Requirements for research with prions and prion-like proteins

Per National Institutes of Health (NIH) guidelines and the Stanford University Administrative Panel on Biosafety (APB) policy, the APB requires researchers to have an approved APB protocol and follow specific guidelines for working with prions and prion-like proteins.

For APB oversight, prions and prion-like proteins are defined as proteins (human or animal) that fall into one of the below categories:

1. Proteins that are highly associated with proteinopathies, including, but not limited to
   a. Major prion protein/PrP/CD230 (Creutzfeldt-Jakob Disease [CJD], variant Creutzfeldt-Jakob Disease [vCJD], Kuru, fatal familial insomnia, bovine spongiform encephalopathy, Gerstmann-Straussler-Scheinker syndrome),
   b. Alpha-synuclein (Parkinson's disease),
   c. Tau, beta-amyloid (Alzheimer's disease),
   d. Tau, RNA-binding protein *F*used in Sarcoma (FUS) (Frontotemporal lobar dementias),
   e. Polyglutamine-containing proteins (polyQ) (Huntington's disease),
   f. Superoxide dismutase 1 (SOD1); transactivation response element (TAR) DNA-binding protein-43 (TDP-43); FUS; Ubiquilin (ALS/Lou Gehrig's disease).
2. Proteins that confer a disease state that is transmissible from cell to cell.
3. Proteins that have a fibrillar or aggregated form that has been shown to "seed" a pathology associated with a disease.

Specific *in vitro* or *in vivo* work with such proteins is classified as BSL2 or ABSL2 and requires an APB-approved protocol. This includes, but is not limited to, the following types of work:

1. Synthesis, use or production of protein in high concentration
2. Generation or use of mutated proteins
3. Generation or use of fibrillar or misfolded forms of proteins

APB protocols (http://eProtocol.stanford.edu) must include established prion disinfection/decontamination and destruction/disposal protocols, or specific Standard Operating Procedures (SOPs). These SOPs must be provided for review by the APB. If necessary, contact Biosafety for appropriate methods. Refer to the following references for established infection control guidelines:

1. WHO Infection Control Guidelines
2. CDC Prion Diseases
3. Biosafety in Microbiology and Biomedical Laboratories 6th ed.
4. Stanford Biosafety website