

TABLE 2.—RECORDKEEPING
RECOMMENDATIONS—Continued

PHS Guideline Section	Description
3.4.3.2	Document full necropsy investigations including evaluation for infectious etiologies.
3.5.1	Justify shortening a source animal's quarantine period of 3 weeks prior to xenotransplantation product procurement.
3.5.2	Document absence of infectious agent in xenotransplantation product if its presence elsewhere in source animal does not preclude using it.

TABLE 2.—RECORDKEEPING
RECOMMENDATIONS—Continued

PHS Guideline Section	Description
3.5.4	Add summary of individual source animal record to permanent medical record of the xenotransplantation product recipient.
3.6.4	Document complete necropsy results on source animals (50-year record retention).
3.7	Link xenotransplantation product recipients to individual source animal records and archived biologic specimens.
4.2.3.2	Record base-line sera of xenotransplantation health care workers and specific nosocomial exposure.

TABLE 2.—RECORDKEEPING
RECOMMENDATIONS—Continued

PHS Guideline Section	Description
4.2.3.3 and 4.3.2	Keep a log of health care workers' significant nosocomial exposure(s).
4.3.1	Document each xenotransplant procedure.
5.2	Document location and nature of archived PHS specimens in health care records of xenotransplantation product recipient and source animal.

FDA estimates the burden for this collection of information as follows:

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN¹

PHS Guideline Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3.2.7.2 ²	18	0	0	0.5	0
3.2.7.2 ²	2	1	2	0.5	1.0
3.4 ³	12	0.33	4	0.08	0.32
3.5.1 ⁴	12	0.08	(0-1) 1	0.25	0.25
3.5.4 ⁵	12	1	12	0.5	6.0
3.5.5 ⁴	18	0.06	(0-1) 1	0.2	0.2
Total					7.77

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²No animal facility and 2 sponsors have ceased operations in the last 3 years.

³FDA's records indicate that an average of 4 INDs are expected to be submitted per year.

⁴Has not occurred in the past 3 years and is expected to continue to be a rare occurrence.

⁵Based on 36 patients treated over a 3 year period, the average number of xenotransplantation product recipients per year is estimated to be 12.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

PHS Guideline Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
3.2.7 ²	1	1	1	16	16.0
4.3 ³	12	1	12	0.83	9.96
3.4.2 ⁴	12	11	132	0.25	33.0
3.4.3.2 ⁵	18	4	72	0.3	21.6
3.5.1 ⁶	12	0.08	(0-1) 1	0.5	0.5
3.5.2 ⁶	12	0.08	(0-1) 1	0.25	0.25
3.5.4	12	1	12	0.17	2.04
3.6.4 ⁷	12	2	24	0.25	6.0