

In the **Federal Register** of July 12, 2018 (83 FR 32302), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated July 2018.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two other human gene therapy final guidance documents entitled “Human Gene Therapy for Hemophilia; Guidance for Industry” and “Human Gene Therapy for Rare Diseases; Guidance for Industry.”

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Human Gene Therapy for Retinal Disorders.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled “Expedited Programs for Serious Conditions—Drugs and Biologics” have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled “Formal Meetings Between the FDA and Sponsors or Applicants” have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance->

[regulatory-information-biologics](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics) or <https://www.regulations.gov>.

Dated: January 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Nurse Corps Loan Repayment Program, OMB No. 0915–0140 Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA’s ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than March 2, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Nurse Corps Loan Repayment Program OMB No. 0915–0140—Revision.

Abstract: The Nurse Corps Loan Repayment Program (Nurse Corps LRP) assists in the recruitment and retention of professional Registered Nurses (RNs) by decreasing the financial barriers associated with pursuing a nursing education. RNs in this instance include advanced practice RNs (e.g., nurse practitioners, certified registered nurse

anesthetists, certified nurse-midwives, and clinical nurse specialists) dedicated to working at eligible health care facilities with a critical shortage of nurses (i.e., a Critical Shortage Facility) or working as nurse faculty in eligible, accredited schools of nursing. The Nurse Corps LRP provides loan repayment assistance to these nurses to repay a portion of their qualifying educational loans in exchange for full-time service at a public or private nonprofit Critical Shortage Facility (CSF) or in an eligible, accredited school of nursing.

A 60-day notice was published in the **Federal Register** on October, 10, 2019 vol. 84, No. 197; pp. 54617–51619.

Need and Proposed Use of the Information: This information collection is used by the Nurse Corps program to make award decisions about Nurse Corps LRP applicants and to monitor a participant’s compliance with the program’s service requirements. Individuals must submit an application in order to participate in the program. The application asks for personal, professional, educational, and financial information required to determine the applicant’s eligibility to participate in the Nurse Corps LRP.

The revised information collection request includes a new form and updates to existing forms for the Nurse Corps LRP in order to expand the service options for awarded participants, promote the use of telehealth for delivering care throughout the nation especially in rural areas, and to reduce the application burden on respondents.

New Form #1—Applicants will be asked to submit a Disadvantaged Background Form. This new form asks the applicant’s site Point of Contact to certify whether the applicant is from a disadvantaged background. The form provides eligibility criteria for the determination.

Updated Form #1—The Participant Semi-Annual Employment Verification Form will be updated to include additional information about the participant’s service including information about telehealth services and whether they work at multiple CSF sites. Telehealth helps expand the reach of providers especially in rural areas where medical service sites are more remote. The information collected will assist Program with determining the impact and utilization of telehealth services in various health care settings which will be used to inform our telehealth policies. Enabling multiple CSF site service will also allow greater flexibility for providers who rotate or split time between multiple sites which

benefits both the participants and the underserved communities—especially in our Federally Qualified Health Centers which support many of our Nurse Corps Nurse Practitioners.

Updated Form #2—The Nurse Corps LRP application will include questions for applicants to provide information regarding telehealth services, multiple CSF sites, and verification of base salary to determine the debt to salary ratio used to rank applicants for award consideration. The application will also be updated to identify applicants

eligible for Nurse Corps LRP psychiatric nurse practitioner funding.

Likely Respondents: Professional RNs or advanced practice RNs who are interested in participating in the Nurse Corps LRP and official representatives at their service sites.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours: The estimates of reporting burden for Applications are as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Corps LRP Application *	7,100	1	7,100	2.00	14,200
Authorization to Release Information Form **	7,100	1	7,100	.10	710
Employment Verification Form **	7,100	1	7,100	.10	710
Disadvantaged Background Form	450	1	450	.20	90
Confirmation of Interest Form	500	1	500	.20	100
Total for Applicants	22,250	22,250	15,810

* The burden hours associated with this instrument account for both new and continuation applications. Additional (uploaded) supporting documentation is included as part of this instrument and is reflected in the burden hours.

** The same respondents are completing these instruments.

The estimates of reporting for Participants are as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Semi-Annual In Service Verification Form	500	2	1,000	.50	500
Nurse Corps CSF Verification Form	500	1	500	.10	50
Nurse Corps Nurse Faculty Employment Verification Form	450	1	450	.20	90
Total for Participants	1,450	1,950	640
Total for Applicants and Participants	23,700	24,200	* 16,450

* The 16,450 figure is the sum of total burden hours for applicants and participants. This revision adds an additional form (the Disadvantaged Background Form).

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

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

The meetings 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; TEP-12: SBIR, Contract Review Meeting.

Date: March 3, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Robert Stephen Coyne, Ph.D., Scientific Review Officer, National Cancer Institute, NIH, Division of Extramural Activities, Special Review Branch, 9609 Medical Center Drive, Room 7W236, Rockville, MD 20850, 240-276-5120, coyners@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI U01 Review.

Date: March 17, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W514, Rockville, MD 20850, (Telephone Conference Call).