

United States Food and Drug Administration (FDA)

Human Tissue Intended for Transplantation

OMB Control No. 0910-0302

SUPPORTING STATEMENT – Part A: Justification

1. Circumstances Making the Collection of Information Necessary

Under section 361 of the Public Health Services (PHS) Act (42 U.S.C. 264), FDA issued regulations under part 1270 (21 CFR 1270) to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B and hepatitis C, and other organisms causing infectious disease through the use of human tissue intended for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and ensure that records are kept documenting that the appropriate screening and testing have been completed.

Accordingly, FDA requests an extension of OMB approval of the recordkeeping provisions found in 21 CFR Part 1270 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

These information collection requirements help prevent the transmission of communicable diseases through human tissue transplantation by requiring that written Standard Operating Procedures (SOPs) be prepared and followed that include: (1) infectious disease testing under §1270.21; (2) determining the medical history of the donor; (3) designating and identifying quarantined tissue; and (4) preventing infectious disease contamination or cross-contamination of tissue during processing. The regulations require maintenance of records of all significant steps in the infectious disease testing, and screening, and require that these records be made available for FDA inspection. Adequate donor screening and testing must be recorded so that the suitability of the tissue can be determined. If FDA is unable to ascertain how the tissue donor was screened or tested, or if the tissue was distributed in violation of the regulations, then recall, retention, and/or destruction orders may be issued by FDA in accordance with codified administrative procedures. Without this information collection, FDA could not monitor the suitability of human tissue for transplantation and could not fulfill its statutory responsibility to ensure that communicable diseases are not spread into or throughout the United States and its Possessions.

3. Use of Improved Information Technology and Burden Reduction

Establishments may maintain records electronically or as original paper records, or as true copies such as photocopies, microfiche, or microfilm. Electronic recordkeeping is specifically referred to in the regulations under § 1270.33(g). Section 1270.33(f) considers that the retrieval of records from another location by electronic means meets the requirements of the regulation. FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

This collection of information applies to small as well as large establishments, however it does not impose undue burden on small entities. Although FDA must apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research's (CBER), Office of Communication, Outreach and Development, Division of Manufacturer's Assistance and Training provides assistance to small businesses.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements. Information collection requires records for each tissue, at the time it is recovered, screened, tested, processed, stored or distributed, and is used to determine the suitability of the human tissue for transplantation and for its final distribution or disposition. The information provided to FDA inspectors is the information necessary to fulfill FDA's statutory responsibility to prevent the spread of communicable diseases. Less frequent collection of information would not ensure the safety of the tissue supply in this country or enable FDA to fulfill these duties. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of September 24, 2019 (84 FR 50039). Two comments were received but were not responsive to the four information collection topics solicited and were therefore not discussed in our 30-day notice of January 9, 2020 (85 FR 1167), and are not addressed in this supporting statement.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

This information collection request (ICR) collects personally identifiable information (PII) or other data of a personal nature. Under part 1270, tissue establishments must determine donor suitability based on the results of donor screening and testing. According to §1270.21(f), donor suitability determination by the responsible person that a donor of human tissue intended for

transplantation is suitable shall include ascertainment of the donor's identity, and accurately recorded relevant medical records (as defined in §1270.3(t)) which documents freedom from risk factors for and clinical evidence of hepatitis B, hepatitis C, and HIV infection. The establishments must also retain the donor screening and testing records, which were used for donor suitability determination, and make those records available for authorized inspection or upon request by FDA (§1270.33(f)). If records related to screening, testing, and suitability of tissue donors are submitted to the FDA, the establishment redacts donor and/or patient identifying information

In consultation with our Privacy Office, we determined that although PII is collected, the information collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimizes the PII collected to protect the privacy of the individuals. The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and regulations pertaining to “*Public Information*” under 21 CFR part 20. Inspectors may copy records as part of an inspection of a tissue establishment. This information is for internal use and may be subject to, in whole or in part, the FOIA and applicable FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature, such as sexual behavior and other matters that are commonly considered private, must be asked by the establishments as part of the donor medical history evaluation. The answers to these questions help determine the suitability of a donor. Donors that do not meet certain criteria would be deferred from donating. The collection of this information is necessary to prevent the transmission of communicable diseases and to protect the public health. Records of such information may be reviewed by FDA during an inspection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The estimated annual burden for this information collection is 626,735 hours.

Table 1. -- Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1270.31(a), (b), (c), and (d) ¹	32	1	32	24	768
1270.31(a) and 1270.31(b) ²	32	2	64	1.0	64
1270.33(a), (f), and (h), and 1270.35(a) and (b)	32	6,198.84	198,363	1.0	198,363
1270.35(c)	32	11,876.12	380,036	1.0	380,036

1270.35(d)	32	1,484.50	47,504	1.0	47,504
		19,562.46	625,999		626,735

¹ Review and update of SOPs.

² Documentation of deviations from SOPs.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. The information collection provisions under 21 CFR Part 1270 include:

21 CFR 1270.31(a) through (d); Recordkeeping

Requires written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process under 21 CFR 1270.21; (2) all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as prescribed in 21 CFR 1270.21; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination of tissues during processing.

21 CFR 1270.31(a) and (b); Recordkeeping

Requires recording and justification of any deviation from the written procedures.

21 CFR 1270.33(a); Recordkeeping

Requires records to be maintained concurrently with the performance of each significant step in the performance of infectious disease screening and testing of human tissue donors.

21 CFR 1270.33(f); Recordkeeping

Requires records to be retained regarding the determination of the suitability of the donors and of the records required under 21 CFR 1270.21.

21 CFR 1270.33(h); Recordkeeping

Requires all records to be retained at least 10 years beyond the date of transplantation if known, distribution, disposition, or expiration of the tissue, whichever is the latest.

21 CFR 1270.35(a) through (d); Recordkeeping

Requires specific records to be maintained to document the following: (1) The results and interpretation of all required infectious disease tests; (2) information on the identity and relevant medical records of the donor; (3) the receipt and/or distribution of human tissue; and (4) the destruction or other disposition of human tissue.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is \$28,203,075.

Activity	Total Burden Hours	Wage Rate per Hour	Total Cost
Recordkeeping	626,735	\$45	\$28,203,075

The cost estimate is based on a Donor Coordinator, at a wage rate of \$45/hour who is responsible for maintaining accurate records for each of the units of tissue received, processed, and distributed annually. This salary estimate includes benefits but no overhead costs.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal Government is \$595,200. There are approximately 383 manufacturers of conventional tissue and eye tissue that will be inspected on a biennial basis. Therefore, it is estimated that approximately half (192 establishments) will be inspected annually. The cost estimate is based on a FDA inspector at an average grade of GS-13/5 (\$59/hour), who takes an average of 50 hours for each establishment to perform the on-site inspection, review of its records, and the report write-up.

Activity	Number of Respondents	Hours per Respondent	Cost per Hour	Total Cost
Inspection	192	50	\$62	\$595,200

15. Explanation for Program Changes or Adjustments

There is no adjustment to the burden hours from the previous estimate, however, we have uploaded cost information to appear at www.reginfo.gov.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt the display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.