Additional responsibilities of the PI when working with rDNA are located in the NIH Guidelines (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). One PI's failure to comply with the NIH Guidelines could affect all NIH-funded projects at the University; therefore, compliance is absolutely mandatory.

3.4.2 Laboratory Staff and Student Responsibilities

Laboratory staff and students are responsible for following the University health and safety policies and the procedures and instructions from their PIs/Instructors. They need to comply with the NIH, CDC and OSHA regulations, use safe laboratory practices, and inform the PI, laboratory supervisor, or regarding any potentially hazardous situations or conditions.

3.4.3 Biosafety Officer

Responsibilities of Biosafety Officer include but not limited to:

- Developing, implementing and coordinating biological safety program for the University.
- Reviewing protocols involving biological materials and recombinant DNA and potential biohazards.
- Reviewing selected agents transfer to and from the University (i.e., Material Transfer Agreement (MTA)).
- Acting as resources for the University on various regulations and guidelines pertaining to the use, handling and disposal of potential biohazards and recombinant DNA.
- Inspecting research and teaching facilities for compliance with regulations involving the use, handling and disposal of potential biohazards and recombinant DNA.

3.5 RISK ASSESSMENT

In order to determine which practices and procedures are required when working with biological materials, a risk assessment should be conducted. At a minimum, the risk assessment should include the following:

- Pathogenicity of the biological material and infectious dose
- Potential outcome of an exposure
- Natural route of exposure
- Other routes of exposure (parenteral, airborne, ingestion, etc.)

- Stability of biological material in the environment
- Concentration of biological material and amount to be manipulated
- Presence of a suitable host
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports
- How the biological material will be used (concentration, sonication, aerosolization, centrifugation, etc.)
- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens
- Local availability of effective prophylaxis or therapeutic interventions

In situations where the information is insufficient to perform a risk assessment, the following conservative approach should be used:

- Universal precautions should always be followed, and barrier protections applied (Gloves, gowns, eye protection), regardless of the origin of the samples.
- Biosafety level 2 should be the minimum requirement for the handling of specimens.

Biological expression systems consist of vectors and host cells. When conducting a risk assessment of these systems, consider whether the following concerns apply:

- Does the expression of the DNA sequences derived from pathogenic organisms increase the virulence of the genetically modified organism (GMO)?
- How well-characterized are inserted DNA sequences?
- Do gene products have potential pharmacological activity?
- Do gene products code for toxins?
- Will a human oncogene be inserted, or will a tumor suppressor gene be silenced?

3.6 BLOODBORNE PATHOGENS

The federal government issued the OSHA BBP Standard (29 CFR 1910.1030) in December 1991. The primary purpose of the BBP Standard is to minimize the risk of occupational exposures to blood and other bodily fluids and protect workers from the infectious diseases associated with them. In addition to HIV and the hepatitis viruses, the BBP Standard covers a wide variety of bloodborne infectious agents that can cause disease. Some of the included agents are simian immunodeficiency virus and the