

**Yale University**  
*Office of Environmental Health and Safety*  
 Principal Investigator Biosafety Requirements

<b>Item</b>	<b>Required Registration</b>	<b>Required Training</b>	<b>Required Inspection</b>
<b>Form 01</b>	Initially annually protocol changes		Start up and annual biological/chemical
<b>Human Materials, including human origin cell lines</b>	Form 01	OSHA Bloodborne Pathogen at start of use and annually	BL2 lab and chemical inspection
<b>Recombinant DNA</b>	<ul style="list-style-type: none"> <li>Form 01</li> <li>rDNA Registration and Biological Safety Committee approval for non-exempt work</li> </ul>	Biosafety	BL2 rDNA for non-exempt protocols
<b>Infectious Agents</b>	<ul style="list-style-type: none"> <li>Form 01</li> <li>State of Connecticut (through OEHS)</li> </ul>	<ul style="list-style-type: none"> <li>BL2 Agents require Biosafety training/BL2+ and BL3 agents require Biosafety and BL3 training</li> </ul>	Biological/Chemical and Connecticut Public Health Department
<b>Biological Safety Cabinets</b>	<ul style="list-style-type: none"> <li>Place on Yale certification contract</li> </ul>	Safe use of Biological Safety Cabinets recommended	Biological Safety Cabinets certified annually by contracted vendor
<b>Medical Surveillance</b>	<ul style="list-style-type: none"> <li>Hepatitis B Vaccine Notification Form if using human blood or body fluids, or work with HBV</li> <li>Serum storage if using BL3 agents or if requested by an employee working with non-human primates</li> <li>Other immunization as recommended/Reporting of suspicious unexplained illnesses</li> </ul>		
<b>Animal Use</b>	<ul style="list-style-type: none"> <li>Form 01</li> <li>Yale Animal Care and Use Committee</li> <li>Yale Animal Resource Center</li> </ul>	<ul style="list-style-type: none"> <li>Yale Animal Resource Center Training</li> <li>BL2 agent use in animals – Biosafety training</li> <li>BL2+ and BL3 agent use in animals – Biosafety and BL3 training</li> </ul>	<ul style="list-style-type: none"> <li>Yale Animal Resource Center and Biosafety start up meeting</li> </ul>
<b>Human Gene Therapy Protocols</b>	<ul style="list-style-type: none"> <li>Yale HIC</li> <li>Yale Biological Safety Committee</li> <li>FDA</li> <li>NIH</li> <li>Yale New Haven Hospital</li> </ul>	<ul style="list-style-type: none"> <li>BL2 vector use – Biosafety Training</li> <li>Human material – OSHA Bloodborne Pathogen Training</li> <li>HIC Yale Biosafety Committee Human Gene Transfer training</li> </ul>	Facility review by Biosafety Office
<b>Select Agents (possession or use) – Call for list</b>	<ul style="list-style-type: none"> <li>Form 01</li> <li>CDC registration (through OEHS)</li> </ul>	<ul style="list-style-type: none"> <li>Shipping and Transport of Infectious Agents required initially and every 2 years</li> <li>Biosafety Training</li> </ul>	<ul style="list-style-type: none"> <li>Yale Select Agent inspection</li> <li>Subject to random CDC inspection every 3 years</li> </ul>
<b>Shipping</b>	<ul style="list-style-type: none"> <li>Registration of OEHS as a trained shipper</li> <li>Shipping Declaration Forms required for transport</li> </ul>	<ul style="list-style-type: none"> <li>Shipping and Transport of Infectious Agents required initially and every 2 years</li> <li>Driver training of transporting infectious or regulated biological material</li> </ul>	
<b>USDA Regulated Agents</b>	<ul style="list-style-type: none"> <li>Form 01</li> <li>USDA Registration (import or use permit)</li> </ul>	<ul style="list-style-type: none"> <li>BL2 Agents require Biosafety training</li> <li>BL2+ and BL3 agents require Biosafety and BL3 training</li> </ul>	<ul style="list-style-type: none"> <li>Yale Biological/Chemical inspection (Yale Animal Resources Center and Biosafety)</li> <li>USDA inspection</li> </ul>