

University of Nebraska Medical Center  
 Biosafety Policies and Procedures

<b>TITLE:</b>	<b>IBC Application and Review Process for New Protocols Utilizing a Select Agent</b> <b>[UNMC-IBC09]</b>
<b>OVERVIEW:</b>	All research protocols using biohazardous materials must undergo review by the Institutional Biosafety Committee (IBC). This policy was designed to address the special requirements necessary for the handling and possession of Select Agents and Toxins.
<b>APPLIES TO:</b>	All principal investigators requesting the use of a select agent or toxin in research activities.
<b>DEFINITION(S):</b>	<i>Select agent</i> - specifically regulated pathogens and toxins as defined in 42 CFR Part 73, including pathogens and toxins regulated by both DHHS and the USDA.
<b>PROCEDURES:</b>	<p>Prior to considering the use of select agents or toxins in research, the PI should contact the UNMC Biosafety Officer. It will be determined if a separate application for a certificate of registration to handle and possess these agents is warranted or if a present application can be utilized.</p> <p>All of the following must be completed prior to the protocol being considered by the IBC for approval:</p> <ol style="list-style-type: none"> <li>1. A certificate of registration has been granted by the US Department of Health and Human Services.</li> <li>2. The laboratory has been approved by the Biosafety Officer as complying to the <i>NIH Guidelines</i>, the <i>BMBL Manual</i>, and the <i>Select Agent Rule</i>; and</li> <li>3. All individuals with access to the select agent or toxin have documentation of the educational and training requirements as outlined in the policy entitled, "<b>Select Agent - Minimal Training and Education Requirements</b>".</li> </ol> <p>Documentation of each prior step must be submitted to the IBC Chair as part of the application process.</p> <p>The approval process as outlined in the policy, "<b>IBC Application and Review Process for New Protocols</b>", will be followed with the additions noted above.</p>
<b>RECORD KEEPING:</b>	<p>The PI should maintain a record of the approved IBC protocol and the approval letter in the <b>Laboratory Biosafety Manual</b>.</p> <p>The IBC Chair will maintain a copy of the protocol and approval</p>

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	letter until such time the project becomes "inactive".
<b>OTHER INFORMATION:</b>	<p>The registration process is detailed and may require 6 months or longer to achieve a federal certificate of registration. During this process a security risk assessment, to include FBI fingerprinting and a University criminal background check will be required of all individuals with access to the select agent and toxin.</p> <p>An assessment of the security for the laboratory will also be evaluated during the laboratory inspection.</p> <p>All provisions of 42 CFR Part 73 must be followed to be considered for IBC approval.</p> <p>Special biosafety training will be required of all individuals with access to select agents and toxins.</p> <p>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 <u><i>NIH Guidelines for Research Involving Recombinant DNA Molecules</i></u> and the <u><i>Select Agent Rule</i></u>, drafts campus biosafety policies and procedures, and reviews individual research proposals for biosafety concerns.</p>
<b>REFERENCES:</b>	
<b>STATUS:</b>	<p>Drafted: September 15, 2003</p> <p>Approved: January 14, 2005</p>