



**Billing Code:**

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **45 CFR Part 5b**

**[Docket Number NIH-2016-0002]**

**RIN 0925-AA62**

### **Privacy Act; Implementation**

**AGENCY:** Department of Health and Human Services.

**ACTION:** Notice of Proposed Rulemaking.

**SUMMARY:** The Department of Health and Human Services (HHS or Department) proposes to exempt confidential source identifying information in a system of records maintained by the National Institutes of Health (NIH) from certain requirements of the Privacy Act. The affected system of records is 09-25-0165, “National Institutes of Health (NIH) Office of Loan Repayment and Scholarship (OLRS) Record System, HHS/NIH/OD” (to be renamed “NIH Loan Repayment Records”). Elsewhere in today’s *Federal Register*, HHS/NIH has published an updated system of records notice (SORN) for system 09-25-0165 for public notice and comment.

**DATES:** Submit either electronic or written comments regarding this document by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments, identified by Docket Number NIH-2015-0002, via any of the following methods:

#### Electronic Submission

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions

provided for submitting comments.

### Written Submission

Submit written submissions in the following ways:

- Fax: 301-402-0169.
- Mail: Daniel Hernandez, Acting NIH Regulations Officer, Office of Management

Assessment, National Institutes of Health, 6011 Executive Boulevard., Suite. 601, MSC 7669, Rockville, MD 20852.

In order to ensure more timely processing of comments, HHS/NIH is no longer accepting notice of proposed rulemaking (NPRM) comments submitted to the agency by e-mail. HHS/NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the ADDRESSES portion of this document under Electronic Submissions.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and follow the instructions provided for conducting a search, using the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** General questions about the proposed exemptions may be submitted to Daniel Hernandez, Acting NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard., Suite. 601, MSC 7669, Rockville, MD 20852, telephone 301- 435-3343, fax 301-402-0169, e-mail [dhernandez@od.nih.gov](mailto:dhernandez@od.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background on the NIH Loan Repayment Programs and System of Records 09-25-0165**

The NIH Loan Repayment Programs (LRPs) are administered by the Division of Loan Repayment within NIH's Office of Extramural Research (HHS/NIH/OER/DLR, hereafter referred to as DLR). DLR provides repayment of student loans for approved applicants to encourage outstanding health professionals to pursue careers in biomedical, behavioral, social, and clinical research. Research health professionals who owe qualified educational debt and who meet eligibility criteria may apply for student loan repayment. Loan repayments utilize a peer review process to determine which applicants to approve. The peer review process is committee-based, with a peer review group comprised of individual reviewers, referees, or other recommenders (hereafter collectively referred to as reviewers). Reviewers are primarily non-government experts qualified by training and experience in scientific or technical fields, or as authorities knowledgeable in disciplines and fields related to the areas under review. Reviewers give DLR expert recommendations and materials (such as ratings, summaries, and communications) about applicants' suitability, eligibility, or

qualifications for student loan repayments under express promises that the reviewers will not be identified as the sources of the information. DLR uses the information solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal loan repayment. System of records 09-25-0165 covers records about health professionals who apply for student loan repayments and about other categories of individuals who are related to the applications. Records about those record subjects include materials and recommendations provided to DLR by reviewers which identify, or could enable identification of, those confidential sources.

## **II. Proposed Exemptions and Affected Records**

HHS/NIH is proposing to exempt materials about LRP applicants in system of records 09-25-0165 from certain provisions of the Privacy Act (5 U.S.C. 552a). The exemption applies only to the extent that a disclosure would reveal the identity of the reviewer or referee who furnished information to the Government under an express promise that his or her identity would be held in confidence. We propose to exempt the system of records from (c)(3), pertaining to the accounting of disclosures, and (d)(1) through (d)(4), pertaining to access, amendment, and notification provisions, based on subsection (k)(5) of the Act (5 U.S.C. 552a(k)(5)). Because records in system of records 09-25-0165 contain information not only about applicants, but also about the reviewers, the proposed exemptions are necessary to enable NIH to prevent applicants from having access to information about the identity of individuals who provided NIH with an expert review or referee report under an express promise of confidentiality. Notwithstanding the exemptions, NIH will consider any requests for notification, access, and amendment that are addressed to the System Manager, as provided in the SORN for system of records 09-25-0165, and to any request for an accounting of disclosures.

Under the Privacy Act of 1974, as amended (5 U.S.C. 552a), individuals have access and amendment rights with respect to records about them in a federal agency system of records, and the right to seek an accounting of certain disclosures made of the records about them, but the Act permits certain types of systems of records (identified in subsections (j) and (k) of the Act) to be exempted from

those requirements of the Act. Subsection (k)(5) permits the head of an agency to promulgate rules to exempt from the requirements in 5 U.S.C. 552a(c)(3) and (d)(1) through (4) investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for access to federal civilian employment, military service, federal contracts, or access to classified information, to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the government under an express promise that the identity of the source would be held in confidence. Referee reports and reviews in system of records 09–25–0165 qualify for exemption under 5 U.S.C. 552a(k)(5), when provided to DLR under an express promise of confidentiality, because it is investigatory material that DLR compiles solely for the purpose of determining applicants' suitability, eligibility, or qualifications for federal loan repayment awards, which are implemented by contracts.

### **III. Exemption Rationales**

The proposed exemptions are necessary to maintain the integrity of the DLR peer review and award processes, which depend on receiving accurate, objective, and unbiased recommendations and evaluations from reviewers about loan repayment applications. Protecting reviewer identities as the sources of the information they provide protects them from harassment, intimidation, and other attempts to improperly influence award outcomes, and ensures that they are not reluctant to provide sensitive information or frank assessments. Case law has held that exemptions promulgated under subsection (k)(5) may protect source-identifying material even where the identity of the source is known to the subject individual(s).

The specific rationales that support the exemptions, as to each affected Privacy Act provision, are as follows:

- *Subsection (c)(3)*. An exemption from the requirement to provide an accounting of disclosures to record subjects is needed to protect the identity of any reviewer source who is expressly promised confidentiality. Providing an accounting of disclosures to an individual who is related to the application under assessment or evaluation could identify particular

reviewers as sources of recommendations or evaluative input received, or to be received, on the application. Inappropriately revealing their identities in association with the nature and scope of their assessments or evaluations could lead them to alter or destroy their assessments or evaluations or subject them to harassment, intimidation, or other improper influence, which would impede or compromise the fairness and objectivity of the loan repayment application review process.

- *Subsection (d)(1)*. An exemption from the access requirement is needed both during and after an award application review proceeding to avoid inappropriately revealing the identity of any source who was expressly promised confidentiality. Protecting these records from access by record subjects is necessary for the integrity of the review process. It ensures such sources provide candid assessments or evaluations to the government without fear that their identities as linked to a specific work product will be revealed inappropriately. Allowing an individual applicant who is the subject of an assessment or evaluation, or another record subject who has a relationship to the application, to access material that would reveal a reviewer could interfere with or compromise the objectivity and fairness of award application review proceedings, constitute an unwarranted invasion of the personal privacy of the reviewer, and violate the express promise of confidentiality made to the reviewer.
- *Subsection (d)(2) through (4)*. An exemption from the amendment provisions is necessary while one or more related application review proceedings are pending, but only if and to the extent that disclosure of information in the amendment request process would reveal inappropriately the identity of any reviewer source who was expressly promised confidentiality. An exemption will be limited to allowing the agency, when processing an amendment request by an applicant or other subject individual, to avoid disclosing the existence of the record sought to be amended and its contents, if doing so would reveal the identity of any reviewer who was expressly promised confidentiality. Revealing the

identity of a reviewer to an individual applicant or other subject individual would interfere with the agency's application review process and constitute an unwarranted invasion of the personal privacy of the reviewer and would violate the express promise of confidentiality made to the reviewer.

Accordingly, pursuant to 5 U.S.C. 552a(k)(5), NIH proposes to exempt records about particular LRP applicants in system of records 09-25-0165 NIH Division of Loan Repayment Record System from the access, amendment, and accounting of disclosures provisions of the Privacy Act (5 U.S.C. 552a(c)(3) and (d)(1) through (4)), to the extent, and based on the specific rationales stated above. Notwithstanding the exemptions, NIH will consider any request for access or amendment that is addressed to the System Manager as provided in the SORN for system of records 09-25-0165, and to any request for an accounting of disclosures.

## **Analysis of Impacts**

### *I. Review under Executive Orders 12866, 13563, and 13771.*

The agency has reviewed this proposed rule under Executive Orders 12866 and 13563, which direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to maximize the net benefits. The agency believes that this proposed rule is not a significant regulatory action under Executive Order 12866, and therefore does not constitute an EO 13771 regulatory action, because it will not (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. legal mandates, the President's priorities, or the principles set

forth in Executive Order 12866. This rule removes certain Privacy Act rights from the subjects of these records in accordance with criteria established in subsection (k)(5) of the Privacy Act (5 U.S.C. 552a(k)(5)). This decision is based on a showing that agency compliance with all of the Privacy Act requirements with respect to those records would harm the effectiveness or integrity of the agency function or process for which the records are maintained (in this case, NIH research and development loan award processes).

*II. Review under the Regulatory Flexibility Act (5 USC 601-612).*

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant regulatory impacts of a rule on small entities. Because the proposed rule imposes no duties or obligations on small entities, we have determined, and the Director certifies, that the proposed rule will not have a significant economic impact on a substantial number of small entities.

*III. Review under the Unfunded Mandates Reform Act of 1995 (Section 202, Public Law 104-4).*

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. The agency does not expect that this proposed rule would result in any 1-year expenditure by state, local, and tribal governments that would meet or exceed this amount.

*IV. Review under the Paperwork Reduction Act of 1995 (44 USC 35-1 et seq.).*

This proposed rule does not contain any information collection requirements subject to the Paperwork Reduction Act.

*V. Review under Executive Order 13132, Federalism.*

This proposed rule will not have any direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, the requirements of Executive Order 13132 are inapplicable.

**List of Subjects in 45 CFR Part 5b**

Privacy

For the reasons set out in the preamble, the Department amends part 5b of title 45 of the Code of Federal Regulations, as follows:

**PART 5b – PRIVACY ACT REGULATIONS**

1. The authority citation for Part 5b continues to read as follows:

Authority: 5 U.S.C. 301, 5 U.S.C. 552a

2. Amend § 5b.11 by adding paragraph (b)(2)(iv)(D) as follows:

**§ 5b.11 Exempt systems.**

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(b) \*\*\*

(2) \*\*\*

(iv)

(D) NIH Division of Loan Repayment Record System, 09-25-0165.

Dated: November 20, 2020.

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Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.

Approved: December 22, 2020.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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