

0910-0456

ABSTRACT:

The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and the general public. The collection of information described in this guideline will provide general guidance to sponsors in the development of xenotransplantation clinical protocols, in preparing submissions to FDA, and in the conduct of xenotransplantation clinical trials. Also, the collection of information will help ensure that the sponsor maintains important information in a cross-referenced system that links the relevant records of the xenotransplantation product recipient, xenotransplantation product, source animal(s), animal procurement center, and significant nosocomial exposures.