

Institutional Biosafety Committee Registration Checklist

Type of Research	Required Documents to be submitted	Notes
<p>Basic rDNA , plasmid, RNA, cDNA work</p> <ul style="list-style-type: none"> • DNA segments are from a single non chromosomal or viral DNA source • No microorganisms are used 	<ul style="list-style-type: none"> <input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date 	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe any gene modifications • Describe the use of transgenics
<p>Biological Agent as Vector</p> <ol style="list-style-type: none"> 1. Introduction or insertion of recombinant DNA into Risk Group 2,3 or 4 Agents (IIID1) 2. Transfer of or cloning of DNA from a Risk Group 2, 3, 4 or restricted Agent into a nonpathogenic prokaryote or lower eukaryote 3. Viral Vectors: Experiments with infectious or defective RG 2,3, 4 virus in the presence of a helper virus in a Tissue Culture System (Use of Poxvirus must be approved by NIH OBA) 	<ul style="list-style-type: none"> <input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work <input type="checkbox"/> HDOA Import Permit approval or Pending authorization from Research Compliance Officer 	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications • Describe the use of transgenics
<p>Use of Animals</p> <ul style="list-style-type: none"> • Creation or crossbreeding of transgenic/knock out animals • Introduction or insertion of recombinant DNA into an animal model (D4) • Insertion or introduction of microorganism or a toxin into an animal model 	<ul style="list-style-type: none"> <input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work <input type="checkbox"/> Containment SOP (see NIH Guidelines Appendix Q) <input type="checkbox"/> IACUC Approval or pending notification from Regulatory Compliance Officer <input type="checkbox"/> HDOA Import Permit approval may be required. <i>Contact Research Compliance Officer.</i> 	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications • Describe the use of transgenics

<p>Use of Plants</p> <p>Creation of transgenic or genetically modified Plants by recombinant DNA methods (D5)</p>	<input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work <input type="checkbox"/> Containment SOP Guidelines	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications • Describe the use of transgenics
<p>rDNA in human cells</p>	<input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications • Describe the use of transgenics
<p>rDNA in Human Clinical Trials (IIIC)</p>	<input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work <input type="checkbox"/> FDA letter confirming IND Number <input type="checkbox"/> Vaccine exemption letter if applicable <input type="checkbox"/> IRB Approval letter Submit all documents to NIH OBA for RAC Review	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications
<p>Cloning or Production of Toxins</p> <p>Toxin that is lethal to vertebrates at LD50 < 100mg/kg body weight (IIIB)</p>	<input type="checkbox"/> IBC registration Form <input type="checkbox"/> Biosafety Training records for all staff on registration <input type="checkbox"/> Shipping/receiving record for Lab Manager/PI <input type="checkbox"/> Lab Inspection Date <input type="checkbox"/> SOP for the work <input type="checkbox"/> Containment & Emergency Response SOPs Submit all documents to NIH OBA for approval	<ul style="list-style-type: none"> • Provide descriptions in “laymen’s” terms. • Describe the gene modifications