TITLE:	**IBC Review Process for Previously Approved Protocols [UNMC-IBC12]**
OVERVIEW:	Research using biohazardous materials undergo an initial IBC review and continuing reviews (CRs) thereafter to maintain an active status. This policy describes the review process for continuation of an active IBC protocol.
APPLIES TO:	Principal investigators (PIs) conducting experiments under a previously approved IBC protocol.
DEFINITION(S):	*Biohazardous materials* - defined as materials of biological origin that have the capacity to produce deleterious effects on humans or animals or are regulated by the federal government including: recombinant DNA and nucleic acid molecules, agents classified as risk group (RG) 2/RG-3/RG-4, RG-2/ RG-3/RG-4 agents used as host/vector systems, potentially infectious material derived from humans and NHPs, large-scale cultures of >10 liters(1), and diagnostic specimens known or reasonably expected to contain RG-2/RG-3/RG-4 agents. Research that requires BSL-4 containment is not permitted at UNMC/UNO.
PROCEDURES:	IBC protocols are initially approved for 1 to 3 years (dependent on the biohazardous agents used) after which time re-review is required. Prior to the expiration date, the PI will be notified that the IBC protocol is up for re-review and instructed to complete the Continuing Review form. This form can be found by clicking the "IBC Continuing Review" link on the left-hand side of the protocol in RSS. The PI must provide updated information on: • status of the project • biosafety incidents • changes to the protocol, including but not limited to, updates to biohazardous agents, scope of work, personnel, lab spaces, funding, and IRB/IACUC protocols If changes are made at the time of a CR, the PI must also concurrently submit a Request for Change (RFC) to be reviewed by the committee. To start an RFC, click on the "View" button, then the "Request Change" button on your protocol. This will allow you to make edits to your protocol. When edits are complete, sign and submit the application.

	Previously approved BL1 studies will undergo an expedited review by a member of the IBC. If in compliance, the study will be re-approved for three years. Previously approved BL2 studies will be reviewed by a member of the IBC who will present the findings of the review at the monthly IBC meeting. If the IBC's findings are appropriately addressed and laboratory inspections are current, the study will be reapproved for three years. Previously approved BL3, ABL3, BL3-SA, ABL3-SA, and Human Gene Transfer studies will be assigned a reviewer who will present the findings at the monthly IBC meeting. If the IBC's findings are appropriately addressed and laboratory inspections are current, the study will be reapproved for one year. For all previously approved studies: • A CR form will still need to be submitted every year to keep the protocol active, but it will not be reviewed by the full committee, and you will not receive a renewal letter. • If a CR form is not received by the expiration date on the notice email, the protocol will expire, and all research must halt until reapproval is granted. • Training for all personnel must be current for re-approval. • If funding sources require an alternative review schedule, the PI should notify the IBC. • The IBC reserves the right to increase the frequency of protocol review if needed.
RECORD KEEPING:	The PI should maintain a record of the approved IBC protocol and all correspondence from the IBC including approval letters in the *Laboratory Biosafety Manual*. The Office of Regulatory Affairs will maintain a copy of the IBC protocol, applications for continuing review and approval letters for 3-6 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 to plan and implement a campus biosafety program 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 DNA Molecules* and the *Select Agent Rule*, drafts campus biosafety

	policies and procedures, and reviews individual research proposals for biosafety concerns.
REFERENCES:	[1] *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) April 2019*
STATUS:	Drafted: October 2004 Revised: December 9, 2004 Approved: January 14, 2005 Revised: April 28, 2005 Approved: May 13, 2005 Revised: October 6, 2022 Approved: November 10, 2022