SOP Title:	**Definitions of IBC Covered Activities and General Policies Covered Under NIH Guidelines**	SOP No.	**1**
		Revision	**0**
Effective Date:	**5/18/2022**	Page	**1 of 2**

Purpose:
This standard operating procedure (SOP) defines the research activities that must be registered at James Madison University under NIH Guidelines and overviews what activities must be undertaken in order to register those activities.

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

Biosafety in Microbiological and Biomedical Laboratories, 6th Edition June 2020
https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

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

Background:
The Institutional Biosafety Committee is a committee of qualified faculty, individuals from the community external to JMU, and administrators who work with investigators and instructors who identify, assess, and ameliorate any hazards which could occur due to activities using infectious agents or recombinant nucleic acids. The committee membership must be compatible with that established under Section IV of the NIH guidelines. *More information about the establishment of this committee can be found in SOP No.2.*

The IBC guides principle investigators in conducting and approving research, teaching, and other activities conducted at, sponsored by, or on behalf of JMU involving any of the following biological agents:

- **Infectious agents (bacteria, viruses, protozoans, fungi, prions, etc.):** any organism or part thereof, capable of causing disease in a living organism (bacteria, viruses, protozoans, fungi, prions, parasites etc.). Human and/or non-human primate cells, tissues, blood or body fluids- cells, blood or body fluids are substances that can potentially harbor infectious agents.
- **Biologically derived toxins:** substances that are chemically produced by a living organism that have toxic properties, i.e. snake venom.
- **Human and/or non-human primate cells, tissues, blood or body fluids:** human and primate cultures, tissues and blood and body fluids are classified as infectious agents because of their possible contamination with infectious agents
- **Recombinant/Synthetic DNA/RNA:** (*according to the NIH guidelines*) are i.) molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell; ii.) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that

are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules; iii.) molecules that result from the replication of those described in (i.) or (ii.). In essence, nucleic acids that can replicate or which are replicated in cells that are distinct from the genome fall into these categories.

- **Transgenic organisms:** an organism whose genome has been altered by the transfer of a gene or genes from another species or breed.
- **Select agents:** a subset of biological agents and toxins that the Departments of Health and Human Services (HHS) and Agriculture (USDA) have determined to have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products.
- **Prions:** a type of protein that can trigger normal proteins in the brain to fold abnormally.
- **Synthetic biology:** the field of science that involves redesigning organisms for useful purposes by engineering them to have new properties.
- **Human gene transfer**: describes research involving the transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into human subjects.
- **Dual use technologies:** are any technologies that have potential for both civilian and military application.

Research at Biosafety level 1 and 2 with these reagents may be performed at JMU but currently JMU is not set up to do high risk work with reagents at Biosafety level 3 and 4. Guidance as to which biosafety level and risk group activities fall under can be found in S.O.P. # 3, Standard Operating Procedure for Biosafety and Risk Group Determination.