

University of Nebraska Medical Center  
 Biosafety Policies and Procedures

<b>TITLE:</b>	<b>Administration of UNMC IBC Protocols Conducted at Laboratories at the University of Nebraska-Lincoln campus [UNMC-IBC33]</b>
<b>OVERVIEW:</b>	<p>The UNMC-UNO IBC is authorized to review research involving biohazardous agents conducted by investigators from UNMC and UNO for compliance with the <i>NIH Guidelines</i>. Some UNMC researchers are not physically located on the UNMC campus at 42<sup>nd</sup> and Dewey Streets, (i.e., those laboratories located at UNL associated with the Colleges of Dentistry and/or Nursing).</p> <p>This policy describes the procedures necessary to oversee research conducted by UNMC investigators at laboratories not physically located on the UNMC campus.</p>
<b>APPLIES TO:</b>	<p>Research conducted by UNMC investigators at laboratories physically located at the University of Nebraska Lincoln campus (i.e., those laboratories located at UNL associated with the Colleges of Dentistry and/or Nursing).</p>
<b>DEFINITION(S):</b>	
<b>PROCEDURES:</b>	<ol style="list-style-type: none"> <li>1. A Memorandum of Understanding (MOA) between UNL and UNMC will authorize review and oversight by the UNL IBC of research conducted on the University of Nebraska Lincoln campus by UNMC investigators. This agreement will be ratified by the UNMC and UNL Vice-Chancellors for Research.</li> <li>2. The IBC application is submitted to the UNL IBC using the UNL submission forms and following the process as outlined by the UNL IBC. This process requires the signature of the responsible UNMC Department Head/Chair prior to submission of the protocol for review by the UNL IBC.</li> <li>3. A signature from the Chair of the UNMC IBC or the Biosafety Officer will verify that the research has been approved by UNMC for submission to UNL for review. This signature can be in the form of an e-mail approval to submit the project to the UNL IBC.</li> <li>4. The UNL IBC reviews the protocol and forwards copies of the results of the review and approval letter to the PI and the UNMC IBC. A copy of the approved IBC protocol along with the approval letter will be sent to the Office of Regulatory Affairs for a formal record of acceptance. The UNMC IBC will be notified of the external approval at the next IBC meeting.</li> <li>5. UNL Environmental Health and Safety will conduct the laboratory inspection for the initial approval process and for periodic follow-ups</li> </ol>

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	<p>per UNL requirements.</p> <p>6. Completion of biosafety training using the web-based training program at UNL will be required.</p> <p>7. The UNMC IBC will be notified of any significant problems with or violations of the <i>NIH Guidelines</i> reported to the UNL IBC.</p> <p>8. Consultation between the UNL IBC Chair and the UNMC IBC Chair will resolve any unanticipated issues that may arise during administration of an active IBC protocol.</p>
<b>RECORD KEEPING:</b>	Copies of the UNL IBC protocol, approval letter, and laboratory inspection results are sent to the UNMC Office of Regulatory Affairs to be kept on file. The study will be assigned a number in the IBC Protocol Tracking Database.
<b>OTHER INFORMATION:</b>	<p>IBC protocol oversight for research conducted at off-site laboratories require a MUA to be processed through the office of the Vice Chancellor for Research and Regulatory Affairs</p> <p>Research conducted at private facilities by UNMC investigators under the jurisdiction and oversight of the UNMC/UNO IBC requires approval of the UNMC Vice-Chancellor for Research.</p>
<b>REFERENCES:</b>	<i>NIH Guidelines</i> , Functions of the IBC, Section IV-B-26
<b>STATUS:</b>	<p>Drafted: July 5, 2005</p> <p>Approved: August 12, 2005</p>