TITLE:	**IBC Application and Review Process for New Protocols [UNMC-IBC08]**
OVERVIEW:	All research protocols using biohazardous materials must undergo Institutional Biosafety Committee (IBC) review. Experiments using risk group (RG) 2 or RG-3 agents must be reviewed and approved prior to the initiation of experiments, while experiments using RG-1 may commence simultaneously with submission of the IBC application. RG-1 studies undergo an expedited pre-review process before approval by full IBC. Experiments using RG-4 agents are not authorized for conduct at this Institution. (Consult the "Other Information" section for a defined list of those experiments that require IBC approval.)
APPLIES TO:	All principal investigators using biohazardous agents in research.
DEFINITION(S):	*Biohazardous materials* - defined as materials of biological origin that have the capacity to produce deleterious effects on humans or animals including: recombinant and synthetic nucleic acids, micro-organisms containing recombinant or synthetic nucleic acids, micro-organisms classified as RG-2, RG-3, or RG-4, biological products derived fromRG-2, RG-3, or RG-4 microorganisms, and diagnostic specimens known or reasonably expected to contain RG-2, RG-3, or RG-4 pathogens. *Risk Group 1 (RG-1)* - biological agent not associated with disease in a healthy human adult [low individual and low community risk]. *Risk Group 2 (RG-2)* - biological agent is associated with disease which is rarely serious [moderate individual and low community risk]. *Risk Group 3 (RG-3)* - biological agent that is associated with serious or lethal disease [high individual and moderate community risk].
PROCEDURES:	New IBC applications using select agents or human gene transfer experiments should refer to the policy, "IBC Application and Review Process for New Protocols Utilizing Select Agents" or the "IBC Application and Review Process for New Protocols Involving Human Gene Transfer Experiments", respectively.

	1. Use the RSS program found at https://net.unmc.edu/rss to start an application. Select "IBC" from the black bar across the top of the page. Select "New Protocol" under the "IBC Application" heading. 2. Once all appropriate sections have been complete, sign the application and submit for pre-review. 3. Applications using RG-1 and RG-2 materials will be pre-reviewed by the IBC Chair. Those using RG-3 biohazardous agents and select agents will be pre-reviewed by the Biosafety Officer and UNMC Select Agent Program Responsible Official, respectively. After any requested modifications have been received, all protocols will then be reviewed by the full IBC membership at a convened meeting. 4. Following the review process, the principal investigator may be asked to amend the application. Comments may be communicated via e-mail or letter. Copies of the transmitted are appended to the meeting minutes. During this review process, all laboratories using RG-2 and RG-3 biohazardous materials will be requested to have a laboratory inspection by the Biosafety Officer. Refer to the policy entitled, "IBC Laboratory Inspection Process" for additional information. 5. The PI will submit the amended application for expedited member review. Further amendments or clarifications may be requested at this time. 6. The required Biosafety Training must be completed and documented for all investigators and participating personnel before the final approval letter is issued for any study. 7. Laboratory inspections for facilities used by BL-2 and BL-3 studies must be current before the final approval letter is issued. 8. If it has been determined that the protocol successfully complies with the IBC requirements as well as the requirements of the *NIH Guidelines*, a letter approving the protocol and authorizing initiation of the experiments will be sent from the IBC Administrator on behalf of the IBC membership to the PI [experiments using RG-1 agents may commence simultaneously with submission of the protocol to the IBC and do not require receipt of this final authorization to begin].
RECORD	The PI should maintain a record of the approved IBC protocol and

KEEPING:	the approval letter in RSS. The IBC office will maintain a copy of the protocol and approval letter for 7 years per NIH and HIPAA requirements. Records for clinical studies involving human subjects will be retained as required by the sponsor.
OTHER INFORMATION:	The IBC has been charged by Federal law with the planning and implementation of the campus biosafety program with a purpose to ensure the health and safety of all personnel working with biohazardous agents. The IBC makes certain that research conducted at the Institution is in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and the *Federal Select Agent Program*, reviews campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns. Experiments that require IBC approval include those that involve: , i. Deliberate transfer of drug resistance to a microorganism that is not known to acquire it naturally, if such acquisition could compromise the ability to control disease in humans, animals, or agriculture ii. Cloning of toxin molecules with LD50 less than 100 ng/kg iii. Human gene transfer iv. Experiments Using Risk Group 2 Risk Group 3 agents as host-vector systems v. Viral vectors for gene transfer vi. Cloning of nucleic acids from risk group 2 or risk group 3 agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems, vii. Use of infectious or defective Risk Group 2 or Risk Group 3 agents, viii. Recombinant or synthetic nucleic acid molecules transferred to any non-human vertebrate or any invertebrate organism ix. Viable recombinant nucleic acid-modified microorganism tested on/in whole animals, x. Genetically engineered plants by recombinant nucleic acid

	methods, xi. Experiments Involving 10 liters of culture (recombinantly modified or not), and A sub-category of risk group agents referred to as Select Agents as defined in "Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188" and "The Agricultural Bioterrorism Protection Act of 2002" , Regulations 7CFR 331, 9CFR 121 and 42CFR 73 are regulated by the Department of Health and Human Services and/or the USDA. These agents require special procedures for transfer and possession. Contact the UNMC Biosafety Officer for further information concerning these biohazardous agents.
REFERENCES:	
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