of microbial agents.
6. Report to the Biosafety Coordinating Committee any biosafety problems, trends, violations of the BMBL or directives, and any investigative findings and recommendations relating to such events.
7. Provide the BCC with a microbial agent inventory annually or more frequently as requested by the BCC.
8. Develop and implement an orientation program for new laboratory directors.
9. Perform routine administrative duties and record keeping for the Biosafety Coordinating Committee.
10. Perform other duties that may be delegated by the Biosafety Coordinating Committee and/or his/her supervisor.

#### D. Laboratory Directors

Laboratory directors are essential persons in the biosafety and biosecurity effort. They are responsible for complying with all rules, regulations, procedures, and policies that govern the use and security of microbial agents. They also carry supervisory roles for students and workers assigned to them and are responsible for their compliance.

Duties and responsibilities shall include, but are not limited to, the following:

1. Participate in the orientation program for new laboratory directors.
2. Develop and implement written laboratory-specific biosafety and biosecurity procedures that are consistent with the nature of current and planned research activities and make available copies of the specific biosafety and biosecurity procedures in his/her laboratory.
3. Develop, with the assistance of the BCC, laboratory-specific emergency plans.
4. Ensure that all WMU employees, researchers, students, and visitors understand and comply with the laboratory-specific biosafety, biosecurity, and emergency procedures.
5. Ensure that all support staff and visitors who may be exposed to any potential biohazard are informed in advance of their risk and of the precautions required to minimize that risk.
6. Issue all visitors a visitor's badge and inform them of their responsibilities encompassed by biosecurity.

7. Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after such equipment is thoroughly decontaminated.
8. Ensure that research materials are properly decontaminated before disposal and that all WMU employees, researchers, students, and visitors involved with biosafety projects are familiar with waste disposal methods.
9. Notify the biosafety officer and BCC chair immediately if a laboratory-acquired infection is known or suspected.
10. Report to the biosafety officer and/or the BCC any microbiological related accidents. **NOTE:** This is in addition to any reports required by WMU, state, or federal agencies.
11. Report to the biosafety officer and/or the BCC perceived violations of the microbiological safety or security policies, procedures, or practices.
12. Ensure that all researchers, students, and visiting scientists working in their laboratory are appropriately trained in microbiological techniques.
13. Require appropriate vaccinations, the submittal of initial serum samples, or a signed waiver from the individual for the biohazards to which he/she will be exposed.
14. Place purchase orders and transfer requests through the BSO for:
  - a. Class III or Class IV agents,
  - b. Class II agents requiring CDC transfer permits, and
  - c. Select agents
15. Inform the BSO of the receipt of any microbial agents covered by this policy.
16. Maintain a current inventory of all microbial agents and supply a copy to the BSO upon request.
17. Create and foster an environment in the laboratory that encourages open discussion of biosafety and biosecurity issues, problems, and violations of procedure.
18. Assist the BSO with shipping requirements for microbial agents.

E. Laboratory Researchers, Students, and Visiting Scientists

Laboratory researchers, students, and visiting scientists are the individuals who directly handle microbial agents. The primary responsibility for safety and security compliance lies with them. It is critical that they be aware of the risks, safe practices, and requirements for use and security of microbial agents.

Duties and responsibilities shall include, but are not limited to, the following:

1. Notify their supervisor and/or the BSO of any violations or deviations from the rules, regulations, procedures, or practices, and of any unusual events involving the use or security of microbial agents.
2. Conscientiously adhere to the laboratory-specific biosafety practices and procedures.
3. Inform the supervisor of any reasons that may preclude or alter the individual's ability to work with or be in proximity to microbial agents.
4. Wear appropriate personal protective equipment according to the type of microbial agents being used.
5. Display a visible WMU identification badge (Bronco Card).

F. Department of Public Safety

The Department of Public Safety (DPS), specifically the Environmental Health and Safety, Police, and Security Administration Divisions, has many responsibilities to ensure the safety and security of all individuals on and around the WMU campus. The responsibilities listed below are not intended to diminish or circumvent any of their established duties and/or responsibilities. When called upon to respond to an emergency or security issue involving microbial agents, the DPS personnel should seek the advice and counsel of the BSO.

Responsibilities shall include, but are not limited to, the following:

1. Establish and maintain policies and procedures for handling letters, packages, or any other material suspected to contain bioterrorism agents.
2. Preserve and maintain any evidence required for criminal prosecution, if necessary.
3. Provide a 24-hour a day emergency contact.
4. Notify the BSO of any actual or potential biosafety/biosecurity issues brought to their attention.

5. Assist as necessary in the development, implementation, and maintenance of a microbiological emergency plan.
6. Assist the BSO and laboratory directors in:
  - a. any emergency involving biohazard containment and clean up.
  - b. meeting the security requirements of the BMBL.
  - c. the shipment of biohazardous waste and material.

G. Sindecuse Health Center

Duties and responsibilities shall include, but are not limited to, working in conjunction with the vice president for research, BCC, BSO, and laboratory directors to obtain and store serum samples, administer applicable vaccinations, and retain the records of serum samples and/or vaccinations.