

TITLE:	IBC34- Biosafety Risk Factor Assessment Process to Determine Appropriate Containment
OVERVIEW:	Each planned experiment where biohazard agents are used must undergo an initial risk assessment to decide on the appropriate containment for an experiment. This policy gives guidance on the steps necessary to conduct a biosafety risk assessment
APPLIES TO:	All research undergoing review by the Institutional Biosafety Committee
DEFINITION(S):	Not applicable
PROCEDURES:	<p>Refer to the IBC website at <<www.unmc.edu/ibc/>> and link to the page entitled, “Exempt Experiments” for examples of experiments that are exempt from the <i>NIH Guidelines</i> and thus do not require registration with the IBC.</p> <p>For experiments that are not exempt, IBC34-Form 1 provides a template to conduct a Biosafety Risk Assessment as part of the process in preparing an IBC protocol. This assessment includes the following risk factor categories as they pertain to the biohazardous agent under review:</p> <ul style="list-style-type: none"> Pathogenicity/virulence Infectious dose Route of spread Communicability Environmental stability Host range Economic aspects Availability of prophylactic and therapeutic treatments Vectors Concentration/volume Recombinant properties <p>For the IBC Application, the Principal Investigator is required to complete a biosafety risk assessment to complete Section II, Part 3 (Biosafety Level of Containment) of the IBC submission form, Protocol for Research Involving Biohazardous Material.</p> <p>The overall Risk Group Classification will be used by the IBC to determine the appropriate containment for the proposed experiment. The IBC will ultimately be responsible for setting the containment level for the requested experiment.</p>

University of Nebraska Medical Center

Biosafety Policies and Procedures

RECORD KEEPING:	A copy of the Biosafety Risk Assessment Summary will be included with the protocol paperwork in the IBC office.
OTHER INFORMATION:	The <i>NIH Guidelines</i> state that, “the IBC must approve the risk assessment and the biosafety containment level of...experiments” [Section II-A-3, Comprehensive Risk Assessment] and “the IBC is responsible for...reviewing research...(which) should include...an independent assessment of the containment levels required.....for the proposed research” [Section IV-B-2-b-(1)].
REFERENCES:	<i>NIH Guidelines</i> , Section II, Safety Considerations
STATUS:	Updated: January 12, 2007