

9. Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

12. Energy Effects

This proposed rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction. This rule involves implementation of regulations within 33 CFR Part 100 that apply to organized marine events on the navigable waters of the United States that may have potential for negative

impact on the safety or other interest of waterway users and shore side activities in the event area. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, and sail board racing. Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

2. In § 100.501, in the Table to § 100.501, temporarily suspend line (c)19.

3. In § 100.501, in the Table to § 100.510, add temporary line 23 to read as follows:

§ 100.501 Special Local Regulations; Marine Events in the Fifth Coast Guard District.

* * * * *

(C.) COAST GUARD SECTOR HAMPTON ROADS—COTP ZONE

No.	Date	Event	Sponsor	Location
23	* September 30, 2012 or in the case of inclement weather October 7, 2012.	* Poquoson Seafood Fest- tival Workboat Races.	* City of Poquoson	* The waters of the Back River, Poquoson, Virginia, bounded on the north by a line drawn along lati- tude 37°06'30" N, bounded on the south by a line drawn along latitude 37°06'15" N, bounded on the east by a line drawn along longitude 076°18'52" W and bounded on the west by a line drawn along longitude 076°19'30" W.
	* * *	* * *	* * *	* * *

Dated: August 1, 2012.

John K. Little,

*Captain, U.S. Coast Guard, Captain of the
Port Hampton Roads.*

[FR Doc. 2012–21211 Filed 8–27–12; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 5b

[Docket Number NIH–2011–0001]

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), through the National Institutes of Health (NIH), is implementing a new system of records, 09–25–0223, “NIH Records Related to Research Misconduct Proceedings, HHS/NIH.” HHS is exempting this system of records from certain requirements of the Privacy Act to protect the integrity of NIH research misconduct proceedings and to protect the identity of confidential sources in

such proceedings. Elsewhere in this issue of the **Federal Register**, HHS is issuing a direct final rule for this action because the agency expects that there will be no significant adverse comment on this rule. HHS is publishing this companion proposed rule under the agency's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency publishing this companion proposed rule under the agency's usual procedure for notice-and-comment rulemaking, to provide a procedural framework to finalize the rule in the event the agency receives any significant comments and withdraws the direct final rule. The direct final rule and this companion proposed rule are substantively identical.

DATES: Submit either electronic or written comments by November 13, 2012. If HHS/NIH receives any significant adverse comments, the agency will publish withdrawing the direct final rule within 30 days after the comment period ends. HHS/NIH will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by [Docket No(s).], by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Fax: 301-402-0169.
- Mail: Jerry Moore, NIH Regulations Office, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669.

To ensure a more timely processing of comments, HHS/NIH is no longer accepting comments submitted to the agency by email. 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 <http://www.regulations.gov>, including any personal information provided.

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

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669, telephone 301-496-4607, fax 301-402-0169, email jm40z@nih.gov.

SUPPLEMENTARY INFORMATION: NIH is implementing a new system of records called, "NIH Records Related to Research Misconduct Proceedings" (09-25-0223). This system of records is part of NIH's implementation of its responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR part 93. The system notice applies to alleged or actual research misconduct involving research: (1) Carried out in NIH facilities by any person; (2) funded by the NIH Intramural Research Program (IRP) in any location; or (3) undertaken by an NIH employee or trainee as part of his or her official NIH duties or NIH training activities, regardless of location. A person who, at the time of the alleged or actual research misconduct, was employed by, was an agent of, or was affiliated by contract, agreement, or other arrangement with NIH, is covered by the system if, for example, he or she is involved in: (1) NIH- or PHS-supported biomedical or behavioral research; (2) NIH- or PHS-supported biomedical or behavioral research training programs; (3) NIH- or PHS-supported activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks and the dissemination of research information; (4) plagiarism of research records produced in the course of NIH- or PHS-supported research, research training or activities related to that research or research training; or (5) an application or proposal for NIH or PHS support for biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information (regardless of whether it is approved or funded).

The term "research misconduct" is defined at 42 CFR 93.103 to mean "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research

results." The general policy of the PHS Policies on Research Misconduct is that "Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds." 42 CFR 93.100(a). The PHS Policies on Research Misconduct provide for a number of HHS administrative actions that can be taken in response to a research misconduct proceeding, such as an adverse personnel action against a federal employee, the suspension of a contract, or debarment. 42 CFR 93.407. In addition, pursuant to 42 CFR 93.318 and 93.401, NIH shall at any time during a research misconduct proceeding notify the HHS Office of Research Integrity (ORI) immediately to ensure that NIH's Office of Management Assessment, HHS' Office of Inspector General, the Department of Justice, or other appropriate law enforcement agencies are notified and consulted, if there is a reasonable indication of possible violations of civil or criminal law that may involve such offices.

NIH's system of records is modeled after the system of records maintained by ORI, entitled "HHS Records Related to Research Misconduct Proceedings, HHS/OS/ORI" System No. 09-37-0021 (59 FR 36717, July 19, 1994; revised most recently at 74 FR 44847, Aug. 31, 2009).

NIH's records related to research misconduct proceedings are located in the Office of Intramural Research in NIH's Office of the Director. NIH is updating its organization and operation of these records, to be exempt from Privacy Act requirements, as provided in the direct final rule and in a new "System of Records Notice" which NIH is publishing in the **Federal Register** for public comment contemporaneously with or soon after publication of this companion proposed rule.

Under the Privacy Act (5 U.S.C. 552a), individuals have a right of access to information pertaining to them which is contained in a system of records. At the same time, the Act permits certain types of systems to be exempt from some of the Privacy Act requirements, including the access requirement. For example, section 552a(k)(2) allows agency heads to exempt from certain Privacy Act provisions a system of records containing investigatory material compiled for law enforcement purposes. This exemption's effect on the access requirement is qualified in that if the maintenance of the material results in the denial of any right, privilege, or benefit that the individual would be otherwise entitled to by Federal law, the

individual must be granted access to the material unless the access would reveal the identity of a source who furnished information to the Government under an express promise of confidentiality. In addition, section 552a(k)(5) permits an agency to exempt investigatory material from certain Privacy Act provisions where such material is compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only 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.

As stated above, NIH may take administrative action in response to a research misconduct proceeding and, where a civil or criminal fraud may have taken place, NIH may refer the matter to the appropriate investigative body. As such, NIH's records related to research misconduct proceedings are compiled for law enforcement purposes, and the subsection (k)(2) exemption is applicable to this system of record. Moreover, where records related to research misconduct proceedings are compiled solely for the purpose of making determinations as to the suitability for appointment as special government employees or eligibility for Federal contracts from PHS agencies, the subsection (k)(5) exemption is applicable.

Exempting the system from Privacy Act provisions pertaining to providing an accounting of disclosures, access and amendment, notification, and procedures and rules is necessary to maintain the integrity of the research misconduct proceedings and to ensure that the NIH's efforts to obtain accurate and objective information will not be hindered.

Accordingly, HHS/NIH is exempting this system under subsections (k)(2) and (k)(5) of the Privacy Act from the accounting, access, and amendment, notification and procedures and rules provisions of the Privacy Act (paragraphs (c)(3), (d)(1)–(4), (e)(4)(G) and (H), and (f)) for the reasons stated below. However, consideration will be given to requests for notification, access, and amendment that are addressed to the System Manager. The specific rationale for exempting the system from each of these provisions is as follows:

- Subsection (c)(3). An exemption from the requirement to provide an accounting of disclosures is needed during the pendency of a research misconduct proceeding. Release of an

accounting of disclosures to an individual who is the subject of a pending research misconduct assessment, inquiry or investigation could prematurely reveal the nature and scope of the assessment, inquiry or investigation and could result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding.

- Subsection (d)(1). An exemption from the access requirement is needed both during and after a research misconduct proceeding, to avoid revealing the identity of any source who was expressly promised confidentiality. Only material that would reveal a confidential source will be exempt from access. Protecting the identity of a source is necessary when the source is unwilling to come forward and report possible research misconduct because of fear of retaliation (e.g., from an employee or co-worker).

- Subsections (d)(2) through (d)(4). An exemption from the amendment provisions is necessary while one or more related research misconduct proceedings are pending. Allowing amendment of investigative records in a pending proceeding could interfere with that proceeding; even after that proceeding is concluded, an amendment could interfere with other pending or prospective research misconduct proceedings, or could significantly delay inquiries or investigations in an attempt to resolve questions of accuracy, relevance, timeliness, and completeness.

- Subsections (e)(4)(G) and (H). An exemption from the notification provisions is necessary during the pendency of a research misconduct proceeding, because notifying an individual who is the subject of an assessment, inquiry, or investigation of the fact of such proceedings could prematurely reveal the nature and scope of the proceedings in a manner that could result in the altering or destruction of evidence, improper influencing of witnesses, and other evasive actions that could impede or compromise the proceeding.

- Subsection (f). An exemption from this requirement to establish procedures for notification, access to records, amendment of records, or appeals of denials of access to records, is necessary because the procedures would serve no purpose in light of the other exemptions, to the extent that those exemptions apply.

As stated above, NIH's system of records is modeled after the system of records maintained by HHS' Office of Research Integrity (ORI). ORI has

exempted these records under subsections (k)(2) and (k)(5) of the Privacy Act from the notification, accounting, access, and amendment provisions of the Privacy Act, to ensure that these investigative files will not be disclosed inappropriately [59 FR 36717 (July 19, 1994)]. Likewise, NIH believes that exempting the new system, "NIH Records Related to Research Misconduct Proceedings, HHS/NIH," from the Privacy Act provisions is essential to ensure that material in NIH's files related to research misconduct proceedings is not disclosed inappropriately. Except for information that would reveal the identity of a source who was expressly promised confidentiality, the access exemption will not prohibit HHS/NIH from granting respondents' access requests consistent with the PHS Policies on Research Misconduct (42 CFR Part 93), including in those cases in which a finding of research misconduct has become final and an administrative action has been imposed.

Analysis of Impacts

HHS/NIH has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that the final rule is not a significant regulatory action under the Executive Order.

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

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 \$136

million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. NIH does not expect that a final rule consistent with this NPRM would result in any 1-year expenditure that would meet or exceed this amount.

List of Subjects in 45 CFR Part 5b

Privacy.

For the reasons set out in the preamble, the Department proposes to amend its Privacy Act Regulations, Part 5b of 45 CFR Subtitle A, 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. In § 5b.11, add paragraph (b)(2)(vii)(D) to read as follows:

§ 5b.11 Exempt systems

* * * * *

(b) * * *

(2) * * *

(vii) * * *

(D) NIH Records Related to Research Misconduct Proceedings, HHS/NIH, 09–25–0223.

Dated: July 20, 2012.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2012–20887 Filed 8–27–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 204

RIN 0750–AH80

Defense Federal Acquisition Regulation Supplement: Clarification of “F” Orders in the Procurement Instrument Identification Number Structure (DFARS Case 2012–D040)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to update instructions for assigning basic and supplementary procurement instrument identification numbers.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before

October 29, 2012, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2012–D040, using any of the following methods:

○ *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by entering “DFARS Case 2012–D040” under the heading “Enter keyword or ID” and selecting “Search.” Select the link “Submit a Comment” that corresponds with “DFARS Case 2012–D040.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “DFARS Case 2012–D040” on your attached document.

○ *Email:* dfars@osd.mil. Include DFARS Case 2012–D040 in the subject line of the message.

○ *Fax:* 571–372–6094.

○ *Mail:* Defense Acquisition Regulations System, Attn: Veronica Fallon, OUSD(AT&L)DPAP/DARS, Room 3B855, 3060 Defense Pentagon, Washington, DC 20301–3060.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Veronica Fallon, telephone 571–372–6087.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to eliminate the requirement to utilize an “F” in the 9th position of the procurement instrument identification number (PIIN) to identify awards to certain vendors, including AbilityOne and Federal Prison Industries (UNICOR), and to other Government organizations. These vendors are uniquely identified today by their DUNS number and/or CAGE code and, therefore, associated contract actions are easily tracked. There is no longer any need for DoD to uniquely identify contract actions with these vendors. Under the proposed rule, contract actions with these vendors will be treated and identified in the same manner as those with any other vendor. This change proposes to limit the use of “F” in the 9th position of the PIIN to those task and delivery orders issued under a non-DoD issued contract or agreement. It is anticipated that this proposed change, which further

standardizes DoD procedures, will also reduce data errors and interoperability problems throughout the Department’s business processes.

II. Discussion and Analysis

DoD is proposing the following changes to the DFARS:

- Revise 204.7003, Basic PII number, paragraph (a)(3), Position 9, by—
 - Deleting from subparagraph (iii) instrument type C, the exception for contracts placed with or through other Government departments or agencies;
 - Deleting from subparagraph (vi) instrument type F, contracting actions placed with or through other Government departments or agencies or against contracts placed by such departments or agencies outside the DoD (including actions from nonprofit agencies employing people who are blind or severely disabled (AbilityOne), and the Federal Prison Industries (UNICOR));
 - Providing at subparagraph (vi) instrument type F direction for its use with blanket purchase agreement calls, orders under contracts, including Federal Supply Schedules, Governmentwide acquisition contracts, and multi-agency contracts, basic ordering agreements issued by departments or agencies outside of DoD; and
- Revising 204.7004, Supplementary PII numbers, paragraph (d)(2)(ii) by providing direction to use “F” in position 9 for calls against blanket purchase agreements and orders placed under non-DoD issued contracts including Federal Supply Schedules, Governmentwide acquisition contracts, and multi-agency contracts, or basic ordering agreements. The proposed text also directs that a supplementary PII number with an “F” in the 9th position is to be used only once, and not for more than one order.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and