UNITED STATES FOOD AND DRUG ADMINISTRATION

Investigational Device Exemptions Reports and Records
21 CFR 812
OMB Control No. 0910-0078

Non-Substantive Change Request for Medical Devices, Investigational Device Exemptions:

The Food and Drug Administration (FDA) requests a non-substantive change to OMB Control No. 0910-0078, which supports Investigational Device Exemptions (IDEs) Reports and Records associated with products regulated by FDA's Center for Devices and Radiological Health (CDRH). We request the amendment of this ICR to move the applicable ICs from OMB Control No. 0910-0741 to OMB Control No. 0910-0078.

Background on IDEs (OMB Control No. 0910-0078)
An Investigational Device Exemption (IDE) allows a device, which would otherwise be subject to provisions of the FD&C Act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The IDE regulation (21 CFR part 812) is designed to encourage the development of useful medical devices, and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards.

Background on "Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices" (OMB Control No. 0910-0741)
In the final rule titled "Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices" (83 FR 7366; February 21, 2018), FDA amended its regulations on acceptance of data from clinical investigations for medical devices. Data submitted from clinical investigations conducted outside the United States intended to support an IDE application, a 510(k) submission, a request for de novo classification, a PMA application, a product development protocol (PDP) application, or an HDE application must be from investigations conducted in accordance with good clinical practice (GCP), which includes obtaining and documenting the review and approval of the clinical investigation by an independent ethics committee (IEC) and obtaining and documenting freely given informed consent of subjects, which includes individuals whose specimens are used in investigations of medical devices. The final rule updates the criteria for FDA acceptance of data from clinical investigations conducted outside the United States to help ensure the protection of human subjects and the quality and integrity of data obtained from these investigations. As part of this final rule, we also amended the IDE and 510(k) regulations to address the requirements for FDA acceptance of data from clinical investigations conducted inside the United States. The final rule provides consistency in FDA requirements for acceptance of data from clinical investigations, whatever the application or submission type.

While the information collections in the final rule were revisions to approved information collections, these collections were submitted to OMB as a new information collection request (assigned OMB control number 0910-0741, "Human Subject Protection; Data Requirements for Medical Device Related Clinical Investigations"), with the expectation that the approved ICRs

would be amended after the rule is finalized and the collections are due for renewal. So far, the following ICRs have been approved by OMB to include provisions/ICs related to human subject protection; data requirements for medical device-related clinical investigations: OMB Control Nos. 0910-0120 (510(k)), 0910-0231 (PMA, PDP), 0910-0332 (HDE, HUD) and 0910-0844 (De Novo). This change request for OMB Control No. 0910-0078 is the last of the amendments related to the final rule. Upon approval of all the amendments, we will request discontinuance of OMB Control No. 0910-0741, "Human Subject Protection; Data Requirements for Medical Device Related Clinical Investigations". The remaining provisions to be moved from 0910-0741 to 0910-0078 appear in the chart below.

Resultant Burden Estimate

We have not changed the burden estimate for these ICs from what is currently approved for OMB Control No. 0910-0741. Consistent with our estimate in OMB Control No. 0910-0741, amending OMB Control No. 0910-0078 to include these ICs increases the total burden estimate by 17,320 hours[1] (15,810 reporting; 1,510 recordkeeping).

We request that the information collections for the following provisions, currently approved in OMB Control No. 0910-0741, be included in OMB Control No. 0910-0078:

Section 812.27--Report of Prior Investigations

Section 812.27 addresses requirements for IDE applications supported by clinical data. For clinical investigations conducted in the United States, sponsors will be required to submit a statement as described in § 812.27(b)(4)(i). For clinical investigations conducted outside the United States, sponsors will be required to submit the information as described in § 812.27(b)(4)(ii).

Section 812.28—Acceptance of Data from Clinical Investigations Conducted Outside the United States

Section 812.28 addresses the requirements for acceptance of foreign clinical data to support an IDE or a device marketing application or submission. The sponsor or applicant must submit a statement as described in § 812.28(a)(1); provide a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP that includes the information in § 812.28(b)(1) through (b)(12) or a cross-reference to another section of the application or submission where the information is located; submit requests for waivers as described in § 812.28(c); and retain records as described in § 812.28(d).

Section 812.140--Records Retention

Section 812.140 addresses record retention requirements for investigators and sponsors. An investigator or sponsor will be required to maintain records as described in § 812.140(d).

[1] We note that the burden hour total listed in the ROCIS system for the current approval (conclusion date: 12/30/2019; approved through: 11/30/2022) is incorrect due to a mathematical error in the reporting burden table. The total burden hours for 0910-0078, currently approved for 45,782, should be 45,783. This error is corrected in the attached supporting statement, which includes the requested changes.

Table 1.--Estimated Annual Reporting Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Report of prior investigations; U.S.--812.27(b)(4)(i)	400	1	400	1	400
Report of prior investigations; outside the U.S.--812.27(b)(4)(ii)	100	1	100	0.25	25
Data from clinical investigations--812.28(a)(1)	1,500	1	1,500	0.25	375
Description regarding GCP--812.28(b)	1,500	1	1,500	10	15,000
Waivers--812.28(c)	10	1	10	1	10
Total					15,810

Table 2.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records from clinical investigations conducted outside the U.S.--812.28(d)	1,500	1	1,500	1	1,500
Retention period--812.140	10	1	10	1	10
Total					1,510

Dated: May 2021