

## Vaccine development at animal biosafety level four: Standards and challenges

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The specific operation and safety procedures for the select agent Animal Biosafety Level Four (ABSL-4) at Texas Biomedical Research Institute in San Antonio, TX (Texas Biomed) has been operational at the BSL-4 level for 13 years and as an ABSL4 for 10 years. All precautions are taken to protect staff, the surrounding community and the environment from any hazardous biological materials. The guidelines originally come from Biosafety in Microbiological and Biomedical Laboratories issued by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) 5th edition, NIH Guidelines for Research involving Recombinant and Synthetic Nucleic Acid Molecules, OSHA regulations and any other applicable federal, state and municipal regulations. All protocols and risk assessments are submitted and approved by the Biohazard and Safety Committee and Recombinant DNA Committee for work with all select agents in the ABSL-4. Recently some pathogens have been deemed Tier 1 meaning they are considered the most likely to cause a serious outbreak. New regulations for working with BSL-4 agents, that are Tier 1, require an institutional suitability assessment which determines an employee's ability to abide by biosafety and biosecurity guidelines. This presentation will discuss how institutions maintain a high containment facility. How risk assessments are performed and how institutions monitor employees for their suitability to continue to work with select agents particularly Tier 1 agents.

### Biography

Jean L Patterson received her PhD from the University of Notre Dame. She did Postdoctoral studies at the Department of Biochemistry at the University of Wisconsin-Madison and the Department of Microbiology at the University of Geneva Medical School, Geneva, Switzerland. Before her appointment as Chair of Virology and Immunology at Texas Biomed she was on the faculty of Harvard Medical School. She has published over a 100 manuscripts in peer reviewed journals. She has served on numerous committees examining the use of high containment labs, such as the NIH Blue Ribbon Panel for the Supplemental Risk Assessment for Boston University's ABSL-4 laboratory.

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