are responsible for the implementation of safe practices and procedures in their schools or departments. They should be aware of and approve all research conducted under their purview. They must ensure departmental compliance with applicable laws, regulations and guidelines covering the use of biological agents in their facility.

is charged by the University Provost to formulate policy and procedures related to the use of biohazardous agents, including: human pathogens, viruses, biological toxins and recombinant DNA (rDNA). As mandated by the National Institutes of Health, experiments involving human gene transfer, formation of transgenic animals and the generation of rDNA or synthetic nucleic acid molecules must be reviewed and approved by the

are responsible for complying with safety guidelines and procedures required for the tasks performed and reporting unsafe conditions to the PI or EHS & Risk Management. They should seek guidance from their PI or EHS & Risk Management when they are uncertain how to handle, store or dispose of any hazardous or biohazardous material. They should not begin working in the laboratory until all technical and safety training has been completed.

Bacteria, viruses, fungi or other infectious agents are studied in the laboratory to find a cause or cure for the diseases associated with these organisms. Since many of these agents are pathogenic to humans, animals, or other forms of life, their use poses risks, which vary with each agent and the way it is used. The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) publish guidelines for work with infectious microorganisms. The publication, entitled

Microorganisms can enter the body through the mouth, the respiratory tract, broken or intact skin and the eyes. It should be noted that in laboratory-acquired infections, the route may not be the same as when the disease is acquired naturally.

Infectious materials and cultures of microorganisms accumulate in large amounts in clinical and microbiological laboratories and since it is necessary to transfer them from one container to another and to manipulate them in various ways, the potential hazards are increased when working with materials. That why it is so important to have documented and deliberate standard operating procedures that are used by Principal Investigators and lab workers to make certain that nobody is exposed to biohazards. Information about standard operating procedure design can be found in the chemical hygiene plan; the Biological Safety Officer can also help set up a design framework.

Infections preceded by overt personal accidents include:

1. Inoculation (resulting from pricking, jabbing or cutting the skin with contaminated instruments such as hypodermic needles, scalpels and glassware; and from animal bites or scratches).

2. Ingestion (resulting from mouth-pipetting, eating, drinking and smoking, which is why these practices are not permitted in the lab).

3. Splashing into the face and eyes.

4. Spillage and direct contact especially with skin that is cut open.

Infections not preceded by personal accidents:

1. Aerosols, droplets and fomites. Aerosols are defined as a cloud of very small liquid droplets produced whenever energy is applied to a liquid, and such liquid is allowed to escape into the environment. It has been shown that if the liquid contains infectious agents, these would be distributed in the aerosol and would remain viable for some time. The larger droplets (greater than 0.1 mm in diameter) will settle quickly and contaminate the surfaces upon which they come to rest. The smaller droplets can rem

Infectious materials must be clearly identified and stored in such a manner as to preclude accidental exposure. This normally includes double or secondary containment and labeling all samples stored in the lab and freezer/refrigerator where these samples are kept.

There are many regulations in place to forestall the problem of laboratory-acquired infections. However, the responsibility for compliance with the regulations to ensure a safe workplace lies primarily with the Principal Investigator and, secondarily, with the laboratory staff. In addition, it is crucial for the PI and laboratory staff to always bear in mind that a large number of organisms that would ordinarily be innocuous can be infectious for immunocompromised persons. Therefore, additional and more stringent measures must be established by the PI in an effort to prevent the occurrence of lab- acquired infections in such individuals.

It is the responsibility of the principal investigator to conduct a risk assessment to determine the proper work practices and containment requirements for work with biohazardous material. The risk assessment process should identify features of microorganisms as well as host and environmental factors that influence the potential for workers to have a biohazard exposure. The principal investigator should consult with a Biosafety Officer to ensure that the laboratory is in compliance with established guidelines and regulations. The following resources are used to assist in the risk assessment: NIH Recombinant DNA Guidelines, WHO Biosafety Manual and the Biosafety in Microbiological & Biomedical Laboratories, 5th ed. (CDC/NIH). When performing a risk assessment, it is advisable to take a conservative approach if there is incomplete information available. Factors to consider when evaluating risk include the following:

: The more severe the potentially acquired disease, the higher the risk. Salmonella, a Risk Group 2 agent, can cause diarrhea and may progress to septicemia if ingested. Viruses such as Ebola, Marburg, and Lassa fever cause diseases with high mortality rates. There are no vaccines or treatment available. These agents belong to Risk Group 4.

: Agents that can be transmitted by the aerosol route have been known to cause the most laboratory-acquired infections. The greater the aerosol potential; the higher the risk of infection. Work with Mycobacterium tuberculosis is performed at Biosafety Level 3 because disease is acquired via the aerosol route.

The greater the potential for an agent to survive in the environment, the higher the risk. Consider factors such as desiccation, exposure to sunlight or ultraviolet light, or exposure to chemical disinfections when looking at the stability of an agent.

: Determine the amount of an infectious agent needed to cause infection in a normal person. An infectious dose can vary from one to hundreds of thousands of organisms or infectious units.

Safety equipment includes biological safety cabinets, enclosed containers (i.e., safety centrifuge cups) and other engineering controls designed to

CDC describes four biosafety levels (BSLs) which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. The recommended biosafety level for an organism represents the conditions under which the agent can be ordinarily handled safely. When specific info

centrifuge safety buckets are used, and if these rotors or safety buckets are opened only in a biological safety cabinet.

13. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.
14. Protective laboratory coats, gowns, aprons, or uniforms designated for laboratory use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, and administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; personnel should never take it home.
15. Gloves must be worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearsi o 3(p)aisures 6710(o)-5(f)12y 4(g)4proeesmft b(h)3(e)9()9(1(ap)

b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

12. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
13. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse.
14. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided, and written records are maintained.
15. Animals and plants not related to the work being conducted are not permitted in the laboratory.

Safety Equipment (Primary Barriers)

16. Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.
17. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.
18. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.
19. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonic eggs, etc., are conducted in a Class II or Class III biological safety cabinet.
20. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety buckets or sealed rotors) are used.
21. Respiratory and face protections are used when in rooms containing infected animals.

Laboratory Facilities (Secondary Barriers)

22. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a . o5/F7 12 Tf4(P)-4(ass)11(166(a)4

present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of covered floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as those around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

25. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and other chemicals used to decontaminate the work surfaces and equipment.
26. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.
27. All windows in the laboratory are closed and sealed.
28. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfectant, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.
29. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily traveled laboratory areas.
30. A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not re-circulated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided deccti134(the)5241(lab)17(o)-5(rat)11(o)-5(r)1

32. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
33.

Recommended dilution is 75 ppm, or approximately 4.5 ml/liter water.

The biosafety cabinet requires regular maintenance and certification by a professional technician to assure that it protects you, your experiments, and the environment. Each cabinet should be certified when it is installed, each time it is moved or repaired, and at least annually.

to the heat load inside the BSC. Flames have burned holes through HEPA filters and have caused explosions in BSCs.

6. Locate liquid waste traps inside cabinet and use a hydrophobic filter to protect the vacuum line. If traps must be located on the floor, place them in a secondary container (such as a cardboard box) to prevent spilling.
7. Wear gloves when there is potential for skin contact with infectious material.

3. Report the accident to the PI and EHS & Risk Management,

manufactured and distributed for healthcare purposes and are considered a low probability of containing pathogens. Biological products are defined as materials used in the prevention, treatment of cure of disease in humans or animals, examples include; vaccines, blood products, therapeutic serums, and antitoxins. Genetically modified organisms (GMO) that are not infectious substances but are capable of altering animals or plants in a way that is not normally the result of natural reproduction can be transported as a Miscellaneous Hazard. GMO that are infectious or carried by an animal host are regulated for transportation. Patient specimens are materials for which there is minimum likelihood that pathogens are present.

Packaging Materials

Potentially hazardous materials must be packaged to withstand leakage of contents, shocks, temperature and pressure changes, and other conditions that may occur during transportation procedures. Biological materials must be packed with the triple packaging principle, with containers including a primary receptacle, a leak proof secondary container with absorbent material, and a durable outer container. The packages must comply with the package instructions from IATA such as PI 602 for infectious substances. Buying certified packages from suppliers that are specific for the materials you want to ship will ensure compliance with the packing requirements.

The proper shipping name, labels and UN markings must also be on the package before sending out for shipment. If using dry ice or liquid nitrogen with your shipment, these materials must be declared and packages properly labeled. Dry ice should never be placed in a sealed container or the package may be at risk of exploding.

Proper biological waste disposal will ensure safety for laboratory personnel, custodian staff, transporter, and the general public. The Texas Administrative Code, Title 30, Part 1, Chapter 326 on Medical Waste Management sets forth waste disposal regulations for biomedical and biohazardous waste generation, treatment, and disposal. These rules must be followed gThwh2(o)-55

Children under 18 years old must not work in laboratories that use hazardous materials such as infectious agents, chemicals and radioactive substances. However, minors may work in the laboratory if they are part of a group or individual educational program approved in advance by the department head.

The student or group must be sponsored by a member of LU's faculty. The faculty sponsor is responsible for ensuring that LU's procedures are followed and that the student's activities are supervised at all times. The student, student's parent or guardian, and PI must complete the Minors Working in Research Laboratories or Animal Facilities form, and submit it to EHS & Risk Management for approval

Bacillus subtilis
Bacillus licheniformis
Escherichia coli K-12 Host Vector Systems
* RG1 agents involve well-characterized agents not

- *Plasmodium*
- *Schistosoma*
- *Toxoplasma* including *T. gondii*

- Adenoviruses , human – all types
- Alpha viruses (Togaviruses) – Group A Arboviruses
    - Eastern equine encephalomyelitis virus
    - Venezuelan equine encephalomyelitis vaccine strain TC-83
    - Western equine encephalomyelitis virus
- Bunyaviruses
    - Bunyamwera virus
    - Rift Valley fever virus vaccine strain MP-12
    - Other viruses as listed in the reference source (see section V-C, Footnotes and References of sections 1 through 4)
- Coronaviruses
- Hepatitis A, B, C, D, and E viruses
- Herpesviruses – except Herpesvirus simiae (Monkey B virus)
    - Cytomegalovirus
    - Epstein Barr virus
    - *Herpes simplex* types 1 and 2
    - Human herpesvirus types 6 and 7
- Orthomyxoviruses
    - Influenza viruses types A, B, and C
- Papovaviruses
    - All human papilloma viruses
- Paramyxoviruses
    - N4 381.1*namestel5(e)5(sT5C)]TJET8.1 198.26 391.49 Tm[ )]TJETBT1 7/J1.4-91 7

- Alphaviruses
  - St. Louis encephalitis virus
  - Venzualan equine encephalomyelitis
- Arenaviruses
  - Lymphocytic choriomeningitis virus (LCM)(neurotropic strains)
- Bunyaviruses
  - Hantaviruses including Hantaan virus
  - Rift Valley fever virus
- Poxviruses
  - Monkeypox virus
- Prions
  - Transmissible spongiform

- o Avian leucosis virus
- o Bovine leukemia virus
- o Feline Leukemia virus
- o Murine leukemia virus
- o Murine sarcoma virus

* Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BL1 containment.

HHS SELECT AGENTS AND TOXINS
Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern equine encephalitis virus Ebola
viruses
Francisella tularensis Lassa
fever virus Marburg virus
Monkeypox virus
Reconstructed 1918 Influenza virus Ricin
Rickettsia prowazekii
SARS-associated coronavirus
Saxitoxin
Shigatoxin
South American haemorrhagic fever viruses Junin
Machupo Sabia
Guarnarito

Staphylococcal enterotoxin
Tetrodotoxin
T-2 toxin
Tick-borne encephalitis complex (flavi) viruses
Kyasanur forest disease
Omsk hemorrhagic fever
Variola major virus (Sma24 547.152ETBT1 0 0 1 103.58 371a