IBC policy for classification of biological material as a biohazard and expectations for working in the laboratory.

Background:

Texas A&M System Regulation 15.99.06 *Use of Biohazards in Research, Teaching and Testing* defines biohazardous materials as:

- Biological agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites and prions) that may cause disease in humans, animals, or plants
- Recombinant or Synthetic Nucleic Acid Molecules as defined in the National Institutes of Health (NIH) *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*)
- Human and non-human primate blood, tissue, cells and cell lines
- Toxins of biological origin as defined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document

The System Regulation states that Principal Investigators and department heads are responsible to ensure that all research, teaching or testing activities involving biohazards, including experiments that may be exempt of the *NIH Guidelines*, are submitted to the system member's Institutional Biosafety Committee for review and approval and that activities involving biohazards must meet the criteria stated in the most current versions of federal or state documents, requirements and laws including the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*), the PHS/CDC and NIH's Biosafety in Microbiological and Biomedical Laboratories (BMBL), the Select Agent Regulations (7 CFR Part 331, 9 CFR part 121 and 42 CFR Part 73), USDA regulations and permits (as applicable), CDC Import permit requirements and the State of Texas Health and Safety Code 81.301 – 81.306. The System Regulation requires system members involved with research, teaching, testing activities utilizing biohazardous materials to establish a rule for carrying out this regulation.

Texas A&M's University Rule 15.99.01.M1 *Use of Biohazards, Biological Toxins and Recombinant DNA and Dual Use Research of Concern* applies to all University employees, students and visitors who utilize rDNA and/or biohazardous materials in the context of their research, teaching and/or testing activities and requires that such activities, performed under the auspices of Texas A&M University, be reviewed and approved by the IBC *prior to initiation*.

Policy Guidelines:

I. Working with Risk-Group 2 (RG-2) Agents in the BSL-2 lab:

To protect personnel and the environment, Texas A&M University's IBCs adhere to the standard and special practices outlined in the BMBL to ensure biohazards and/or rDNA are used safely. The BMBL states that activities involving high concentrations or large volumes of RG2 or above agents should be confined to a properly maintained BSC or other physical containment device (such as an aerosol tight centrifuge rotor or safety cup). Likewise, the BMBL recommends that procedures with the potential for creating infectious aerosols or splashes (e.g. pipetting, shaking,

mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals) be confined to a properly maintained BSC or other physical containment devices. It is the expectation of the TAMU IBCs that RG-2 agents should be handled following strict adherence to all standard and special microbiological practices as described in the BMBL. The BMBL also states that, with good microbiological techniques, some activities with RG-2 agents may be performed safely outside of physical containment, provided the manipulations do not entail substantial risk. Thus, special consideration may be given by the IBC, on a case-by-case basis, to researchers who submit a request to perform specific, low risk activities with RG-2 agents outside of primary containment. Such requests must be accompanied with a justification and a description of how personnel will be protected from the risk of exposure.

Additionally, TAMU IBCs expect that personnel working with infectious agents (or potentially infected materials) are made aware of the potential hazards of the agents in use, and are trained in the practices and techniques required for handling such materials safely. The laboratory director or Principal Investigator (PI) in charge of the laboratory is responsible for providing or arranging personnel training, appropriate to their duties and responsibilities. PIs may designate this responsibility to a senior lab member, as appropriate.

II. Classification of materials as to risk and appropriate biosafety level

Sometimes, there is limited information available to make an appropriate assessment of risk. For example, the hazards present in a sample or specimen collected from animals or the environment may contain agents with zoonotic potential. The precise nature of agents that may be present in a diagnostic specimen will be unknown until the agent has been identified as to genus and species. The BMBL recommends that, in such cases, it may be prudent to assume the specimen contains an agent (or agents) requiring a minimum containment level of BSL-2, unless additional information suggests the presence of an agent of higher risk.

Therefore, animal specimens potentially containing infectious agents (e.g. diagnostic specimens obtained from animals suspected of having an infectious disease, animal specimens from geographical regions experiencing an epidemic of infectious disease) should be handled as RG-2 materials requiring BSL-2 containment, unless the manipulations to the material and the nature of the suspected RG2 agent are such that they can be handled outside of physical containment, as described above. Similarly, soil, water, and other environmental samples to be used for cultivating pathogens or suspected to contain infectious agents should also be contained in a BSL-2 laboratory, with the same exception described above.

With the exception of samples obtained from pregnant sheep or bats, tissues collected from animals not purposefully infected or not suspected of containing an infectious agent, are not the subject of IBC review. However, researchers working with such materials are encouraged to take appropriate precautions (i.e., wear gloves, wash hands, no eating or drinking in the lab, etc.) since the possibility that zoonotic agents may be present cannot be excluded. Likewise, environmental (e.g. soil, water, etc.) samples collected from locations not expected to be contaminated with human pathogens and not collected or used for the purpose of isolating or

enriching for any human pathogens may be handled in a BSL-1 laboratory following standard precautions.

Materials not meeting the definition of a biohazard per Texas A&M System Regulation 15.99.06, i.e., agents not known to cause disease in humans, animals or plants, are also not the subject of IBC review.