

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

PHS Guideline Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record-keeper	Total Hours
4.2.3.2 ⁶	12	0.08	(0–1) 1	0.17	0.17
4.2.3.3 and 4.3.2 ⁶	12	0.08	(0–1) 1	0.17	0.17
4.3.1	12	1	12	0.25	3.0
5.2 ⁹	12	3	36	0.08	2.88
Total					148.49

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

²A one-time burden for new respondents to set up a recordkeeping system linking all relevant records. FDA estimates 1 new sponsor annually.

³FDA estimates there is minimal recordkeeping burden associated with maintaining the record system.

⁴Monitoring for sentinel animals (subset representative of herd) plus all source animals. There are approximately 6 sentinel animals per herd x 1 herd per facility x 18 facilities = 108 sentinel animals. There are approximately 24 source animals per year (see footnote 7 of this table 4); 108 + 24 = 132 monitoring records to document.

⁵Necropsy for animal deaths of unknown cause estimated to be approximately 4 per herd per year x 1 herd per facility x 18 facilities = 72.

⁶Has not occurred in the past 3 years and is expected to continue to be a rare occurrence.

⁷On average 2 source animals are used for preparing xenotransplantation product material for one recipient. The average number of source animals is 2 source animals per recipient x 12 recipients annually = 24 source animals per year. (See footnote 5 of table 3 of this document.)

⁸FDA estimates there are approximately 12 clinical centers doing xenotransplantation procedures x approximately 25 health care workers involved per center = 300 health care workers.

⁹Twenty-four source animal records + 12 recipient records = 36 total records.

Because of the potential risk for cross-species transmission of pathogenic persistent virus, the guideline recommends that health records be retained for 50 years. Since these records are medical records, the retention of such records for up to 50 years is not information subject to the PRA (5 CFR 1320.3(h)(5)). Also, because of the limited number of clinical studies with small patient populations, the number of records is expected to be insignificant at this time.

Information collections in this guideline, not included in tables 1 through 4 of this document, can be found under existing regulations and approved under the OMB control

numbers as follows: (1) “Current Good Manufacturing Practice for Finished Pharmaceuticals,” 21 CFR 211.1 through 211.208, approved under OMB control number 0910–0139; (2) “Investigational New Drug Application,” 21 CFR 312.1 through 312.160, approved under OMB control number 0910–0014; and (3) information included in a license application, 21 CFR 601.2, approved under OMB control number 0910–0338. (Although it is possible that a xenotransplantation product may not be regulated as a biological product (e.g., it may be regulated as a medical device), FDA believes, based on its knowledge and experience with

xenotransplantation, that any xenotransplantation product subject to FDA regulation within the next 3 years will most likely be regulated as a biological product.) However, FDA recognized that some of the information collections go beyond approved collections; assessments for these burdens are included in tables 1 through 4 of this document.

In table 5 of this document, FDA identifies those collection of information activities that are already encompassed by existing regulations or are consistent with voluntary standards which reflect industry’s usual and customary business practice.

TABLE 5.—COLLECTION OF INFORMATION REQUIRED BY CURRENT REGULATIONS AND STANDARDS

21 CFR Section	Description of Collection of Information Activity	21 CFR Section (unless otherwise stated)
2.2.1	Document off-site collaborations	312.52
2.5	Sponsor ensure counseling patient + family + contacts	312.62(c)
3.1.1 and 3.1.6	Document well-characterized health history and lineage of source animals	312.23(a)(7)(a) and 211.84
3.1.8	Registration with and import permit from the Centers for Disease Control and Prevention	42 CFR 71.53
3.2.2	Document collaboration with accredited microbiology labs	312.52
3.2.3	Procedures to ensure the humane care of animals	9 CFR parts 1, 2, and 3 and PHS Policy ¹
3.2.4	Procedures consistent for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) and consistent with the National Research Council’s (NRC) Guide	AAALAC International Rules of Accreditation ² and NRC Guide ³