SOP Title:	**Biosafety Level and Risk Group Determination**	SOP No.	**3**
		Revision	**0**
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Purpose: To assist principal investigators in determining the risk group for their research protocol.

Background: A critical step in planning the use of a biohazardous material is to make an initial determination regarding the appropriate level of risk associated with the agent and its proposed uses. Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans. A complete risk assessment of the experiment is needed to assign the correct risk group. Risk assessment is the process that enables the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can help prevent Laboratory-associated infection.

References:
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Ed.
https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

NIH Guidelines:
https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

American Biological Safety Association: https://my.absa.org/Riskgroups

American Type Cell Culture Collection: https://www.ATCC.org

Condition:

Biosafety levels (BSL) describe the general measures and infrastructure needed to work with an infectious agent. There are four levels from 1 (lowest) to 4 (highest). JMU only supports work with infectious agents or nucleic acids that can be handled at the BSL1 and BSL2 level. The infectious agents are also classified into 1 (lowest) of 4 (highest) levels called Risk Groups.

Risk Groups are classifications that describe the relative hazard posed by infectious agents or toxins in the laboratory. The risk group to which an infectious agent or toxin is assigned is the primary, but not only, consideration used in a biological risk assessment to determine the appropriate biosafety level in which a worker can handle the infectious agent or toxin. Other considerations:

1. The ability of an infectious agent or toxin to cause disease.
2. The way in which the infectious agent or toxin causes disease.
3. The planned activities performed in the laboratory.
4. Safety equipment and design elements present in the laboratory.
5. Health status and training of the laboratory worker.

Risk group levels do not always correspond to biosafety levels. For example, a specific research project's biological risk assessment for the use of human immunodeficiency virus (HIV), a Risk Group 3 agent, may correctly determine that HIV can be handled under Biosafety Level 2 conditions. Risk groups are designated from 1 (the lowest risk) to 4 (the highest risk).

The NIH Guidelines defines the risk groups as:

Risk Group 1 (RG1): Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community. Risk Group 1 contains non-pathogenic organisms like yeast and E. coli K-12.

Risk Group 2 (RG2): Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community.

Risk Group 3 (RG3): Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.

Risk Group 4 (RG4): Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community.

Currently JMU only supports work with Risk Group 1 and 2 agents. More information in defining these risk groups can be found in SOP No. 2.

Procedures for determining the Biosafety Level to which your protocol should be assigned:

1. Look up (in the BMBL Appendix of agents) the RG for the agent(s) you will be using. The highest risk group is assigned if there are multiple agents. Alternatives for using the BMBL appendix include looking up the risk group and biosafety level at trusted sites where organisms and cell cultures are purchased like the ATCC.
2. Examine procedures that will be done with the agent (i.e. centrifuging, pipetting, culture, etc.)
3. The amount of the agent being used, stored, manipulated.
4. Review safeguards available in the laboratory (i.e. biosafety cabinet, down draft lab bench, PPE etc.)
5. Using the above criteria, assign a risk group number to your research protocol.

Once the Biosafety level or Risk group is determined, experiments or activities which use infectious agents or recombinant or synthetic nucleic acids are to be registered by the Principal Investigator as either exempt or non-exempt from NIH guidelines. Exempt experiments or activities are those which are described in Section III-F of NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. Many activities using experimental systems such as *E. coli K-12*, *Saccharomyces cerevisiae*, and nucleic acids that cannot be reproduced in cells fall into this category. Work with exempt agents does not require a specific protocol for handling but does require registration with the JMU IBC. (SOP No. 4). Activities that are not exempt require that a non-exempt protocol registration be submitted to JMU that is approved by the IBC (SOP No. 5). These activities include working with agents that require specific handling under NIH, BMBL, or CDC guidelines or if working with *E. coli* or *Saccharomyces cervisiae* using large scale culturing (>10 L) of biological agents in a single vessel.