

are set forth in 21 CFR 314.50, and approved under OMB control number 0910-0001. This information collection supports part 315, currently approved under OMB control number 0910-0409.

Based on past submissions (human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals), we estimate two submissions will be received annually. We estimate the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly

one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulations do not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved under OMB control number 0910-0001). In fact, clarification in

these regulations of FDA's criteria for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Diagnostic Radiopharmaceuticals—315.4, 315.5, and 315.6	2	1	2	2,000	4,000

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

Table 1 contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by the applicable regulations. This estimate does not include time needed to conduct studies and clinical trials or other research from which the reported information is obtained.

Dated: October 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-23836 Filed 11-1-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; NINR Clinical Trial Planning Grant.

Date: November 17, 2017.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Nursing Research, One Democracy Plaza, 6701 Democracy Boulevard, Room 703, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Boulevard, Room 710, Bethesda, MD 20892, (301) 594-5966, wli@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: October 30, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S.

FOR FURTHER INFORMATION CONTACT:

Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact Michael Shmilovich, shmilovm@nih.gov at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR 404 to achieve commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology follows.

Endo-Cameral Closure Device

Description of Technology: Devices and methods for closing a hole in the wall of a cardiovascular structure from the inside using a self-assembling closure device. The closure device can be delivered to the subject hole from the inside of the cardiovascular chamber using a transcatheter approach. The methods are techniques involve deploying the closure device from the delivery device such that an endo-cameral portion of the closure device self-expands first to cover the hole from the inside, and then extra-cameral arms of the device are released to self-deploy against the outside of the wall by