ROCKY MOUNTAIN LABORATORIES

BIOLOGICAL EXPOSURE CONTROL PLAN

Version 20

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Abbreviations Used:

Animal Exposure Program (AEP)

Biological Exposure Assessment Program (BEAP)

Biological Safety Cabinet (BSC)

"*Biosafety in Microbiological and Biomedical Laboratories* Current Edition (BMBL)

Biosafety Officer (BSO)

Department of Labor (DOL)

Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (DIR NIAID)

Division of Occupational Health and Safety (DOHS)

Employee Assistance Program (EAP)

Exposure Control Plan (ECP)

Hepatitis B virus (HBV)

Hepatitis C virus (HCV)

Human Immunodeficiency virus (HIV)

Human T-lymphotropic virus (HTLV)

Infectious Disease (ID)

Institutional Biosafety Committee (IBC)Integrated Research Facility Biosafety Manager (IRFBSM)

Laboratory Acquired Infection (LAI)

Maximum Containment Laboratory (MCL)

Medical pathological waste (MPW)

NIH Biological Surety Program (NIH BSP)

Non-human primate (NHP)

Occupational Health and Safety Administration (OSHA)

Occupational Medical Service (OMS)

Occupational Safety and Health Manger (OSHM)

Office of Operations Management (OOM)

Other potentially infectious material (OPIM)

Personnel protective equipment (PPE)

Principal Investigator (PIs)

Quarantine Permit Service Office (QPSO)

Ravalli County Health Emergency Advisory Team (HEAT)

Rocky Mountain Laboratories (RML)

Security Control Center (SCC)

Simian-human Immunodeficiency virus (SHIV)

Simian Immunodeficiency virus (SIV)

Tuberculosis Surveillance Program (TSP)

Waste and Anesthetic Gas (WAG)

SECTION 1. INTRODUCTION

The Rocky Mountain Laboratories (RML) is a component of the Division of Intramural Research of the National Institute of Allergy and Infectious Diseases (DIR NIAID). Research at RML currently involves the study of infectious agents at Biosafety Levels 1, 2, 3 and 4 (BSL-1, BSL-2, BSL-3 and BSL-4). The majority of research studies at RML are performed at BSL-2 in standard laboratories designed to lower the risk of exposure to infectious agents which are less likely to cause more serious human disease and for which effective medical interventions are readily available (Risk Group 2). Nevertheless, biological exposures can occur while working with these pathogens. Research studies on more serious human pathogens (Risk Groups 3 and 4) are conducted in BSL-3 or BSL-4 labs and require highly trained personnel, detailed research protocols, and highly specialized biocontainment facilities. Historically, these BSL-3 and BSL-4 labs across the US have proven to be extremely safe. However, incidents have occurred in workers who were exposed to infectious agents, or, in very rare instances, developed laboratory-acquired infections (LAI). Detailed information about Risk Group 2, 3, and 4 agents and BSL-2, BSL-3 and BSL-4 facilities may be found in the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories (current ed)" (BMBL).

Exposures to biological hazards may result from improper functioning or operation of laboratory, biocontainment, or decontamination equipment. In addition, RML workers may be at risk for exposure to infectious agents through contact with human and nonhuman primate body fluids and tissues. Several levels of operational safeguards are utilized to minimize the risk of exposure to biological hazards. The RML **Exposure Control Plan** (**ECP**) outlines the institutional oversight and management of potential exposures to infectious agents. The ECP is in compliance with the Occupational Health and Safety Administration (OSHA) Blood Borne Pathogens Standard (29 CPR 1910.1030), and serves as both the written program, for compliance purposes, and as a training document. Occupational exposure may be defined as any reasonably anticipated skin, eye, mucous membrane, parenteral contact with, or respiratory exposure (via aerosol) to infectious agents, blood, or other potentially infectious material that may result from the performance of a worker's duties. Adverse health consequences may arise when a breach of all exposure controls occurs, and an infectious agent is transmitted to the exposed worker.

PROGRAM ADMINISTRATION

The ECP is reviewed and updated by the NIH Division of Occupational Health and Safety (DOHS) personnel and the RML Institutional Biosafety Committee (IBC) at least annually and whenever necessary to (A) document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure; and (B) reflect changes in equipment or processes that reduce exposure to bloodborne pathogens or biological hazards.

The DOHS Staff solicits input from workers, including non-managerial level workers, who have the potential to sustain occupational injuries in the identification, evaluation, and selection of new technology that can reduce injuries in the workplace. The review and implementation of safer sharps devices for laboratory use is documented in each subsequent annual review of the ECP.

A copy of the ECP is available to all RML workers, upon request, by contacting the RML Biosafety Office. Additionally, the ECP can be located on the RML share drive in the "Biosafety Folder".

SECTION 2. EXPOSURE RISK ASSESSMENT

In order to protect RML workers from exposures to biohazards, it is necessary to identify all personnel at risk. At RML, the principal method by which exposure determination information for laboratory personnel is gathered is with the **Registration Document** (Appendix 1)

PROCEDURE FOR REGISTERING MATERIALS (POTENTIALLY) INFECTIOUS FOR HUMANS AND ANIMALS

- All PIs working with human or animal pathogens, human blood, body fluids, or tissues, biological toxins, or body fluids of Old-World non-human primate (NHP) species, must submit a properly completed registration to the RML Biosafety Officer for subsequent review by the RML Institutional Biosafety Committee (IBC). For the purposes of this registration, a pathogen is defined as any organism known to or suspected of causing infection in humans or animals and a toxin is a proteinaceous substance that is highly toxic to humans.
    - Regarding cell lines, because it is not possible to test every cell line for every possible virus or ever make the claim any particular cell line is pathogen free, all human cell lines be accorded the same level of biosafety consideration as a line known to carry HIV. Additionally, individuals should not utilize their own cells to generate induced pluripotent stem cells (iPSC) or work with iPSCs that have been generated from their own cells due to the risk of auto-inoculation of potentially cancerous cells. If you are not sure if something needs to be registered, investigators can contact the RML Biosafety staff for help in determining correct precautions to take and whether registration with the RML IBC is required.
- All registrations must be submitted via the Electronic Registration System https://ers.ors.nih.gov/
- The IBC reviews the registration form to ensure that the material will be manipulated at the appropriate biosafety level, that appropriate equipment is being used, and that the personnel listed have received the proper training. After review and approval by the IBC the registration document is reviewed by the RML Occupational Medical Service (OMS), (see Section 4) to ensure that personnel are enrolled in the appropriate medical services and offered any additional counseling or immunizations appropriate for the work being performed. The PI is responsible for ensuring all participating workers are enrolled and participating in relevant RML OMS services.
- Information collected on the registration document is updated by the PI or Supervisor and reviewed by the IBC every 5 years to ensure that exposure determinations are adequately performed and correct. Annual laboratory surveys and routine walk-through visits of areas are made to ensure that appropriate equipment is being used and procedures are being followed.

RISK FOR OCCUPATIONAL EXPOSURE TO HUMAN/NON-HUMAN PRIMATE BLOOD, BODY FLUIDS OR TISSUES

The OSHA Blood Borne Pathogens Standard (Title 29 Code of Federal Regulations, Part 1910.1030), requires employers to identify, in writing, tasks and procedures as well as job classifications where occupational exposure to human blood, body fluids or other potentially infectious material (OPIM) occurs. All individuals working in the

following jobs with the potential to be exposed to human blood or OPIM are offered the hepatitis B vaccine (see Section 4) and receive appropriate training.

Job classifications, in which all or some of the workers may have occupational exposure, include:

- Laboratory personnel including scientists, post-doctoral researchers, post-baccalaureate researchers, graduate students, visiting scientists, and laboratory technical staff,
- Law enforcement and emergency response personnel, and
- Housekeeping, Maintenance, and other support personnel.

Tasks and procedures in which workers may have occupational exposure:

- Laboratory personnel: see section above on Procedure for Registering Materials (Potentially) Infectious for Humans and Animals.
- Security officers: may face the risk of exposure to blood during the conduct of their duties. For example, at a crime scene or during the processing of suspects, RML security officers may encounter blood-contaminated hypodermic needles or weapons or be called upon to render emergency aid. Therefore, RML security officers are covered under the ECP for bloodborne human pathogens and are offered hepatitis B virus (HBV) immunization by their employer and will receive appropriate training.
- First Aid response personnel: often provide emergency medical services and, therefore, encounter exposures common to those experienced by paramedics and emergency medical technicians. Job duties in the pre-hospital setting may be performed under uncontrolled conditions. First Aid response personnel are therefore covered under the ECP for bloodborne human pathogens and are offered HBV immunization and will receive appropriate training.
- Housekeeping, Maintenance, and other support personnel: The RML Waste Management Plan describes waste handling procedures at RML. However, housekeeping, maintenance, and other support personnel may face the risk of exposure to human blood, body fluids, OPIM during the conduct of their duties. For example, housekeeping and maintenance personnel may encounter human body fluids while cleaning lavatories, or performing maintenance on a sewer system, respectively. Therefore, Housekeeping, Maintenance, and other support personnel are covered under the ECP for bloodborne human pathogens and are offered HBV immunization by their employer and will receive appropriate training.

SECTION 3. EXPOSURE CONTROL METHODS/METHODS OF COMPLIANCE

BIOSAFETY LEVELS

Biosafety levels evolved as guidelines to protect microbiological workers and are based on an understanding of the risks associated with practices and procedures involved in working with agents transmissible by different routes. The practices, procedures, and facility requirements associated with different Biosafety levels are described in the CDC/NIH publication "*Biosafety in Microbiological and Biomedical Laboratories* current Edition (BMBL) and are to be adhered to by all RML workers working with potentially infectious material. A copy of this publication should be in all laboratories and is available to all RML workers upon request from the Biosafety Office. The document is also available online at: https://www.cdc.gov/labs/BMBL.html

At RML, IBC conducts situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures.

DOHS Staff will perform certification of Biosafety Level 2, 3, and 4 laboratory facilities annually.

WORK PRACTICE CONTROLS

Work practice controls are used to eliminate or minimize worker exposure to blood or other potentially infectious materials OPIM. Where potential occupational exposure remains after institution of these controls, engineering controls, administrative controls and/or personal protective equipment is used.

A laboratory-specific biosafety manual is prepared or adopted and periodically reviewed and updated at least annually or more often as necessary. Laboratory personnel are advised of potential hazards and required to read instructions on special practices or precautions outlined in the registration.

Standard precautions or the equivalent (see below) are observed to prevent contact with blood or OPIM. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

- All specimens of human blood, tissue, and body fluids are handled utilizing Biosafety Level 2 practices and procedures, which equates with the concept of Standard Precautions in the clinical setting. In laboratories working with HIV or, other human retroviruses, infected cell lines, and/or simian immunodeficiency virus (SIV) at the research scale, Biosafety Level 3 practices and procedures are utilized in a certified Biosafety Level 2 facility.

- *Macacine alphaherpesvirus 1* (also known as B virus, Monkey B virus, Herpes B, *Macacine herpesvirus 1*, Cercopithecine herpesvirus 1 or CHV-1) can represent a significant hazard to those who handle Old World NHPs or their viable tissues and body fluids. Biosafety Level 2 practices and facilities are recommended for all activities involving the use or manipulation of any viable NHP tissues or body fluids. Laboratories using or manipulating old-world NHP specimens must register with DOHS using a registration. Enrollment in the Animal Exposure Program (AEP) is required for personnel who have direct contact with a variety of animals (including NHPs), their viable tissues, body fluids, wastes or living quarters. Bloodborne Pathogen safety training given by the RML DOHS staff and is required both initially and annually for personnel who handle the tissue, blood, or body fluids of macaques, unless the worker can document equivalent safety training.

- Large-scale work (greater than 10 Liters) with HIV or the other human retroviruses must be performed in a Biosafety Level 3 facility using full Biosafety Level 3 practices and procedures. These requirements may extend to other human bloodborne pathogens.

- HIV and HBV Research Laboratories and Production Facilities: RML may have laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. Such laboratories must follow the same pathogen registration procedures described above. A laboratory is considered a production facility when greater than 10 (ten) liters of HIV are produced. The RML IBC will conduct a risk assessment based on the organism involved and the methodology used. The laboratory in question is required to follow the appropriate level of biological containment practices and procedures as determined by the RML IBC. In general, laboratories that use HIV, HBV, and SIV are required to operate at Biosafety Level 2 with 3 practices as described in the BMBL, although high titer HIV, SIV, SHIV, and HTLV are handled in a BSL-3 facility using BSL-3 practices and containment equipment. A clothing change room is included in the design of HIV and HBV research laboratories and production facilities.

Certain laboratory procedures or other factors may require that these organisms be handled at a higher biological safety level than described above. The IBC will conduct situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures.

Fire, emergency response, and law enforcement personnel are required to follow procedures specific for their job categories, as outlined in "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers". Copies of this document are available from the OMS nurse.

Food and drink are strictly prohibited in any laboratory or animal care setting. They may not be brought into or walked through a laboratory, an animal care setting, or any area where infectious material is stored; nor can they be consumed in a laboratory, animal care setting, or area that stores infectious material. Similarly, smoking, applying cosmetics and handling contact lenses are prohibited in areas where there are potentially infectious materials.

COMMUNICATION OF HAZARDS TO WORKERS

Workers must be notified of the presence of potentially infectious materials in any workspace. Laboratories and other work areas handling human blood and body fluids and any human pathogens or unfixed old-world NHP blood and tissues must be posted with an NIH-approved Biohazard Sign. Work areas are posted by DOHS Staff upon completion of a safety survey and certification of the area at the appropriate biosafety level.

The biohazard sign must be affixed to the entry door and must include:

- Pathogen name
- The biosafety level
- List of personal protective equipment that must be worn in the laboratory
- Any special requirements (i.e. immunizations) required for entry to a workspace
- Any special procedures for entering the laboratory
- Emergency contact information (name, phone number)

All containers used to transport infectious materials between laboratories or buildings are labeled with stickers carrying the international biohazard-warning symbol.

The poster "1-2-3 Emergency Procedures for Exposure to Blood, Body Fluids, and Infectious Materials" is placed prominently in all work areas where there is a potential for exposure to human blood, body fluids, human retroviruses, or other potentially infectious material. Copies of this poster may be obtained from the Biosafety Office.

ENGINEERING CONTROLS

Engineering controls are used to eliminate or minimize worker exposure to blood or other potentially infectious materials. At the RML these engineering controls include, but are not limited to, biological safety cabinets, mechanical pipetting devices, sharps disposal containers, self-sheathing needles, sharps with engineered sharps injury protections, and needleless systems.

PRIMARY BARRIERS

Class II biological safety cabinets (BSCs) or other physical containment devices are used when procedures with a high potential for creating potentially infectious splashes or aerosols are conducted. Such procedures may include centrifuging, grinding, vortexing, blending, sonic disruption, transferring liquids, homogenizing, withdrawing liquids under pressure, and opening containers of infectious materials having internal pressures different from ambient pressures.

Intranasal inoculations or animal necropsies are performed on an open bench, if it is determined by the Biosafety Officer that conducting the procedure in a biological safety cabinet would place the worker at a significantly increased risk of percutaneous exposure to a blood-borne pathogen. In these cases, strict adherence to mucous membrane protective practices is required, which includes surgical face masks and goggles or face shields with eye protection, as well as using appropriate gloves and protective garments. In addition, when a biosafety cabinet cannot be used, alternate containment should be used and is chosen based on a risk assessment.

Annual inspection and certification of all biological safety cabinets (BSC), fume hoods and other local exhaust ventilation equipment is performed by the DOHS Staff. Concerns or questions should be directed to the RML Safety Manager at 406-274-2803.

PROCEDURES FOR WORKING IN A BIOLOGICAL SAFETY CABINET (BSC)

- Wear appropriate personal protective equipment. At a minimum, this will include a buttoned laboratory coat and gloves. Personal clothing should include long pants and closed toe shoes.
- Know the type of cabinet (A2, B1, or B2) and its limitations providing protection from chemical hazards.
- Turn the cabinet on for at least 10 - 15 minutes prior to use. (Cabinets in BSL-3 or BSL-4 remain on at all times)
- Disinfect work surface with suitable disinfectant.
- Place all work items in cabinet before starting work.
- Place items into the cabinet so that they can be used efficiently without unnecessary disruption of the airflow, working with materials from the clean to the dirty side.
- Adjust your seat so that your face is above the cabinet opening.

- Delay manipulation of materials for approximately 1 minute after placing the hands/arms inside the cabinet.
- Minimize the frequency of moving hands in and out of the cabinet.
- Do not block air intake or front grillwork.
- Avoid sudden movements as these disrupt the laminar airflow.
- Use an overflow collection bottle with the appropriate disinfectant when using a vacuum system. Be sure to have an in-line HEPA filter on the discharge side of the vacuum trap and replace when it becomes wet or damaged. Clean or dispose of the vacuum filter flask regularly.
- Decontaminate BSC after each use
- Don't store items on top of the BSC. They can damage the filter assembly.

Mechanical Pipetting Devices

Mechanical pipetting devices are used for all pipetting activities. Mouth pipetting is strictly prohibited.

Handwashing Facilities

RML provides handwashing facilities that are readily accessible to workers. When provision of handwashing facilities is not feasible, RML provides either an appropriate antiseptic hand cleanser in conjunction with paper towels or antiseptic towelettes.

EYE WASHING/ CHEMICAL SHOWER STATIONS

RML provides emergency eye washes and chemical shower stations that are accessible to workers. These facilities are located within in every lab to ensure all workers have feasible access for proper exposure management.

Needleless Systems

Needleless systems are devices that do not use needles. Needleless systems may be used for:

- The collection of bodily fluids or withdrawal of body fluids after venous or arterial access is established (e.g. in-dwelling catheter)
- The administration of medication or fluids
- Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps

Devices with Engineered Sharps Injury Protections

Devices with engineered sharps injury protection are non-needle sharps or a needle device that is engineered with injury protection. These devices utilize non-needle technology or incorporate built-in safety features or mechanisms that effectively reduce the risk of exposure incidents. These devices may be used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids. Laboratories and animal care areas performing these activities are required to evaluate the availability and use of engineered protective devices.

Plasticware

Substitution of plastic materials for glass whenever possible can help to greatly reduce sharps related injuries and exposure to blood and OPIM.

Sharps Containers

Puncture resistant sharps containers are used at all work sites where needles and syringes, Pasteur pipettes, scalpel blades, razor blades, and other sharps are used. These containers must be closable, labeled as described below in the labeling section and must be leak-proof on the bottom and sides. During use, the container must remain upright. When three-quarters filled, the containers are autoclaved and then disposed of by incineration. Puncture resistant sharps containers are available from the RML Stockroom.

Safety Devices for Centrifuges

For low-speed centrifugation of infectious materials, centrifuge safety cups are recommended. If used, the cups are loaded and unloaded within a BSC. High-speed centrifugation of infectious materials should be performed using a safety rotor that is loaded and unloaded within a BSC.

Vacuum Traps and Filters

Vacuum traps and filters serve as the first barrier of protection against transfer of biological material into building vacuum systems. Whenever a bench-line vacuum is in use in a laboratory a trap must be installed before the vacuum inlet that has an in-line filter installed between the trap and the vacuum inlet. If the in-line filter becomes wet or damaged, it must be replaced.

Personal Protective Equipment

A variety of personnel protective equipment (PPE) in a variety of sizes is available to all RML workers through the RML Stockroom or through vendor catalogs. The items stocked by RML for use by its workers are reviewed by DOHS Staff to ensure that the items stocked meet the needs of the user community. New items are added as specific safety needs are identified. All personnel are encouraged to discuss their needs for PPE with the DOHS staff. Inquiries can be sent to: rmlorsdohsteam@mail.nih.gov. If equipment is required that is not currently available through the RML Stockroom, it is ordered from the appropriate source at no cost to the worker. However, personal preference alone is not justification for special ordering of PPE.

PPE must prevent infectious material from reaching work clothes, street clothes, undergarments, skin, eyes, mouth, and mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. It is the supervisor's responsibility to ensure workers are utilizing PPE effectively and properly. If the worker refuses to wear PPE to protect themselves from infectious material, their supervisor must ensure that they do not work with infectious material.

Supervisors are responsible for ensuring the laundering, repairing, and replacing of PPE when needed. Laundry that is contaminated with infectious material must be labeled and handled as a biohazard. If contaminated items cannot be laundered, they must be disposed of as biohazardous waste. All forms of PPE are removed before leaving the laboratory or animal care setting and may not be worn in any public area or outside of any building. Once PPE is removed it is placed in a designated area for storage, laundering, or disposal.

Clothing

In any laboratory or animal care setting, the first line of defense against biological exposures is the clothing worn by the individual entering the area. Therefore, in order to provide the best protection an individual must cover themselves as much as possible with street clothing. Personal clothing should include long pants and closed toe shoes. Shorts, capris, short skirts, and any leg covering that falls above the ankle are prohibited in laboratory settings. Tights and nylons do not serve as a substitute for appropriate leg covering. As such, open toe shoes or any

shoe that does not cover the top and sides of an individual's foot are not permitted in the laboratory or animal care setting.

Gloves

Gloves are worn by all workers when directly handling potentially infectious material or when in contact with contaminated surfaces. Based on individual need, the worker may choose vinyl examination, surgical latex, or nitrile gloves. Gloves are changed routinely and rigorous hand washing policies are established in laboratory areas. Workers must inspect gloves routinely and replace them whenever they are visibly soiled, torn, or punctured. All used and potentially contaminated gloves are discarded into the medical pathological waste (MPW) stream. Hand washing is mandatory when gloves are removed and upon completion of work.

Other Protective Garments

Laboratory coats, gowns, aprons, or suits, whichever is most appropriate for the particular application, are worn by all personnel manipulating or otherwise handling infectious or potentially infectious materials. Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can be reasonably anticipated, for example necropsies, dissections, or tissue removal within an animal facility. These garments are not worn outside of the laboratory area unless the worker is transporting hazardous material. After disposable protective garments are used, they are discarded in the MPW stream as described in the RML Waste Management Plan. Cloth laboratory coats are not to be taken home by the worker for laundering. If lab coats have pockets, they must be inspected, and any items removed prior to placing in the collection bin for laundering. RML provides laundry service for laboratory clothing, uniforms, and linens, for information about this service, contact the Logistics Department Coordinator (OOM).

Masks, Eye Protections, and Face Shields

Masks in combination with eye protection (such as goggles or glasses with solid side shields) or chin length face shields, are worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

Respirators

Respirators must not be used in the laboratory without prior approval of the DOHS. Supervisors are not authorized to select or recommend the use of respiratory protection, regardless of the type. Call or email the safety specialist if you feel respiratory protection is required. Surgical facemasks, used for mucous membrane protection, are not considered respirators and are not to be used in situations where respiratory protection is required. All respirator users must be enrolled in the RML Respiratory Protection Program. Each lab will supply and maintain the recommended respiratory protective device.

Training and Education

Training for workers, in compliance with the OSHA Bloodborne Pathogen Standard, is provided on an annual basis for all RML workers or as needed. PIs and Supervisors are responsible for assuring that all workers under their direction who may be potentially exposed to an infectious agent including bloodborne pathogens attend one of these sessions prior to handling infectious materials and that they receive refresher training on an annual basis. Consult DOHS for training dates.

PIs and Supervisors are responsible for job-specific safety training and must document that workers selected for jobs involving manipulation of infectious materials have been adequately trained to perform these tasks.

NIH law enforcement officers receive training consistent with the information provided in the HHS publication entitled *Guidelines for Prevention of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers.* These guidelines were developed in response to P.L. 1000-607 *The Health Omnibus Programs Extension Act of 1988,* portions of which are specific for personnel working in the emergency response or law enforcement arenas. Training is provided upon employment and updated annually as required.

Training Records

Training records are completed for each worker upon completion of training. These documents will be kept for at least three years by the DOHS. The training records include the dates of training, the contents or summary of the training sessions, the names and qualifications of persons conducting the training, and the names and job titles of all workers attending the training.

Worker training records are provided upon request to the worker or the worker's authorized representative within 15 working days. Such requests should be addressed to the DOHS.

Transportation of Infectious Materials

All potentially infectious materials that must be transported between RML and outlying facilities is packaged and transported according to applicable Federal regulations (42 CFR 72 and 73 and 49 CFR 171-178). Guidance in complying with regulations pertaining to the shipment of biological materials can be obtained by contacting the Biosafety Officer. Contact the Responsible Official prior to any shipments or transfers of biological material identified as Select Agents by the CDC and HHS.

International shipment of biological materials is coordinated through the Quarantine Permit Service Office (QPSO) at NIH so that the correct import and export documents can be issued (NIH Manual Issuance 1340-1). These shipments must be packaged and labeled according to International Air Transport Association (IATA) Dangerous Goods Regulations. Contact the NIH QPSO (qpso@mail.nih.gov) or DOHS Staff for more information.

Under no circumstances are personal vehicles to be used to transport infectious materials to or from the RML Campus. Public transportation may not be used. Only Government vehicles or commercial carrier can transport materials.

All containers used to transport infectious materials between laboratories or buildings are placed in labeled, sealed and unbreakable primary and secondary containers. The containers are labeled with stickers carrying the international biohazard-warning symbol.

Labeling

Any container used to store blood or OPIM must have a biohazard warning label affixed. Biohazard warning labels have an orange red or fluorescent orange label, the word "BIOHAZARD, and the biohazard symbol is printed on the label in a highly contrasting color such as black. The type of label may be a sticker, bag, or fixed container. Blood or OPIM is labeled with a material that cannot be easily removed or lost. Examples of containers that need to be labeled include but are not limited to the following: refrigerators, freezers, sharps-safe boxes, medical pathological waste (MPW), equipment contaminated with blood or OPIM, transportation and shipping vessels.

Decontamination and Biological Spill Cleanup

All work surfaces where blood, body fluids, infectious agents or materials are handled are disinfected daily with an appropriate disinfectant. Additionally, work surfaces are disinfected after any overt spill. Work surfaces are covered with plastic-backed absorbent toweling to facilitate clean up and reduce production of aerosols that may result from a spill. Spills within work areas are cleaned up by laboratory or research personnel. Housekeeping staff is not authorized to clean up spills of potentially infectious material in laboratories or autoclave rooms.

The basic rules for responding to biological spills in a laboratory are:

- **Conduct an Assessment** If entering a laboratory from the outside, ensure it is safe to enter. Persons in the laboratory that are unconscious can be an indication of asphyxiation, Oxygen Deficient Environment or exposure to a Central Nervous System chemical. If this is the case, Dial "0" and request RML Safety or the Hazardous Materials Response Team.
- **Tend to the injured** - ensure receipt of immediate medical care. Dial "0" or 911 if medical care is needed
- **Isolate the spill** - evacuate the immediate spill area or the entire lab/suite in the case of an aerosolizing spill. If necessary, post signs warning others of spill.
- **Dial "0"** (or (406) 363-9400 from a cell phone): for any spill that you cannot easily handle or do not have the training to handle yourself
- **Contain the spill** – wearing the appropriate protective equipment, place absorbent material around, on, or in the flow path of the spilled material if it can be done safely.
- **Clean up the spill** – as indicated. Carefully, pour disinfectant (a 1 in 10 dilution of household bleach is appropriate for most spills) around the edges of the spill working toward the center. Allow time for the disinfectant to act (10 minutes for bleach solutions). Using paper towels, wipe up the spill, working from the outside edges toward the center. Be careful to avoid cuts with broken glass. To eliminate the potential for cuts use tongs, dust pan, or some other device for pickup and carefully discard into an approved sharps container.
- **Report the spill –** as indicated**,** wait for assistance to proceed with cleanup

Standard Operating Procedures covering decontamination and spill cleanup have been developed for each biosafety level at RML. BSL-3 and BSL-4 labs have laboratory suite and pathogen specific standard operating procedures for decontamination and spill cleanup.

Infectious Waste Disposal

All infectious waste is chemically deactivated and/or autoclaved (see below). All workers must comply with the guidance given in the RML Waste Management Plan. Additional copies of this document are available from the RML Radiation Safety & Environmental Compliance Office and on RMLshare in the Hazwaste Disposal folder.

Autoclave procedures

Be sure you know how to run the autoclave before using it!

SOLID WASTE

- Place all solid waste for autoclaving in TWO red/orange biohazard bags. DO NOT OVERFILL, there is a 25 lb weight limit.
- Do not place sharps (needles, broken glass) in autoclave bags. Use a sharps container and/or broken glass box instead.
- Close the bag loosely with rubber bands or autoclave tape (steam cannot penetrate the bag if it is wrapped too tightly).
- Attach a red "**Medical Pathological Waste**" or white "**Texwipe**" sticker to each bag of waste (attach with autoclave tape since the adhesive on the sticker loses adhesiveness during autoclaving). Write your name and room number on this tag.
- Handle bags by the top. Place a shallow tray under each item to contain spills. Do not overload the autoclave.
- Use at least one Steam Sterilizer Integrator per load. Don't depend on the sterility indicator on the autoclave bag itself or autoclave tape. These only reveal that the sterilization temperature was reached but not for how long, whereas the steam sterilizer integrator will indicate that the proper temperature was reached for the proper amount of time.
- Autoclave using the proper "Waste" cycle. In the event of an equipment failure, notify the biomedical technicians. If necessary, autoclave waste in an alternate autoclave within the building.
- Always wear protective gloves when unloading autoclave.
- Stand back as door opens to avoid scalding by released steam.
- Remove autoclave bags promptly. Keep them well segregated from bags that have not been autoclaved to avoid any possible confusion.
- Once the material has been autoclaved and cooled, place in a secondary clear bag and close the clear bag so that the biohazard bag is secured inside. Transfer to the appropriate red bag waste collection point depending on the work area.
- The RML incinerator operators collect biohazardous waste from collection points and transfer it to the incinerator. In the event the incinerator is not operable, waste is collected and securely stored until it can be properly incinerated.

LIQUIDS

- Liquid waste: add small amount of appropriate disinfectant (not bleach) to each container, place autoclave tape on all items, and write "WASTE" on all items.
- Loosen caps.
- Autoclave using the proper "Liquids" cycle.
- When cycle is finished, open the door and wait at least 10 minutes before removing items to minimize the risk of explosion due to super-heated liquids.

EQUIPMENT REPAIR AND TRANSFER

All equipment which may have been exposed to hazardous materials (i.e., known hazardous chemical, radiological, or biological substances) must be appropriately decontaminated and certified as being clear of hazards, using NIH Form 2683 before transfer, service, or repair is done. These forms are available online: https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/245/NH2683.PDF and need to be printed. Included is all scientific/medical equipment and any office furniture/equipment or supplies that have been used in clinical areas, laboratories, or other potentially hazardous locations.

SECTION 4. RML OCCUPATIONAL MEDICAL SERVICE (OMS)

The following are some of the medical services provided by the RML OMS nursing staff:

MEDICAL CLEARANCE TO WORK IN A BSL-3 AND/OR BSL-4 LABORATORY

RML staff, both federal and contract workers, who work in BSL-3 or BSL-4 laboratories or have access to the critical infrastructure for those spaces must participate in the NIH Biological Surety Program (BSP, see the NIH Manual Chapter 3037 for additional details.) The BSP provides enrollment and annual medical evaluations to assure that program participants are physically and mentally capable of working safely in a BSL-3 and/or BSL-4 environment and that they have received all work-related immunizations, testing, and counseling.

MEDICAL CLEARANCE FOR DOMESTIC & INTERNATIONAL TRAVEL FOR FIELD RESEARCH

All employees who conduct field research, especially those who travel internationally, must meet with OMS for a pre-travel medical evaluation. OMS provides appropriate counseling and medical countermeasures such as immunizations, and medications. Services, including reference materials, are tailored to mitigate risk to the traveler's health based on the proposed itinerary and work activities while on travel as well as their personal health history. For field work, OMS provides general and location-specific guidance on incident response and emergency procedures in case of exposure to biohazards such as human or animal body fluid or high-consequence pathogens. OMS support for field workers includes 24/7 on-call consultation while on travel for exposures, injuries, or illnesses, for pre-stationed agent-specific postexposure chemoprophylaxis whenever possible, and administrative support for case reporting and compensation claims. Post-travel medical services include evaluations of returning travelers symptomatic for possible travel-related illnesses and risk-based measures such as monitoring protocols based on exposure potential to pathogens of concern. Travelers who return after recognized field exposures would be managed according to procedures described in Section 5.

ANIMAL EXPOSURE PROGRAM

The Animal Exposure Program (AEP) is a collection of medical services for workers who have contact with animals, their viable tissues, body fluids, wastes and living quarters. RML workers are eligible for the AEP if they participate in at least one of the following activities: 1) direct care of animals or housing; 2) direct contact with animals (live or dead), their tissues, body fluids, or wastes; or, 3) work with a zoonotic disease agent. Eligible workers must

participate in the program. Workers are required to report all bite and scratch injuries to the RML OMS nurse, their supervisor, and the Chief of the Rocky Mountain Veterinary Branch.

Tuberculosis Surveillance Program

The Tuberculosis Surveillance Program (TSP) is a medical surveillance program whose purpose is to minimize the risk of transmission of *Mycobacterium tuberculosis* to NHPs at RML by providing early detection of infection among RML workers and medical evaluation, chemoprophylaxis and referral for clinical care as indicated. Periodic evaluation is mandatory for individuals working with *M. tuberculosis* in a laboratory or working with live NHPs. TB screening is offered to employees who may be at increased risk for exposure to *M. tuberculosis* due to work-related travel to areas with high TB-prevalence.

Emergency Care

At least two OMS clinicians provide 24 hour on-call coverage for potential exposures to biologic agents studied in BSL-3 and BSL-4 laboratories with an expected response time of 15 minutes or less.

Medical Records

Occupational medical records are maintained for each worker with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records." The RML OMS nurse is responsible for generating and maintaining the required medical records. These confidential records are kept in the RML OMS nurse office (building 5, room 204) for at least the duration of employment plus 30 years.

Medical records are provided upon request of the worker or to anyone having written consent of the worker within 15 working days. Such requests should be sent to the RML OMS nurse.

Section 5. Exposure Response and Management

Exposure Response

Exposure Reporting and Management Responsibilities

- Supervisors and Principal Investigator (PIs):
    - Notifies workers of the presence of potentially hazardous materials in their workplace.
    - Assures that all suspected work-related injuries and illnesses are reported promptly to OMS.
    - Immediately notifies the Biosafety Officer (BSO) of accidents involving biological hazards.
    - Promptly notifies the Integrated Research Facility Biosafety Manager (IRFBSM) for any unexplained absence of a worker in the IRF (Buildings 25 and 28).
    - Promptly notifies the Chief Scientist of RML BSL-4 Laboratories of any unexplained absence of a worker that works in the Maximum Containment Laboratory (MCL).
- Workers:

- Must promptly report all work-related incidents, injuries, and illnesses, including those that may involve a biological hazard, to their supervisor and the RML OMS nurse.
    - Examples of injuries include inhalation, mucous membrane contamination and percutaneous exposure to potentially infectious fluids.
- During work hours (8 AM to 5 PM), the RML OMS nurse can be contacted by dialing 406-375-9600. After normal work hours or on weekends, the worker notifies their supervisor and the OMS on-call physician by dialing 301-496-1211.
- Workers who work with BSL-3 or -4 agents must report the following to the RML OMS nurse or on-call OMS physician:
    - Any febrile illness even in the absence of a recognized potential exposure. All BSL 3 and BSL4 workers are advised to obtain a thermometer and establish their baseline when healthy and at rest. Because there is no number that adequately defines the lowest cut-off for all ABSL/BSL-3/4 workers who feel ill and measure a temperature that is 1.5°F (0.8°C) above their typical baseline must contact the OMS physician immediately. To avoid obscuring a fever it is important that you do not take any medications that could prevent a febrile response to an infection. If you normally take medications that may affect your body's ability to mount a fever you must discuss this with an OMS clinician.
    - All changes in their personal health or medical treatment that may compromise their ability to work safely in a BSL-3 or BSL-4 laboratory. If unsure if a condition may compromise work safety, contact the RML OMS nurses for clarification.
- It is strongly suggested that RML workers disclose their place of employment, job duties and responsibilities to their health care provider when seeking medical attention.

- The IRFBSM:
    - Informs the RML Biosafety Officer, and the RML Associate Director, Office of Scientific Management, of the occurrence if it occurs in a BSL-3 or BSL-4 laboratory.
    - Promptly investigates the circumstances of injuries or incidents involving a potential exposure to a biohazard.
    - The IRFBSM investigates the circumstances of injuries involving a potential exposure to a biohazard, or any unexplained absences (as reported by supervisors or PIs) in the IRF (Building 25 or 28).
- The RML OMS nurse:
    - Confirms the details of the injury or incident during the evaluation of the affected worker and obtains contact information for the worker, the supervisor and PI.
    - Notifies the OMS physician of the worker's potential exposure or change in health status.
    - Provides any indicated postexposure medical measures, in consultation with the OMS physician, until the affected worker is discharged from OMS or transferred for further evaluation and specialist care

- Enters the incident into the OMS accident reporting system and issues and directs the worker to the DOL website. This will document the incident and assist the worker to receive the appropriate Workers' Compensation guidance (see the OMS Occupational Injury and Illness procedure for additional details).

- The OMS physician:
  - Interviews the worker, discusses the details of the incident with the supervisor or PI, and confers with the IRFBSM.
  - Consults with an infectious disease (ID) specialist or subject matter expert(s) in cases of potential exposure to a serious human pathogen, and with the ID specialist at Providence St. Patrick Hospital in Missoula, MT, if further evaluation and management is clinically warranted.
  - Notifies the worker of the consensus opinion of subject matter expert(s), and provides additional counseling and further medical care indicated, up to and including transfer of care to a specialist and obtains consent from the affected worker when transfer of care is recommended.
  - Directs the RML OMS nurse to facilitate additional medical management as indicated, up to and including arranging for transportation to Providence St. Patrick Hospital in cases when transfer of care from OMS to the ID specialist is recommended and accepted. Transfers patient care, if medically indicated and with the affected worker's consent, to the accepting ID specialist at Providence St. Patrick Hospital (physician-to-physician transfer of care), from OMS care.
  - Informs the DOHS Director of the incident and the consensus estimate for the risk of exposure and whether transfer of care is recommended and confirms that the responsible staff in the NIH Office of Communications and Public Liaison is contacted. Informs the Associate Director for Scientific Management at RML of the occurrence of the incident.
  - Notifies the Ravalli County Public Health Officer of any incident with an estimate of "elevated risk of exposure" to an agent of public health concern, or when the affected worker is transported to Providence St. Patrick Hospital and provides details relevant to public health concerns while safeguarding the protected worker's protected health information.

Response for Biohazard Exposures Requiring Immediate Medical Attention

First aid is administered immediately at the workplace for all injuries that may involve a biological hazard.

- Contaminated skin wounds are irrigated and scrubbed with soap and water or povidone-iodine or chlorhexidine for 15 minutes.
- Contaminated eyes or mucous membranes are irrigated for 15 minutes with normal saline or water.

The injured/exposed worker immediately initiates first aid and alerts the supervisor or PI of the injury or illness. The supervisor or PI notifies the OHSM/IRFBSM of the injury or incident and directs the worker to proceed to the OMS nurse. The OHSM/IRFBSM complete the Exposure Risk Assessment Guide, attached in Appendix 3. If the supervisor or PI is not immediately available, the worker completes first aid and proceeds directly to the RML OMS nurse. If the supervisor or PI cannot be located and notified immediately, the OMS nurse notifies the OHSM/IRFBSM. After normal work hours or on weekends, the worker calls OMS on call service by dialing 301-496-1211. If emergency

assistance is needed after hours, the worker either dials 911 or notifies the RML Security Control Center (SCC) by dialing "0".

If the RML OMS nurse is not confident that the first aid was administered properly the nurse repeats the first aid. (See the OMS Wound Care Guidelines procedure for additional details.) The nurse quickly obtains information of the circumstances of the incident and a targeted medical history from the affected worker, and reports these to the OMS physician.

The OMS physician confirms the worker's history and consults with the supervisor or PI as well as the IRFBSM. If the physician suspects that the worker may have sustained a clinically significant exposure to a biohazard, the physician consults with clinical subject matter expert(s), e.g. an ID specialist at Providence St. Patrick Hospital. If the affected worker sustained a potential exposure to a human pathogen (see Exposure Risk Assessment Guide, Appendix 3, for risk of exposure estimates of "High/moderate" or "minimal" risk, , and a clinical evaluation by a local ID specialist, up to and including transfer to the Regional Referral Hospital (Providence St. Patrick Hospital, Missoula, MT) may be indicated, the OMS physician consults with the on-call ID specialist at Providence St. Patrick Hospital and transfers clinical responsibility for the worker to the designated ID specialist at Providence St. Patrick Hospital to the accepting specialist for further medical care. The post-exposure risk assessment and the decision to consult with the local ID specialist for possible transfer of the worker's typically occurs within an hour from the time the incident is reported to the RML OMS nurse. When an RML researcher reports a suspected case of occupational illness involving a RG3 or RG4 agent the same principles of risk assessment and medical management apply.

Once the ID specialist at Providence St. Patrick Hospital accepts the case, he or she takes appropriate steps to prepare for the arrival of the injured or ill worker and alerts the Missoula County Public Health Officer of the incident or case. The OMS physician notifies the affected worker and the RML OMS nurse of the ID specialist's acceptance of the case.

If the incident involves a potential exposure to NHP body fluid, the OMS physician determines whether the worker should initiate post exposure prophylaxis with valacyclovir stored in the NHP bite-scratch kit and consults with the Chief of the RML Veterinary Branch, or their designee, on the need to obtain specific diagnostic samples.

Immediate first aid is critical in post exposure management to NHP body fluids. The worker should immediately stop what task they are performing, notify a co-worker of what happened, safely remove any PPE per protocol or exit the lab via chemical shower, and begin first aid. As soon as possible the exposed worker should contact an OMS physician, by calling OMS main line 301-496-4411 or after hours at 301-496-1211 for a telephonic assessment. This will allow the worker to receive post exposure prophylaxis as soon as possible. Immediately after the OMS physician has been notified, the worker is to report to RML OMS.

Response for Biohazard Incidents That Do Not Require Immediate Medical Attention

The worker immediately alerts the supervisor or PI of the incident. Incidents may include:

- An obvious release of infectious material or infected animals. For this purpose, a release is considered to be any loss of material outside of primary containment.
- Failure of biocontainment facilities or equipment.
- Failure to execute proper biosafety practices and procedures.

The Supervisor or PI immediately notifies the OHSM/IRFBSM of incidents involving biological hazards. The OHSM/IRFBSM investigates the incident and completes the Exposure Risk Assessment Guide (see Appendix 3). The

OHSM/IRFBSM notifies the RML OMS nurse of the incident and sends the Exposure Risk Assessment Guide to the RML OMS nurse for review and signature. Once reviewed by the RML OMS nurse, the OMS physician reviews and signs the guide. If an incident is deemed negligible/no risk, a worker does not require OMS services, but is offered evaluation. If additional information is required for OMS review of the incident, they directly contact the worker(s) involved in the incident. A worker whose level of risk of exposure to a high-consequence pathogen (e.g., RG3, RG4, or lentivirus) is estimated at any level of risk of other than "no risk" is instructed to contact OMS for an evaluation immediately. During RML OMS clinic hours the worker is directed to see the RML OMS nurse. If the incident occurs after normal work hours or on weekends, workers call OMS on call service by dialing 301-496-1211.

The nurse quickly determines the circumstances of the incident and obtains a targeted personal medical history from the injured worker and then alerts the OMS physician of the incident. The OMS physician proceeds as described above in the "Emergency Medical Response for Biohazard Exposures".

Response to Biohazard Incidents while Performing Field Work

First aid is administered immediately at the worksite for all injuries that may involve a biological hazard.

- Contaminated skin wounds are irrigated and scrubbed with soap and water or povidone-iodine or chlorhexidine for 15 minutes.
- Contaminated eyes or mucous membranes are irrigated for 15 minutes with normal saline or water.

The injured/exposed worker immediately initiates first aid and alerts the supervisor or PI of the injury or illness. As soon as practical, the injured/exposed worker notifies OMS of the incident. Immediate medical treatment, if needed, should be sought in the local area. Follow-up with OMS is required for all incidents that occur while performing field work.

Response to Illnesses Suspicious for Exposure While Performing Field Work

Worker must isolate from others, including don a surgical mask for any respiratory symptoms. Notify onsite supervisor or responsible senior staff to initiate illness response for field workers. Call OMS on-call provider for risk assessment and to discuss available countermeasures available on location.

Post-Exposure Clinical Evaluation and Follow-up

The ID specialist at Providence St. Patrick Hospital serves as medical consultant to OMS or attending physician in emergency management, short-term care, and follow-up of workers who sustained a potential occupational exposure to a RG3 or RG4 pathogen or who experience a change in health status compatible with a LAI due to an RG3 or RG4 agent. The ID specialist at Providence St. Patrick Hospital reviews the circumstances of the exposure or presenting illness, evaluates the worker, and develops an appropriate plan for further clinical evaluation and treatment.

If required, worker counseling is provided through the Employee Assistance Program (EAP). The NIH EAP has affiliate providers in Montana. RML workers schedule EAP appointments by calling 1-301-496-3164.

Post-Exposure Incident Review

In the event a worker sustains a potential exposure to an infectious agent, the Biosafety Officer or the IRFBSM as well as the worker's supervisor reviews the incident. In certain cases, the review will involve members of the Biological Exposure Assessment Program (BEAP), (see below). An incident report will be entered in the PI Dashboard Injury Log by DOHS and will include a description of the incident, notifications made to appropriate entities (see below), and necessary follow-up measures. As part of the incident review, a Sharps Injury Log is maintained for recording percutaneous injuries and mucous membrane exposures. The log contains information on the type and brand of device involved in the incident; the department and work area where the incident occurred; and an explanation of how the incident occurred. The log is maintained by the Biosafety Officer and used to gather information that may aid in the implementation of safer technologies. The information in the sharps injury log is recorded and maintained in such manner as to protect the confidentiality of the potentially exposed worker.

All work-related needlestick injuries and cuts from sharp objects that are contaminated with potentially infectious material (as defined by 29 CFR 1910.1030) is entered in the OSHA 300 Log as an injury using the OSHA 301 Injury and Illness Incident Report and marked as a Privacy Case. All required records are kept for a minimum of five (5) years following the end of the calendar year that the records cover.

Incident Reporting

On the discovery of a theft, loss or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the containment area) of a select agent or toxin, laboratory personnel must immediately notify the RML Select Agent Program. The RO/ARO will immediately notify appropriate law enforcement agency(ies) and the CDC DSAT of such an incident, as stipulated in 42 CFR 73.19. A CDC/APHIS Form 3 will be submitted by the RO within 24 hours of the discovery and submitted to the CDC Select Agent Program within 7 calendar days.

Incidents involving research subject to the NIH Guidelines must immediately be reported to biosafety staff. Incidents with recombinant material must be reported to NIH Office of Science Policy (OSP) within 30 days for any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses. Spills or accidents in BSL-2 laboratories resulting in an overt exposure must be reported immediately. Incidents occurring in BSL-3 or BSL-4 laboratories resulting in an overt or potential exposure must be immediately reported. According to the NIH Guidelines, it is the responsibility of RML, IBC, BSO, and Principal Investigator to report incidents. At RML, all incidents are reported to OSP by biosafety staff according to the OSP reporting requirements.

Exposure Management

Biological Exposure Assessment Program (BEAP)

The BEAP has been established to evaluate possible exposures or illnesses related to the use of infectious agents or research animals at RML. The membership of the BEAP includes relevant stakeholders from RML, NIAID DIR, DOHS, local public health officials, and relevant subject matter experts. The mission of the BEAP is to provide timely assessment of biological incidents, or work-related exposures or illnesses; to make appropriate notifications; to evaluate any risk or threat to lab operations, workers, facilities, the public or the environment; to draft an incident report, follow-up plan and corrective action plan; and to devise timely and factual communication processes.

Membership of the BEAP

The following individuals are the members of the RML BEAP assigned to the RML campus:

- The RML Associate Director for Scientific Management
- The RML Associate Director for Operations Management
- The RML DOHS Safety Manager/Responsible Official for Select Agents and Toxins
- The Biosafety Officer
- The RML OMS nurse
- The Safety Officer
- The ID specialist from Providence St. Patrick Hospital
- The relevant PI(s) or supervisor(s)
- The relevant Laboratory Chief(s)
- The Chairperson of the Institutional Biosafety Committee
- The Chief Scientist for RML BSL-4 Laboratories (if the incident involves a BSL-4 issue)
- The IRF Biosafety Manager
- The RML Communications and Public Liaison Officer
- The RML Emergency Preparedness Coordinator
- The RML Emergency Manager
-

The following individuals are the members of the RML BEAP assigned to the Bethesda NIH campus:

- The Director of the NIAID Division of Intramural Research (NIAID DIR)
- The Director of the NIH Division of Occupational Health and Safety (NIH DOHS)
- The responsible OMS physician
- The Chief of the DOHS Biorisk Management Branch

The following individuals will be notified, consulted and/or added to the RML BEAP as needed on an ad hoc basis. Additional members must be approved by DOHS/OMS prior to any meetings of the BEAP

- The Chief of the Rocky Mountain Veterinary Branch
- The leader of the RML Hazmat Team
- The RML Emergency Preparedness Coordinator
- The RML Radiation Safety Officer
- The Ravalli County Health Officer
- Ravalli County Public Health Nursing Department
- External subject matter experts
- The worker sustaining the exposure

OPERATIONS OF THE RML BEAP

The Exposure Response Plan and the specific SOPs for particular infectious agents dictate the obligations for RML workers to report biological incidents, potential exposures and/or possible work-related infectious diseases. These incidents may become evident in several ways:

- Obvious release of or exposure to infectious materials or infected animals. For this purpose, a release is considered to be any loss of material outside of primary containment.

- Exposure to research animals or their blood/body fluids (i.e. non-human primates at risk for transmitting Herpes B virus)
- Recognition of unexplained febrile illness (defined as a temperature that is 1.5°F (0.8°C) above the employee typical baseline), even in the absence of an obvious exposure but with onset of illness after working with an infectious agent that is within the incubation period of the infectious agent of concern.
- An illness consistent with work-related illness in the absence of any obvious exposure as reported by an RML worker, RML visitor, or his/her health care provider. (NOTE: The State of Montana requires all Montana health care providers to report patients diagnosed, or suspected, with any reportable disease to their county health departments.)
- Failure of biocontainment or failure to execute proper biosafety practices and procedures with or without potential for exposure.
- Identification of a possible work-related reportable disease by the Ravalli County Public Health Nursing Department

CONVENING THE BEAP AND RELATED NOTIFICATIONS

- An incident that involves a potential exposure or illness resulting from a BSL-3 or BSL-4 agent triggers a meeting of the BEAP if the final exposure risk classification on the Exposure Risk Assessment Guide (See Appendix 3) classifies the risk as "High/Moderate" or "minimal" or the incident results in transport of the individual(s) to Providence St. Patrick Hospital. The BEAP is not required to convene but may be convened if the risk is classified as "Negligible/No Risk".

- DOHS, OMS, and the Associate Director for Scientific Management, determine whether to convene the BEAP for incidents that involve an exposure or illness resulting from a BSL-2 agent.

- The BEAP reviews the incident and evaluates measures already taken or proposed to deal with the incident, consulting with external subject matter experts as needed.

- The BEAP determines the need for internal and external notifications and develops a communication strategy.

    - In the event of any potential exposure in BSL-3 or BSL-4 areas or release of BSL-3 or BSL-4 agents, the OMS physician notifies the Ravalli County Public Health Officer and the head of the Ravalli County Public Health Nursing Department. The OMS physician can delegate the RML Associate Director for Scientific Management to notify public health officials if needed. The County Health Officer and the ID Specialist evaluate the need to notify the public and local or state governmental officials.

    - The Responsible Official for the RML Select Agent Program notifies the CDC Division of Select Agents and Toxins in the event of any Select Agent release or exposure, and also completes and submits a "Report of Theft, Loss or Release of Select Agents and Toxins" form (APHIS/CDC Form. 3) within 7 calendar days of the incident.

    - The ICS Liaison Group will be notified and for any incidents involving select agents, this notification must come from the Responsible Official (RO). For incidents not involving select agents, this notification may be made by the Liaison Officer.

    - The RML BEAP, in conjunction with the NIAID/NIH Office of Communication and Government Relations, prepares, approves, and releases any news statements or social media communications.

    - Notification may include convening a special meeting of the RML Community Liaison Group.

- The BEAP assesses any immediate threat or risk to laboratory operations, workers, facilities, the public and the environment, and identifies measures necessary to address, abate, or mitigate any residual or ongoing threat or risk. This will include determining the level of decontamination or any interruption of operations that might be required.
- The BEAP determines the need to collect and quarantine any samples of potentially infectious materials involved in the incident, or to stop laboratory operations in the affected area.
- In the event the incident is related to work with experimental animals, the BEAP determines the need to collect and quarantine any live animals, animal sera, secretions or tissue samples for future analysis.
- The BEAP continues to meet as necessary to monitor the incident, investigate the cause of the incident, and evaluate additional recommendations and other measures needed to resolve the incident, provide for all appropriate internal and outside notifications, and implement remedial or corrective actions.
- The Biosafety Officer, IRF Biosafety Manager, or DOHS Safety Manager/RO works with the relevant staff to develop a corrective plan to prevent future incidents.
- The OMS Physician, in consultation with the ID specialist Providence St. Patrick Hospital, and local county health officer(s), advises the BEAP if observation of close contacts, family members or others is warranted.
- In the event that it is determined that an incident poses a potential public health hazard, the Ravalli County Health Officer and the Ravalli County Public Health Nursing Department will be notified. The specific management of perceived or actual public health hazards is the province of the Ravalli County Public Health Nursing Department and the Ravalli County Health Emergency Advisory Team (HEAT). The role, membership, and methods for convening the HEAT are contained in Tab 5.50 of the Ravalli County Emergency Operations Guidelines. The HEAT team is the first group convened in the event of an actual or perceived public health emergency and will advise local emergency responders in their response to an incident.
- RML/NIH cooperates with state and local officials in responding to any incident arising at RML that the BEAP determines poses a public health hazard. Assistance is provided whether the incident arises from possible exposure of a worker or a visitor. Both state and local officials have authority over public health matters. While the NIH is restricted under Federal law from agreeing to pay expenses in advance or providing any full indemnification to affected individuals and is limited by the Privacy Act in the amount of personal medical information that it can provide, RML/NIH provides full technical assistance to state and local officials in responding to any such incidents and in ensuring that the public health and the health of any potentially affected individuals are protected. While no local or state health agency has indicated that it will seek reimbursement from the NIH for expenses that might result from responding to public health incidents arising from potential exposures of individuals at the RML, the NIH may explore possible mechanisms for reimbursing state and local agencies for any such expenses that arise.
- If deemed necessary, the RML Incident Command System is activated. RML has an Incident Management Team (IMT) that can assist in managing the incident if it is beyond the capability of the Biosafety Officer or the BEAP.

- The BEAP meetings will be run under the ICS framework but will not utilize the Incident Management Team (IMT). The participants will only include those members listed above or ad hoc members approved by DOHS/OMS.
- The RML Emergency Preparedness Coordinator will facilitate the planning and execution of the meeting(s). This will include organization of a pre-meeting briefing with the IC staff (listed below) and Liaison Officer to review the agenda, finalize scheduling, etc.
    - The DOHS Safety Manager or designee will serve as the Incident Commander.
    - The RML Emergency Preparedness Coordinator will serve as the Planning Section Chief.
    - The Associate Director for Scientific Management will serve as the Liaison Officer.
    - The Associate Director for Operations Management will serve as the Operations Section Chief.

- The RML Associate Director for Scientific Management is a Core Member of the Ravalli County HEAT (see below). In the event that the HEAT is activated for an incident or illness in the community, the Associate Director for Scientific Management, in consultation with DOHS and OMS, determines the need to convene a meeting of the BEAP.

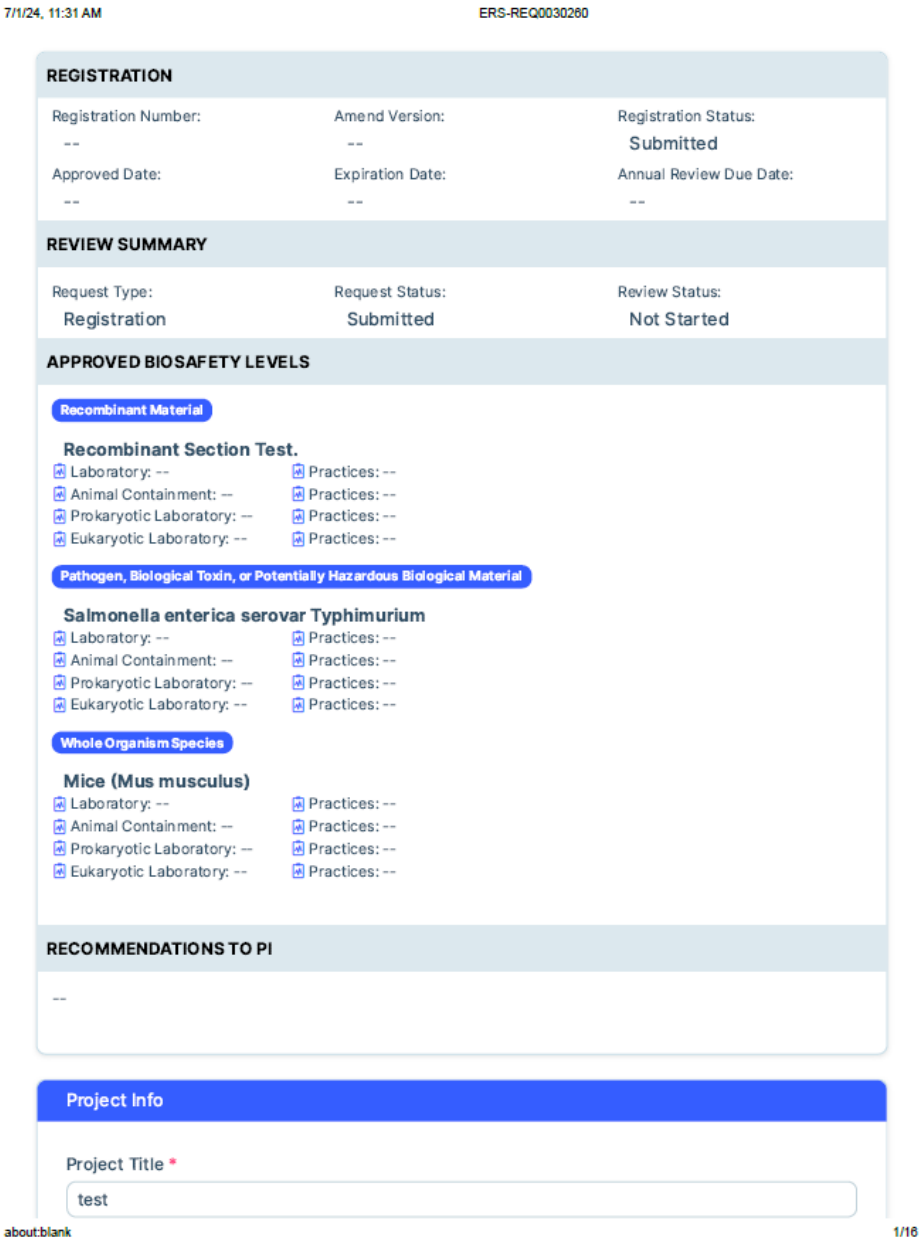
MEETINGS OF THE BEAP

- The BEAP meets as needed as outlined above.
- Meetings are convened by the RML Associate Director for Scientific Management as directed by the Incident Commander and Emergency Preparedness Coordinator.
- The RML Emergency Preparedness Coordinator facilitates the RML BEAP meetings. In the absence of the Emergency Preparedness Coordinator, the Associate Director for Scientific Management or Associate Director for Operations Management facilitates the meeting. A sample agenda is attached as Appendix 2The RML Emergency Preparedness Coordinator and DOHS/OMS maintains all records, correspondence, and BEAP meeting notes.
- The Biosafety Officer, the IRF Biosafety Manager, or the DOHS Safety Manager/RO with the assistance of others as needed, is responsible for preparing a post-exposure incident review on each incident. This report, at a minimum, contains a description of the incident, all measures taken to deal with the incident, and all recommendations implemented to prevent a recurrence. The BEAP reviews and approves this report. The review is forwarded to the proper officials and authorities.
- In the event that the incident involves a Select Agent, the Responsible Official for the RML Select Agent Program must complete and submit an immediate notification to DSAT within 24 hours and a final “Report of Theft, Loss or Release of Select Agents and Toxins” form (APHIS/CDC Form 3) to DRSC within 7 calendar days.
- The Biosafety Officer or the IRF Biosafety Manager provides a summary of any incident to the RML Institutional Biosafety Committee at the next scheduled meeting.

SECTION 6. APPENDICES

Appendix 1: Registration Document

Contact the BSO for a full copy of the registration document.



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REGISTRATION

Registration Number:	Amend Version:	Registration Status:
--	--	Submitted
Approved Date:	**Expiration Date:**	**Annual Review Due Date:**
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REVIEW SUMMARY

Request Type:	Request Status:	Review Status:
Registration	Submitted	Not Started

APPROVED BIOSAFETY LEVELS

Recombinant Material

Recombinant Section Test.

- Laboratory: -- Practices: --
- Animal Containment: -- Practices: --
- Prokaryotic Laboratory: -- Practices: --
- Eukaryotic Laboratory: -- Practices: --

Pathogen, Biological Toxin, or Potentially Hazardous Biological Material

Salmonella enterica serovar Typhimurium

- Laboratory: -- Practices: --
- Animal Containment: -- Practices: --
- Prokaryotic Laboratory: -- Practices: --
- Eukaryotic Laboratory: -- Practices: --

Whole Organism Species

Mice (Mus musculus)

- Laboratory: -- Practices: --
- Animal Containment: -- Practices: --
- Prokaryotic Laboratory: -- Practices: --
- Eukaryotic Laboratory: -- Practices: --

RECOMMENDATIONS TO PI

--

Project Info

Project Title *

test

about:blank 1/16

Field description

Principal Investigator *

0013793925 / Rebecca Anderson (ORS)

Search by NED ID, First Name or Last Name

Description

Please provide a brief summary of the purpose and aims of your proposal. *

test

Lay/plain language is strongly encouraged here. Please spell out abbreviations.

Please highlight the background and rationale of this study. *

test

Please spell out abbreviations.

What is the estimated start date of your project? (Please use the comment function to identify other important information regarding timing, and to give IRB # and/or the IND #, if applicable) *

04/16/2024

MM/DD/YYYY

Researchers

Name	Email	Phone

Locations

Site	Building	Room	Room Type
Rocky Mountain Labs Campus	RML 31	31217A	LAB

Research Type

Are you proposing a gene transfer study in humans? *
- ○ Yes
- ◉ No

Are you proposing work with recombinant or synthetic nucleic acids? *
- ◉ Yes
- ○ No

Are you proposing work with a pathogen, biological toxin, or potentially hazardous biological material? *
- ◉ Yes
- ○ No

This also includes work with **human cell lines** and **any viral vectors** (e.g. lentiviral, retroviral, adenoviral).

Will live multicellular organisms (e.g. animals, arthropods, aquatic species, nematodes, plants) be used in this project? *
- ◉ Yes
- ○ No

Are field studies included in this project? *
- ○ Yes
- ◉ No

Recombinant Section Test. - Recombinant Material Details

What protein(s) and/or siRNAs targeting proteins are being expressed? Please define abbreviations. *

Recombinant Section Test.

Including recombinant or synthetic nucleic acids.

Describe the biological functions, if known, of the gene(s) or sequence(s) being studied, modified, or inserted. *

test

Describe how the recombinant or synthetic nucleic acids will be used. *

test

What is the biological origin of the sequences that will be modified or expressed? *

- ☐ human
- ☐ animal
- ☐ aquatic species
- ☐ plant
- ☐ arthropod
- ☐ fungus
- ☐ bacterium
- ☑ virus
- ☐ yeast
- ☐ other
- ☐ N/A

Multiple selections allowed.

Please list each recombinant vector that will be used AND it's purpose or vector type.

test

Please use the format of [plasmid name] - [type] | Some vector type examples are (not exhaustive): Expression plasmid, Transfer plasmid, Packaging plasmid, Envelope plasmid

Indicate the recombinant construct (e.g. plasmid) category/ies used. *

- [x] Basic cloning
- [ ] Bacterial expression
- [ ] Bacterial recombination
- [ ] Eukaryotic expression
- [ ] Eukaryotic recombination
- [ ] Bacterial/yeast artificial chromosome
- [ ] Gene editing
- [ ] Viral full-length clone or equivalent
- [ ] Viral vector
- [ ] Other
- [ ] N/A

Multiple selections allowed.

If you are working with viral rDNA, what percent of the viral source genome will be cloned into your recombinants? *

- (•) Less than 60 %
- ( ) Greater than 60 %
- ( ) N/A

If needed, please further describe the percent of source viral genome that will be cloned into your recombinants.

test

Indicate how the recombinant molecule(s) is being created. *

- [x] Obtained outside NIH
- [ ] Obtained from NIH collaborator
- [ ] Obtained from NIH core service
- [ ] Created in lab

Multiple selections allowed.

Please describe how the recombinant molecule(s) you are using are being created and the company or laboratory who created it. *

test

What is the duration of the protein or nucleic acid expression? *

- (•) Stable
- ( ) Transient
- ( ) Not Applicable

If a viral vector is to be used, will an infectious virus be generated (including replication incompetent viruses)? *

- (•) Yes
- ( ) No
- ( ) N/A

Will studies include cloning of a toxin molecule with a LD50 of less than 100 nanograms per kilogram body weight? *

- ( ) Yes
- (•) No

Has this vector been used previously in human gene transfer or therapy products? *

(●) Yes ( ) No ( ) N/A

Recombinant Section Test. - Recombinant Material Handling Risks

Discuss integration or expression risks to workers. If none, please explain. *

test

What will the expression product be exposed to in this study? *

- [ ] Plant cells
- [x] Animal cells/sera
- [ ] Cell lines
- [ ] Whole organisms
- [ ] Other

Multiple selections accepted.

Describe "other" exposure type.

test

Does this work involve the use of gene drive modified organisms? *

( ) Yes (●) No

Gene drives are genetic elements that are transmitted to progeny at super-Mendelian (>50%) frequencies, ultimately becoming the dominant/only gene in the population.

Which NIH Guidelines section(s) best applies to the proposed research? * **read more**

- [ ] III-A
- [ ] III-B
- [ ] III-C
- [x] III-D
- [ ] III-E
- [ ] III-F

Multiple selections accepted.

Recombinant Section Test. - Recombinant Prokaryotic Cell Work

Are you proposing work with prokaryotic cells, including nonpathogenic strains? *

(●) Yes ( ) No

E.g. E. coli.

What prokaryotic host(s) will you use in this project? Pathogenic prokaryotic hosts must also be described in the previous section. *

- [ ] E. coli
- [ ] B. subtilis
- [ ] commensal bacteria
- [x] non-pathogenic bacteria
- [ ] pathogenic bacteria
- [ ] other

Multiple selections accepted.

If necessary, describe the prokaryotic host(s) will you use in this project.

test

Describe your experiment, identifying the objectives of the work. *

test

What is the proposed prokaryotic work biosafety level? (Select one option) * **read more**

○ BSL 1 ◉ BSL 2 ○ BSL 2/3 ○ BSL 3 ○ BSL 4

Recombinant Section Test. - Recombinant Eukaryotic Cell Work

Are you proposing work with eukaryotic cells? *

◉ Yes ○ No

Indicate cell types that will be used. *

- ☑ Established human cell line
- ☑ primary human cells
- ☑ established nonhuman primate cells
- ☑ primary nonhuman primate cells
- ☐ animal cells
- ☐ insect cells
- ☐ plant cells
- ☐ yeast
- ☐ fungi
- ☐ protozoa
- ☐ other

Multiple selections accepted.

Describe the eukaryotic cell experiment(s). *

test

What is the proposed eukaryotic work biosafety level? (Select one option) * **read more**

○ BSL 1 ◉ BSL 2 ○ BSL 2/3 ○ BSL 3 ○ BSL 4

Salmonella enterica serovar Typhimurium - Pathogen, Biological Toxin, or Potentially Hazardous Biological Material Details

What organism or toxin will you be using? (Click "Search" button to begin) *

Salmonella enterica serovar Typhimurium

What is the strain, genotype or catalog number? (If not applicable, write N/A) *

test

Will you be working with a volume greater than 10 Liters? (If yes, please leave a comment.) *

○ Yes ◉ No

What types of human or nonhuman primate body fluids or tissues will be manipulated, if any? (Select all that apply) *

☑ Blood	☐ Urine	☐ Spinal Fluid	☐ Tissues
☐ Serum	☐ Feces	☐ Semen	☐ Cells
☐ Eggs	☐ Other	☐ Not Applicable	

Note: Work with any human cell lines must be indicated here by selecting 'Cells' - this includes items such as established cell lines, primary cells, etc.

Is this agent a biological toxin? *

○ Yes ◉ No

Will resultant organism be antibiotic resistant? *

○ Yes ◉ No ○ N/A

Will resistance to this compound(s) affect treatment in the event of a workplace exposure? *

○ Yes ◉ No

Please describe immunization, pre-exposure prophylaxis, and/or post-exposure treatment available for this agent. *

test

Is a permit required from the CDC, USDA or FDA for acquiring or working with this agent? If "Yes," please upload permit(s) to Supporting Documents. *

○ Yes ◉ No ○ N/A

Will your agent be radiolabeled? *

○ Yes ◉ No

Agent is pathogenic (or toxic) to: (Select all that apply) *

☑ Humans ☑ Animals ☐ Plants ☐ Other ☐ N/A

Salmonella enterica serovar Typhimurium - Pathogen, Biological Toxin, or Potentially Hazardous Biological Material Handling and Storage

With which techniques will you manipulate your samples? (Select all that apply) *

☐ Aerosolization	☑ Cell Sorting	☑ Centrifugation	☐ Blending/Mixing
☐ Dissection	☑ Sonication	☑ Pipetting	☐ Other

This agent will be concentrated using the following: *

- [ ] Will Not Be Concentrated
- [x] Centrifugation
- [ ] Filtration
- [ ] Precipitation
- [ ] Other

What containment equipment will be available? (Select all that apply) *

- [ ] BSC Class I
- [x] BSC Class II
- [ ] BSC Class III
- [ ] Chemical Fume Hood
- [ ] Containment Centrifuge
- [ ] Other

Specify how agent will be inactivated prior to other laboratory manipulation. *

- [x] Not Inactivated
- [ ] Heat
- [ ] Chemical
- [ ] Radiation
- [ ] Other

Multiple selections accepted.

Please indicate disinfectants that will be available for decontamination. *

- [ ] Chlorine solutions (e.g. bleach, Clidox)
- [ ] Alcohols
- [ ] Iodophors
- [ ] Peroxides
- [ ] Phenolic Compounds
- [x] Quaternary Ammonium Compounds
- [ ] Other

Multiple selections accepted.

Identify refrigerator and freezer location(s) not already indicated that will be used to store this agent. *

test

Use [building #]/[Room #]

What is the primary method for tracking samples/inventory? *

- ( ) Paper
- ( ) Digitized spreadsheet
- (•) Electronic database

Salmonella enterica serovar Typhimurium - Prokaryotic Cell Work (Pathogen, Biological Toxin, or Potentially Hazardous Biological Material)

Does work with this agent involve prokaryotic cells? *

- (•) Yes, I have additional details
- ( ) Yes, all details described in Recombinant DNA section
- ( ) No, I am not performing prokaryotic work

If necessary, describe the prokaryotic host(s) will you use in this project. *

test

APPENDIX 2. SAMPLE RML BEAP AGENDA

Rocky Mountain Laboratories
Biological Exposure Assessment Program Meeting
Date

SAMPLE AGENDA

1. Attendance – on site and by phone

2. Incident Summary
    a. Reminder of procedures to protect PHI during discussions
    b. Summary of incident – DOHS/Biosafety

3. Summary of case management – OMS
    a. What is the likely illness or agent:
    b. How was diagnosis made and by whom? – OMS
    c. Current status of the staff member? – OMS
        i. i. Is person in self-quarantine? Yes/No
        ii. ii. Is person in a medical facility? Yes/No
        iii. iii. Is person showing signs or symptoms? Yes/No
    d. Is the staff person an employee or contractor:
    e. Are there other considerations related to the staff member?

4. Notifications (see Incident Notification System in ECP)
    a. NIAID DIR,
    b. NIH DOHS,
    c. NIH OSP (if recombinant agents involved)
    d. Ravalli County Public Health Dept and Health Officer
    e. Montana Dept Health and Human Services
    f. Internal RML notifications – Hot Line, email and Intranet
    g. CDC, completion of DSAT CDC/APHIS Form 3
    h. RML CLG- special meeting?
    i. Review RML Incident Notification Scheme

5. Evaluation of threat or risk to lab operations, workers, facilities, the public, environment
    a. Need to collect or quarantine lab samples
    b. Need to quarantine animals and/or collect sera, secretions, or tissues for future analysis
    c. Need to observe additional workers, contacts or family members

6. Drafting of post-exposure incident report and corrective action plan
    a. Report to IBC at next meeting

7. Development of communication instruments and strategy
    a. NIAID/RML news statement-proactive vs. reactive
    b. Coordination with Providence St. Patrick Hospital
    c. Strategy for media interactions

8. Other

9. Schedule follow-up meeting

APPENDIX 3. INJURY AND EXPOSURE RISK ASSESSMENT GUIDE

Safety Incident Investigation Report			
Date	**Location**	**Brief Synopsis**	
Report by:		**Agent Involved**	☐ Yes ☐ No
Report Detail: *(Provide a description of the incident. This should include a timeline of the incident, the agent/animal worked with, PPE worn, description of procedures conducted at the time of the incident, notifications made, follow-up procedures for decontamination and program improvement, and results of root cause analysis. Attach additional sheets if necessary.)*			

National Institutes of Health – Division of Occupational Health and Safety

BioRisk Management Program

Exposure Risk Assessment Guide

Instructions: Complete the following risk assessment guide, in consultation with the Biosafety/High Containment Safety Manager or designee and OMS clinician, following any work-related incident with a potential exposure to an infectious agent or toxin in a biosafety level 3 or 4 laboratory (BSL 3/ABSL 3/ BSL 4/ABSL 4), hereafter referred to as bioagent. Potential exposure is defined as an incident in which a worker may have contact with a bioagent, for example by percutaneous injury, cutaneous and mucous membrane contamination, inhalation, or ingestion. Both of the following conditions must be met to result in an occupational exposure:

1. A bioagent must be present (in source material or relevant space, e.g., release from primary containment, BSC).
2. The person was not appropriately protected such that a breach in personal protective equipment (PPE) or innate protection (for example intact skin) resulted in a potential exposure (for example by percutaneous injury, cutaneous and mucous membrane contamination, inhalation, or ingestion) to the bioagent.

Select the applicable categories below (more than one may apply) and circle the associated exposure risk classifications in the right column. Assign the final exposure risk classification as the highest level of any of the applicable categories. If there are any factors that increase or mitigate the risk and justifies a different risk classification, provide details in the Notes section. If the incident involved more than one bioagent and the exposure risk classification differs, specify each agent and the associated risk classification in the Notes section.

A. INCIDENT SETTING

Date (MM/DD/YY): _____ Time: _____

Location: ☐ Bethesda ☐ IRF-RML ☐ IRF-Frederick Building: _____ Room/Area: _____

Biosafety Level: ☐ BSL-3 ☐ ABSL-3 ☐ BSL-4 ☐ ABSL-4 ☐ Other: _____

B. AGENT/SOURCE MATERIAL

I. AGENT INFORMATION ☐ N/A

Agent(s) present: ☐ Yes ☐ No

If No, continue to section ANIMAL INFORMATION

Select agent(s) present: ☐ Yes ☐ No

Agent (s) _____

_____

☐ Culture ☐ Solution ☐ Body fluid ☐ Frozen ☐ Dried

☐ Other: _____

Agent likely to be aerosolized: ☐ Yes ☐ No

Prior inactivation/decontamination: ☐ Yes ☐ No ☐ N/A

II. ANIMAL INFORMATION ☐ N/A

Species: _____

_____

Animal ID/Cage #_____

Nonhuman primate (NHP) involved: ☐ Yes ☐ No

Species: _____

Old World NHP: ☐ Yes ☐ No

If Yes, date of last herpes B test: _____

Result: ☐ positive ☐ negative

Body fluid/tissue involved:

☐ Blood ☐ Saliva ☐ Tears ☐ Urine [☐ Feces ☐ CSF

[ ] Other: _____

C. EXPOSURE CATEGORY (Complete all that apply) — RISK CLASSIFICATION

I. PERCUTANEOUS INJURY (CUT, PUNCTURE, ABRASION) ☐ N/A

A. Sharp Instruments or Objects:

☐ Needlestick
- ☐ Hollow-bore needle (may contain more source material)
- ☐ Suture needle (typically solid)
- ☐ Other needle: _____

☐ Scalpel

☐ Broken glassware/lab equipment

☐ Other Sharp: _____

B. Animal Bite or Scratch:

☐ Bite

☐ Scratch

1.	☐ Did not occur in the presence of agent(s) or an animal infected with any agent(s).	NO RISK
2.	☐ Involved sterile instrument or medium, or body fluid/tissue of an animal free of infection (naïve to experimental agents, free of natural infections) but in the presence of agent(s).	NEGLIGIBLE
3.	☐ Involved likely non-viable agent(s) or body fluids/tissue of an infected animal unlikely to contain viable agent(s).	MINIMAL
4.	☐ Involved likely viable agent(s) or body fluid/tissue of an infected animal likely to contain viable agent(s).	HIGH/MODERATE
II.	**MUCOSAL CONTAMINATION** (CONTACT OF LIQUID OR SOLID WITH EYE OR MUCOUS MEMBRANE) ☐ **N/A**	
1.	☐ Did not occur in the presence of agent(s) or an animal infected with any agent(s).	NO RISK
2.	☐ Involved sterile medium or body fluid/tissue of an animal free of infection (naïve to experimental agents, free of natural infections) but in the presence of agent(s).	NEGLIGIBLE
3.	☐ Involved likely non-viable agent(s) or body fluids/tissue of an infected animal unlikely to contain viable agent(s).	MINIMAL
4.	☐ Involved likely viable agent(s) or body fluid/tissue of an infected animal likely to contain viable agent(s).	HIGH/MODERATE
III.	**DERMAL CONTAMINATION** (CONTACT OF LIQUID OR SOLID WITH SKIN) ☐ **] N/A**	
1.	☐ Did not occur in the presence of agent(s) or an animal infected with any agent(s).	NO RISK
2.	☐ Involved sterile medium or body fluid/tissue of an animal free of infection (naïve to experimental agents, free of natural infections) but in the presence of agent(s).	NEGLIGIBLE
3.	☐ Intact skin contact involved likely non-viable agent(s) or body fluids/tissue of an infected animal unlikely to contain viable agent(s).	MINIMAL
4.	☐ Intact skin contact followed immediately by standard cleansing* of the affected area but involved likely viable agent(s) or body fluids/tissue of an infected animal likely to contain viable agent(s).	MINIMAL
5.	☐ Involved likely viable agent(s) or body fluids/tissue of an infected animal likely to contain viable agent(s). ☐ Non-intact skin contact. ☐ Intact skin contact with delay in standard cleansing* of the affected area. * *Anything other than immediate cleansing of the affected area according to established protocol.*	HIGH/MODERATE
IV.	**INHALATION** (CONTACT OF AIRBORNE AGENT(S) WITH RESPIRATORY TRACT, MUCOUS MEMBRANES, EYES) ☐ **N/A**	
Not wearing required respiratory protection: ☐ Yes ☐ No Break in respiratory protection/suit integrity: ☐ Yes ☐ No Failure of positive pressure suit/powered air-purifying respirator: ☐ Yes ☐ No If yes to any of the above, and one of the following:		
1.	☐ No discernable increased risk than would normally occur from entering a biosafety lab (used appropriate PPE and no breach in laboratory technique occurred	NO RISK
2.	☐ Did not occur in the presence of agent(s) or an animal infected with any agent(s).	NO RISK
3.	☐ Involved aerosol of sterile solution or body fluid of an animal free of infection (naïve to experimental agents, free of natural infections) but in the presence of agent(s).	NEGLIGIBLE
4.	☐ Involved ☐ aerosolized viable agent(s) that remained contained in BSC or ☐ aerosol not likely to contain viable agent(s) outside of primary containment or ☐ aerosol containing agent(s) not likely to aerosolize outside of primary containment.	MINIMAL
5.	☐ Involved likely viable agent(s) in aerosol (e.g., failure of BSC or centrifuge to contain agent, inadequate decontamination of lab equipment or PPE).	HIGH/MODERATE

NOTES/DETAILS *(Attach additional sheets if necessary)*			
Final Exposure Risk Classification (Highest level of any applicable category above)	☐ High/Moderate	☐ Minimal	☐ Negligible/No Risk
Biological Exposure Assessment Program (BEAP) Activated?	☐ Yes	☐ No	☐ Not Applicable

Safety Manager	Signature	Date
Biosafety Officer	Signature	Date
OMS Provider	Signature	Date

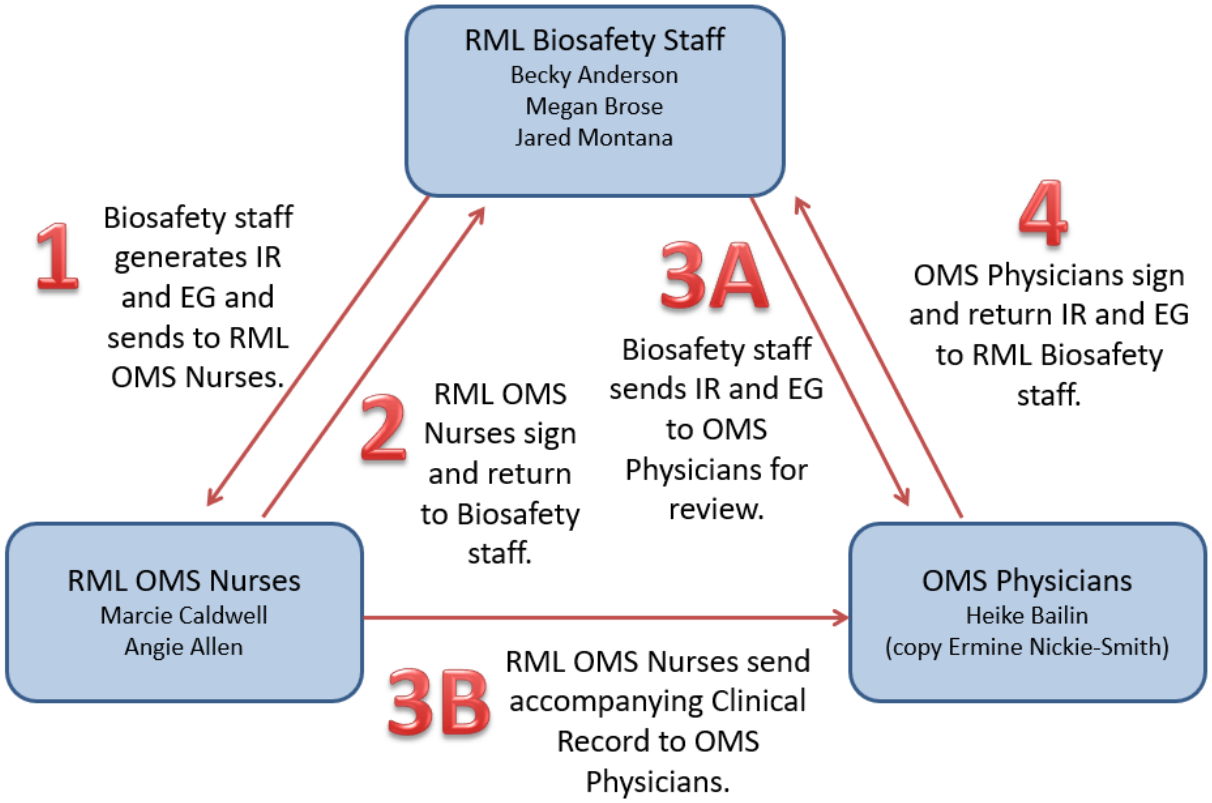
NIH OMS Review		
Notes:		
OMS Physician	Signature	Date

SHARPS INJURY LOG *(Complete for percutaneous injuries involving sharp devices.)*	
Type/brand name of the device involved in the injury/exposure:	
1. Did the device have engineered sharps injury protection?	☐ Yes ☐ No
2. Was the protective mechanism activated?	☐ Yes ☐ No
3. Did the injury/exposure occur before, during, or after activation of the protective mechanism?	☐ Before ☐ During ☐ After
4. How did the injury/exposure occur?	☐ While using the sharp?
	☐ Between steps of a multi-step procedure?
	☐ After use and before disposal of the sharp?
	☐ While placing sharp into sharps container?
	☐ Sharp left in inappropriate place?
	☐ Overfilled sharps container?
	☐ Disassembling the sharp?
	☐ Other

References:

1. Rusnick, JM et al. Management guidelines for laboratory exposures to agents of bioterrorism. JOEM 46(8):791-800; Aug 2004
2. Risi, G. Management of Laboratory Exposures to CDC Category A Infectious Diseases with Emphasis on Biosafety Level 4 Agents. Developed for Rocky Mountain Laboratories.
3. University of Texas Medical Branch (UTMB) Biological Exposure Evaluation and Risk Assessment documents. Developed by A. Nelson Avery, MD
4. Centers for Disease Control and Prevention and National Institutes of Health. 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. U.S. Government Printing Office, Washington, D.C.

Flow of Documents After an Incident Occurs



Injury Investigation Report (IR) and Exposure Guide (EG) were combined and the document is now called the Exposure Risk Assessment Guide. The flow of signatures for this document is represented above.

APPENDIX 4. HEPATITIS B VIRUS & WASTE AND ANESTHETIC GAS SURVEILLANCE PROGRAM

HEPATITIS B VIRUS (HBV) VACCINATION AND POST-EXPOSURE EVALUATION AND FOLLOW-UP

OCCUPATIONALLY ACQUIRED HBV

Hepatitis B is the leading occupationally acquired illness among health care workers, affecting approximately 15,000 workers annually. HBV, formerly known as "serum hepatitis," is one of several viruses that attack the liver producing swelling, tenderness, and liver damage. HBV is spread primarily through contact with blood and body fluids that contain blood.

SYMPTOMS OF HBV

The most frequent symptoms of HBV infection include fatigue, mild fever, muscle or joint pain, nausea, vomiting, loss of appetite, and abdominal pain. Many symptoms suggest a flu-like illness but tend to last longer and jaundice may occur in up to 25% of cases. However, 50% of infected individuals have no symptoms.

RISK OF HBV INFECTION

The risk of HBV infection for RML workers is considered to be high if their jobs entail frequent contact with human blood and body fluids. RML workers can protect themselves from occupationally acquired HBV infection by practicing Biosafety Level 2 practices (equivalent to Standard Precautions in a clinical setting) and by becoming immunized against HBV.

HBV VACCINE

A recombinant HBV vaccine is available, free of charge, to all RML workers who may come in contact with blood and body fluids during the performance of their duties. To receive the vaccine, Federal employees can call the RML OMS nurses, contract staff must work with their direct employer. It is strongly recommended that eligible workers accept the vaccine.

The recombinant HBV vaccine does not contain any human blood products; it is both safe and effective. Clinical studies have shown that over 90% of healthy adults administered the vaccine developed antibody to the hepatitis B virus. The HBV vaccine may also be used prophylactically in combination with hepatitis B immune globulin (HBIG) and is 90% effective in preventing hepatitis B following a documented exposure.

Side effects of the vaccine are minimal. The most common complaint (20%) is a sore arm lasting one or two days. A few individuals have reported headache, fatigue, weakness, or rarely, a low-grade fever. Eligible workers who decline to accept the vaccination must sign the following statement:

> "I understand that due to my occupational exposure to blood or other potentially infectious material I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me."

Hepatitis C Virus

Occupationally Acquired HCV

HCV is a leading cause of chronic liver disease and is the leading reason for liver transplant in the United States. Although the potential for HCV transmission associated with percutaneous injury is low, varying between 3 and 10% depending on the study, the risk of infection appears to correlate with the severity of the wound. It is estimated that greater than 85% of people who acquire an HCV infection will become chronically infected, and greater than 70% of HCV-infected people will have chronically elevated levels of liver enzymes. About 5% to 10% of infections will not be detected unless polymerase chain reaction is used to detect HCV RNA. Cirrhosis and primary hepatocellular carcinoma may result from chronic HCV.

Symptoms of HCV

HCV infection has two phases. The first, experienced by 75% of infected people, is a flu-like illness that includes headache, loss of appetite, nausea and vomiting, and fatigue. Eventually, 20-30% of infected people will progress to the second phase of HCV infection, which includes the development of overt signs and symptoms such as jaundice, clay-colored stools, and dark brown urine.

Risk of HCV Infection

Workers who must routinely handle human blood and body fluids are considered to be at risk for HCV infection. The risk of occupationally acquired infection may be reduced through the use of Biosafety Level 2 practices and procedures (equivalent to Standard Precautions in a clinical setting) and appropriate mucous membrane and eye protection.

HCV Vaccine

There is currently no vaccine available to prevent infection with HCV, and immune globulin is not recommended for post-exposure prophylaxis. It is therefore very important to use PPE, and to be especially careful when handling sharps. It is also very important to report any potential exposure to RML OMS.

Waste and Anesthetic Gas (WAG) Surveillance Program

NIH DOHS established a WAG Surveillance Program to:

1. Identify and quantify occupational exposure levels (through surveys and site assessments) to the anesthetic gases used at RML.
2. Provide information and recommendations for engineering controls and work practices that are effective in minimizing exposure to anesthetic gases.

Perform biennial leak testing via area monitoring of all vaporizers and scavenging systems per NIH requirements. For more information on the WAG program, contact the Industrial Hygienist at (406) 802-6398.