Introduction

The purpose of this document is to increase awareness of biological hazards frequently encountered in research, clinical, and teaching laboratories at Youngstown State University. Additionally, this manual provides guidance on recommended practices when working with and disposing of biological hazards. Biological hazards include infectious or toxic microorganisms (including viral vectors), biological toxins, and substances from which transmission of infectious agents or toxins could be reasonably anticipated such as tissues from humans and research animals. Due to the diverse nature of biological hazards, they are often generically referred to as "agents". The intrinsic danger associated with a particular biological hazard may be mitigated or compounded by the presence of recombinant or synthetic nucleic acids (rsNA).

The safety principles described herein are based on sound safety practices, common sense, current data, good housekeeping, thorough personal hygiene, and a plan for responding to unanticipated events. Many of the practices and procedures described have been adapted from the CDC Biosafety in Microbiological and Biomedical Laboratories manual as well as the NIH guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules.

General Principles

Globally, numerous government agencies have classified microorganisms that are pathogenic to humans into Risk Groups (RG) based on the transmissibility, invasiveness, virulence or capability of causing disease, lethality, and the availability of vaccines or therapeutic interventions. Risk groupings of infectious agents usually correspond to Biosafety Levels (BSL or BL), which describe the recommended containment practices, safety equipment, and facility design features necessary to safely handle both benign and pathogenic microorganisms. The list of pathogenic microorganisms includes bacteria, viruses, fungi, parasites, and other infectious entities. The classification scheme ascends in order of increasing hazard from Risk Group 1 (RG1) agents, which are non-pathogenic for healthy adults to RG4 agents, which display a high morbidity and mortality and for which treatments are not generally readily available.

Risk Groups

In the United States, Risk Groups are only assigned to pathogens that pose a risk to humans. That is, only human and animal pathogens capable of infecting humans are assigned a risk group. The Risk Group listing found in the NIH Guidelines is an accepted standard even when recombinant or synthetic nucleic acids (rsNA) technology is not being used.

	Definition	Examples
Risk Group 1	Agents not associated with disease in healthy adult humans	*E. coli K-12, Saccharomyces cerevisiae*
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventative or therapeutic interventions are often available	*E. coli O157:H7, Salmonella, Cryptosporidium*, Hepatitis A, B, C, D, and E viruses
Risk Group 3	Agents associated with serious or lethal human disease for which preventative or therapeutic interventions may be available	*Yersinia pestis, Brucella abortus, Mycobacterium tuberculosis*, Human Immunodeficiency Virus (HIV), Transmissible spongiform encephalopathies (TSE) agents
Risk Group 4	Agents associated with serious or lethal human disease for which preventative or therapeutic interventions are not usually available	Ebola virus, Macacine herpesvirus (Monkey B virus)

The American Biological Safety Association (ABSA) also provides a comprehensive Risk Group database. This database also provides references to other global agencies and their Risk Group classification.

Another reliable source of information regarding human pathogens is available from the Health Canada website. This site provides detailed Pathogen Safety Data Sheets for a large number of human pathogens. These documents describe the hazardous properties of a specific pathogen and recommendations for work involving the agent in a laboratory setting. These documents are also designed to aid in the risk assessment for working with the described agents. Microorganisms that are RG1 require standard laboratory facilities and microbiological practices whereas those in RG4 require elaborate procedures, engineering controls, and facilities for maximum containment. Many of the agents likely to be handled experimentally at YSU are RG2 pathogens, designated as moderate hazard. These agents typically require more sophisticated engineering controls (such as facilities and equipment) than standard laboratories. Special handling and decontamination procedures are often required as well.

Microorganisms classified as RG 2 or higher have been reported to cause infection and disease in otherwise healthy adults. Many have been associated with laboratory-acquired infections. Furthermore, lab-acquired infections with RG2 agents are significantly more common that lab-acquired infections with RG3 or RG4 agents. The progression from invasion to infection to disease following contact with an agent depends upon the route of transmission, inoculum, invasive characteristics of the agent, and resistance of the person exposed. Not all contacts

result in infection and even fewer develop into clinical disease. Even when disease occurs, severity can vary considerably. It is prudent to assume virulence and handle such agents at the prescribed biosafety level.

Routes of Infection

Pathogens may be transmitted via one or more routes of infection. The route(s) depends on the characteristics of the particular pathogen. The most common routes of infection are inhalation of infectious aerosol, dusts, or small droplets, exposure of mucous membranes to infectious droplets, ingestion from contaminated hands or utensils, or percutaneous inoculation (injection, incision, or animal bite). The Pathogen Safety Data Sheets are a valuable resource for identifying the most common route(s) of infection for a particular pathogen.

Exposure Sources

Specimens

Any Specimen from human patients or animals may contain infectious agents. Specimens most likely to harbor such microorganisms include blood, sputum, urine, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, feces, and tissues. Personnel in laboratories handling human blood, body fluids, and non-human primate material, or even human cell lines that have been screened for pathogens should practice Universal Precautions. Universal Precautions is an approach to infection control wherein all human blood and certain human body fluids are treated as if known to be infectious and contain blood-borne pathogens such as HIV, Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV). Such personnel are required by law (OSHA 29 CFR 1910.1030) to undergo blood-borne pathogen training.

At YSU, this training requirement can be satisfied online by contacting the EOHS Department. A PI must notify EOHS if laboratory personnel shall be exposed to bloodborne pathogens or human source materials. Upon notification, the Bloodborne Pathogens training will be assigned to the appropriate individual(s).

Cultures

Accidental spilling of liquid infectious cultures is an obvious hazard due to the generation of aerosols and/or small droplets. However, even routine manipulations of cultures may release microorganisms via aerosol and/or small droplet formation. Such manipulations include, but are not limited to:

- Popping stoppers from culture vessels
- Opening closed vessels after vigorous shaking/vortexing
- Spattering from flame-sterilized utensils
- Expelling the final drop from a pipette

Manipulate cultures of infectious agent carefully to avoid the uncontrolled release of aerosols or the generation of large droplets or spills. Centrifugation should involve the use of gasket-sealable tubes, carriers, and rotors, when available. Seal microplate lids with tape or replace them with adhesive-backed film. Load, remove, and open tubes, plates, and rotors within a biological safety cabinet or chemical fume hood.

Equipment used for manipulations of infectious materials, such as cell sorters and automated harvesting equipment, must be evaluated to determine the need for secondary containment and to consider decontamination issues. Costly equipment of this type is often operated as multi-user or core facilities; the inherent variability in risk from one project to another makes it imperative that operators and users of these facilities understand risks and methods for risk mitigation.

Use of well-established human or animal cell cultures in laboratories requires special consideration. Cell or tissue cultures in general present few biohazards, as evidenced by their extensive use and low risk of infection to laboratory personnel. However, when a cell culture is inoculated with or known to contain an etiologic agent, it should be classified and handled at the same biosafety level as the agent itself.

Biosafety Level 2 containment conditions should be used for cell lines of human origin, even those that are well-established, and for all human clinical material (such as tissues and fluids obtained from surgery or autopsy). Non-human primate cell cultures derived from lymphoid or tumor tissue, cell lines exposed to or transformed by a non-human primate oncogenic virus, and all non- human primate tissue should also be handled at BSL2. Manipulation of large volumes of human or non-human primate tissues or cell lines, or manipulations that have the potential to create aerosols, should all be performed within a biosafety cabinet.

<u>Animals</u>

It is imperative that care and thoughtfulness be exercised when using animals to isolate and propagate microorganisms, study pathology, or produce antibodies. Laboratory animals may harbor microorganisms that can produce human diseases following exposure through bites, scratches, or excreted material. In the process of inoculating animals, an investigator can be exposed to infectious material by accidental self-inoculation or inhalation of infectious aerosols. During surgical procedures, necropsies, and processing of tissues, aerosols can be produced unintentionally. Or the operator can inflict self-injury with contaminated instruments. Since animal excreta can also be a source of infectious microorganisms, investigators should take precautions to minimize aerosols and dust when changing bedding and cleaning cages.

Exposure Potential

While it can be assumed that investigators in research and clinical laboratories have more experience than students in teaching labs, safety consciousness and the establishment of a culture of safety is an ongoing process that cannot be ignored. Risk assessments should be an ongoing process in all laboratories taking into account the individual, training received, research conducted, agents and equipment used, operational controls, and facility limitations. Whenever possible, it is recommended that teaching laboratories make use of avirulent strains of infectious microorganisms. It is critical, however, that even attenuated microorganisms be handled with care. Students should be cautioned against and train to prevent unnecessary expose, as exposure to an avirulent strain may cause harm to an immunocompromised individual. Establishment of safety consciousness is integral to the conduct of good science.

Experiments in research laboratories using high concentrations or large quantities of pathogens increase the risk of exposure. The use of animals in research on infectious diseases also presents greater opportunities for exposure. As recommended for teaching laboratories, attenuated or avirulent strains should be used whenever possible.

Biohazard Containment

Although the most important aspect of biohazard containment is the awareness and care used by personnel in handling infectious materials, certain features of laboratory design, ventilation, and safety equipment can prevent dissemination of pathogens, should their accidental release occur.

Risk Group designations often correlate directly with the physical containment level appropriate for a given research activity. It is important to note that while Risk Group designations are set by health agencies and inflexible, Biosafety Level designations are set by the local Institutional Biosafety Committee and may be flexible. A brief description of the requirements (according to the BMBL) for each Biosafety Level is provided. Generally, RG1 agents require BL1 containment, RG2 agents require BL2 containment, etc. However, each determination of the appropriate containment should be based on an initial risk assessment and a thorough consideration of the agent itself and how it is to be manipulated. Specific BL1 and BL2 containment requirements can be found later in this document. For BL3 and BL4 requirements please contact the Chair of the Institutional Biosafety Committee (IBC).

Biosafety Levels

Biosafety Levels consist of combinations of laboratory practices and procedures, safety equipment and laboratory facility design features commensurate with laboratory operations performed, and are based on the potential hazards imposed by the agents used and for the specific lab activity. It is the combination of practice, equipment, and facility that form the

basis for physical containment strategies for infectious agents. There are four biosafety levels with Biosafety Level 1 (BSL1) being the least stringent and Biosafety Level 4 (BSL4) being the most stringent. The general recommendations for the four Biosafety Levels are as follows:

- BSL1 is recommended for agents that are non-pathogenic
- BSL2 is recommended for potentially pathogenic and pathogenic agents transmitted by direct contact (percutaneous inoculation, ingestion, or mucous membrane exposure)
- BSL 3 is recommended for pathogenic agents with the potential to be transmitted via aerosol
- BSL 4 is recommended when total separation between the pathogenic agent and PI is critical

	BIOSAFETY LEVEL			
	1	**2**	**3**	**4**
Restricted access	Yes	Yes	Yes	NA
Controlled access	No	Desirable	Yes	Yes
Isolation of lab	No	No	Desirable	Yes
Room sealable for decontamination	No	No	Yes	Yes
Inward airflow ventilation	No	Desirable	Yes	Yes
Mechanical ventilation via building system	No	Desirable	Desirable	No
Mechanical, independent ventilation	No	No	Desirable	Yes
Filter air exhaust	No	No	Yes	Yes
Double door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Effluent treatment	No	No	No	Yes
Autoclave on-site	Yes	Yes	Yes	Yes
Autoclave in lab room	No	No	Yes	Yes
Double-ended autoclave	No	No	Desirable	Yes
Class I or II BSC	No	Yes	Yes	Desirable
Class II BSC	No	No	Desirable	Yes

Biosafety Level 2 Practices and Procedures

The following practices correspond to BSL2 containment. They are important for the prevention of laboratory infection and disease, as well as for the reduction of the potential for contamination of experimental material.

Personal Hygiene:

- Do not eat, drink, take medicine, chew gum, use tobacco, apply cosmetics or lotions, or handle contact lenses in the lab.
- Do not store food and drink for human consumption in the lab; this includes fridges and freezers as well as desks and cabinets.
- Wash hands frequently after handling infectious materials, after removing gloves and protective clothing, and always before leaving the lab.
- Keep hands away from mouth, nose, eyes, face and hair.
- Do not store personal items such as coats, boots, bags, and books in lab.

General Requirements:

- Principal investigators and/or lab supervisors are responsible for training employees and students ensuring they are informed of hazards
- Good housekeeping practices are essential in labs engaging in work with infectious microorganisms. The PI must establish regular cleaning and decontamination procedures for all shared equipment and common areas.
- When working with rsDNA and/or agents at RG2/BSL2 or higher, IBC approval MUST be obtained before work can begin. If you are uncertain of BSL contact the chair of the IBC.
- When RG2/BSL2 (or higher) pathogens are used in long-term studies, a biohazard sign must be posted at the entrance that identifies the PPE necessary for safety entry.
- Custodial and janitorial staff must be notified that hazardous areas are off limits; signs must be posted.

Procedures for Handling Infectious Microorganisms:

- Plan and organize the materials and equipment before starting work.
- Keep the lab doors closed and limit access to personnel involved with the task(s).
- PPE includes a fully fastened lab coat, protective gloves, and splash goggles.
- When practical, perform all aerosol-producing procedures (shaking, mixing, blending) in a properly functioning biological safety cabinet.
- Centrifuge materials containing infectious agents must be in shatter-resistant closable tubes. After centrifuging open the tubes in a biological safety cabinet.
- Avoid using needles and syringes when possible. When necessary, dispose of used syringes and needs in a sharp's container. NEVER RECAP NEEDLES.
- Wipe work surfaces with an appropriate disinfectant after experiments and immediately after spills.
- Decontaminate all materials before disposal.

Biological Safety Cabinets

Biological Safety Cabinets (also called Biosafety Cabinets or BSCs) are the primary means of containment developed for working safely with infectious organisms. When functioning correctly BSCs are very effective at controlling infectious aerosols. BSCs are a type of laboratory safety equipment utilizing airflow to maintain the safety of the worker. BSCs are distinct from other safety equipment of this type, such as chemical fume hoods and clean benches. BSCs are designed to provide personnel, environmental, and product protection when appropriate practices and procedures are followed.

There are three kinds of BSCs, designated as Class I, Class II, and Class III, that have been developed to meet varying research and clinical needs. All BSCs use HEPA filters to ensure no particles enter the working space of the cabinet, get recirculated within the cabinet, or get exhausted to the environment. There are various sub-types of each class of BSC. The sub-type depends on the percentage of air recirculated or exhausted.

Horizontal laminar flow clean benches are not biological safety cabinets and should never be used for work with hazardous or potentially hazardous materials or agents. This equipment protects the material in the cabinet but not the worker or the environment.

Similarly, chemical fume hoods are not biological safety cabinets. They draw air in from the room, potentially protecting the worker, but do not protect the material in the cabinet and exhaust unfiltered air into the environment. Chemical fume hoods may be appropriate for some biohazardous agents.

Biosafety Cabinet Operation:

- Turn on the blower and fluorescent light, close drain valve.
- Before loading equipment allow the air to circulate to purge potentially contaminated air. NIH recommends the blower run 15 min prior to use, CDC recommends 4-5 min.
- Check grilles for obstructions.
- Disinfect the interior surfaces of the BCS.
- Load only the items needed for the procedure, avoid clutter and excess storage.
- Disinfect the exterior of all containers prior to starting.
- Segregate clean and dirty material on separate sides of the cabinet.
- Materials should be placed 6 inches from the back and front grille.
- Wash hands thoroughly with soap and hot water before and after procedures.
- Wear PPE; lab coat, gloves, and splash goggles.
- Avoid rapid movement during procedures both within and outside the cabinet but within the vicinity of the BCS.
- Move hands and arms straight into and out of the work area; never sweep hands/arms out of the work area.

- Disinfect the exterior of all containers before removal.
- Decontaminate interior work surfaces after completing the work.
- Run the blower for an additional 2 minutes after work and before removing any materials.

Decontamination and Spills inside a BCS:

- Small spills:
    - Do not turn off BCS.
    - Cover the spill with absorbent paper towels.
    - Carefully pour a disinfectant (10% bleach solution) onto the towel-covered spill.
    - Remove the contaminated toweling and place into a biohazard bag.
    - Wipe down any splatter with decontamination solution.
    - Remove PPE and place into biohazard bag.
    - Wash hands.
- Large Spill
    - Do not turn off BCS.
    - Ensure the drain valve is closed.
    - Decontaminate and remove all materials possible.
    - Pour disinfectant (10% bleach solution) directly onto the work surface and through the grilles into the drain pan.
    - Allow 20-30 minutes for contact time with the disinfectant before cleaning.
    - Empty the drain pan into a hazardous waste container with proper labeling.

Biological (infectious) Waste Disposal

The following biohazardous waste disposal guidelines are designed to protect the public, the environment, laboratory and custodial personnel, waste haulers, and landfill/incinerator operators at each stage of the waste handling process. Generators of biohazardous waste must ensure that the labeling, packaging, and intermediate disposal of waste conforms to these guidelines. Use the definitions below to facilitate your understanding of appropriate decontamination and disposal guidelines.

- Decontamination- Refers to the process of removing disease-causing microorganisms and agents, rendering an object safe for general handling.
- Disinfection- Refers to a process that kills or destroys most disease-causing microorganisms, except spores.
- Sterilization- Refers to process that destroys all forms of microbial life, including spores, viruses, and fungi

Infectious Waste needing Decontamination:

Microbiological laboratory wastes such as cultures derived from clinical specimens and

pathogenic microorganisms.

- Lab equipment that may have come in contact with clinical specimens, pathogenic microorganisms, or cultures derived from them.
- Tissues, large quantities of blood and/or bodily fluids from humans.
- Tissues, large quantities of blood and/or bodily fluids from infectious animals.

Waste NOT needing Decontamination:

The following are not included as infectious waste but still need to be handled properly. Place these items into a container or plastic bag prior to disposal. Items soiled or spotted, but not saturated, with human blood or bodily fluid

- Containers, packages, waste glass, lab equipment, and other materials that have had no contact with blood, body fluids, clinical cultures, or infectious agents.
- Noninfectious animal waste (bedding,) from an animal that is not known to be carrying an infectious agent that can be transmitted to humans.

Packaging of Waste

Laboratory materials used in experiments with potentially infectious microorganisms, such as discarded cultures, tissues, media, plastics, sharps, glassware, instruments, and laboratory coats must be decontaminated before disposal or washing for reuse. Collect contaminated materials in leak-proof containers labeled with the universal biohazard symbol. Autoclavable biohazard bags are recommended. All infectious waste must be brought to EOHS Cushwa 2120 as soon as the container becomes 3/4 full or a maximum weight of 30 pounds.

Uncontaminated sharps and other noninfectious items that may cause injury require special disposal even if they do not need to be decontaminated. Sharps need to be collected in rigid, puncture-resistant containers to prevent wounding of workers, custodial personnel, and waste handlers. If a package is likely to be punctured from sharp-edged contents, double bagging or boxing is needed.

Methods of Decontamination

Choosing the right method to eliminate or inactivate a biohazard is not always simple. The choice depends largely on the treatment equipment available, the target agent, and the presence of interfering substances (e.g. media, high organic content, tissues) that may protect the organism from decontamination or mitigate the effects of the decontamination equipment.

Autoclave/Steam Sterilization:

There are two main autoclaves located in the EOHS department that are used for all infectious waste before the infectious waste transporter removes the waste from campus. They are operational during normal work days and process approximately 300 pounds of infectious

waste a month. The operation and maintenance of the autoclave is the responsibility of the EOHS department and is in accordance with the manufacture's recommendations.

Chemical Disinfection:
Where autoclaving is not appropriate, an accepted alternative is to treat material with a chemical disinfectant. The disinfectant should be freshly prepared at a concentration known to be effective against the agent in use. The disinfectant choice should be one that quickly and effectively kills/inactivates the agent at the lowest concentration and with minimal risk to the user. However, higher concentrations of disinfectant are necessary to clean up large spills.

It is important to be aware that common laboratory disinfectants can be a hazard to the user. Also, once material has been treated with chemicals it cannot be autoclaved. For specific disposal information after chemical treatment contact the EOHS department at eohs@ysu.edu.

Sewage Treatment:
Most fluid waste can be discarded through the sanitary sewer by pouring it into a sink drain and flushing the drain with water. This includes human blood and infectious cultures as long as they have been properly decontaminated. Care should be taken to avoid generation of aerosols. The routine processing of municipal sewage provides chemical decontamination. If the fluid is contaminated with infectious agents or biological toxins, however, it must be decontaminated by chemical disinfection or steam sterilization before sewer disposal.

Emergency Plans

Emergency plans should be tailored for a given biohazardous situation and may vary from one lab to another. The laboratory supervisor should prepare instructions specifying immediate steps to be taken. These instructions should be displayed prominently in the laboratory and periodically reviewed with laboratory personnel. No single plan will apply to all situations but the following general principles should form the basis of laboratory-specific plans.

In an emergency situation, attention to immediate personal danger overrides containment considerations. Currently, there is no known biohazard on YSU campus that would prohibit properly protected and masked fire or security personnel from entering any biological laboratory in an emergency.

Spill Protocol:
If a large spill or release were to occur outside of a BSC the following steps should be taken.

- Anyone in the area should immediately leave the area and remove any contaminated clothing and wash exposed skin.
- Close the lab and post a NO ENTRY sign on the door(s).

- Notify the PI and/or lab supervisor as well as EOHS. Outside normal business hours call campus police.
- Do not reenter the room until the extent of the hazard and its dissemination has been determined. Wait at least 30 minutes for droplets to settle and aerosols to be cleared by the building ventilation.
- Anyone that enters the lab must wear appropriate PPE.
- Use a concentrated disinfectant and thoroughly clean and decontaminate the entire lab.
- Decontaminate all reusable materials and dispose of contaminated non-reusable materials in biohazard waste bags/containers.

Exposure Protocol:
Determine the necessity and extent of medical treatment for persons exposed to infectious microorganisms. Personnel accidentally exposed via ingestion, skin puncture, or obvious inhalation of an infectious agent should be given appropriate first aid and, if necessary, taken to the nearest emergency room. For exposures to the eyes or mucous membranes, the exposed area should be flushed with running water for 15-20 minutes. Seek medical attention as soon as possible following exposure and also contact EOHS at 330-941-3700.

Reporting:
The importance of reporting accidental spills or exposure events is not to identify fault or failure within the laboratory or on the part of the laboratory personnel. The goal of reporting such incidents is to identify opportunities to refine standard operating procedures for the laboratory and improve laboratory safety. Importance is always placed on personal health as well as the health and safety of coworkers, the research community, and the general public.

The secure and responsible conduct of life sciences research depends, in part, on observation and reporting by peers, supervisors, and subordinates. Individuals working with potentially infectious material and/or rsNA constructs with either direct or indirect, acute or latent disease potential must understand and acknowledge their responsibility to report activities that are inconsistent with a culture of responsibility or are otherwise troubling. Likewise, institutional and laboratory leadership must acknowledge their responsibility to respond to reports of concerning behavior and undertake actions to prevent retaliation stemming from such reports.

Where appropriate, an individual should report to his/her PI, supervisor, Department Chair, or Dean. In instances where confidentiality is important, reports may be made to the office of Internal Audit at mmdilullo@ysu.edu or anonymously at hotline website or the EOHS department at Report a Safety Concern.

Transporting Hazardous Biological Materials

For the purposes of transportation, dangerous goods are those substances or articles that have the potential to cause harm to individuals, property, or the environment in the event of an accident or incident. Since infectious substances pose a risk to health (in the form of disease) if an individual is exposed to them during transport, they are considered dangerous goods when transported. This is important to note, as the hazard level of a particular substance may not be the same in transport as it is when being manipulated in a laboratory. In order to avoid such exposures, national and international regulations govern how shipments of infectious substances are to be prepared and transported.

National and international regulations dictate that any individual involved in the transport of hazardous materials must be trained, tested, certified, and retain a record of their training. This includes individuals who are responsible for the preparation and packaging of a shipment, marking and labeling packages, preparing shipping documents, loading and unloading transport vehicles, and supervising any of the afore mentioned activities.

There are various national and international regulatory bodies that have provided guidance and requirements for the shipment of dangerous goods. The United States Department of Transportation (DOT) regulates the transport of dangerous goods via roadways and railways.

Appendix A. Institutional Biosafety Committee

Section IV-B-2 of the NIH *Guidelines* mandates the formation of an Institutional Biosafety Committee and the appointment of a Biological Safety Officer (BSO) by the institution. For more information regarding the NIH-mandated requirements for the IBC and the most up-to-date version of the NIH *Guidelines*, please visit the NIH website .

Membership and Procedures of the IBC:
The IBC must be comprised of no fewer than five members selected so that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment.

According to the NIH *Guidelines*, the IBC shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*. Due to the limited amount of research conducted at YSU that is subject to Appendix P, the YSU IBC does not retain an individual with such expertise. Instead, the YSU IBC will call upon an individual with the appropriate expertise in the event it is necessary.

The IBC shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*.

The NIH *Guidelines* identifies several categories of research, such as *recombinant or synthetic nucleic acid molecule research at BSL3, BSL4, or Large Scale (greater than 10 liters),* that requires a Biological Safety Officer's presence on the IBC. YSU does not perform research at these levels and such work would require special approval from the IBC.

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human research participants, the institution must ensure that: (1) the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary); (2) all aspects of Appendix M of the NIH *Guidelines* have been appropriately addressed by the Principal Investigator; (3) no research participant shall be enrolled in a human gene transfer experiment until the NIH protocol registration process has been completed; and (4) final IBC approval is granted only after the NIH protocol registration process has been completed.

Functions of the IBC:

As outlined by the NIH *Guidelines*, the IBC is responsible for reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the NIH *Guidelines*. At the discretion of the IBC, the review includes the following:

- Assessment of containment levels for the proposed research
- Assessment of the facilities, procedures, practices, and training and expertise of the personnel involved with the research.
- Ensuring that no research participant is enrolled in an experiment until the NIH protocol registration process has been completed, IBC approval has been obtained, IRB approval has been obtained, and all applicable regulatory authorizations have been obtained.

Following review, it is the responsibility of the IBC to notify the PI of the result of the IBC's review and subsequent approval, if applicable. The IBC is also responsible for setting the containment level of research involving recombinant or synthetic nucleic acids in organisms from Risk Groups 2, 3, and 4, as well as such research involving live animals and plants. The IBC is also responsible for periodically reviewing the recombinant and synthetic nucleic acids research conducted at the institution to ensure compliance with the NIH *Guidelines*. Finally, the IBC must adopt and ensure implementation of emergency plans covering accidental spills and personnel contamination resulting from recombinant or synthetic nucleic acids research.

Relationship with Research and EOHS

At YSU, Research and EOHS work closely with the IBC to manage many day-to-day operations of the IBC and to ensure IBC policy implementation. Several members of the Research staff act as administrators to the IBC and maintain accurate records of the IBC meetings. Some Research and EOHS staff also sit on the IBC and act as voting members. Research is responsible to implement and ensure compliance with IBC policy and IBC decisions. Although the IBC, Research and EOHS are responsible for different aspects of the program, they work together to ensure the safety of the YSU research community as well as the broader Youngstown and Mahoning Valley as well.