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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 46

NATIONAL SCIENCE FOUNDATION

45 CFR Part 690

DEPARTMENT OF TRANSPORTATION

49 CFR Part 11

Federal Policy for the Protection of Human Subjects: Proposed Six Month Delay of the General Compliance Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: In a final rule published on January 19, 2017, federal departments and agencies made revisions to the Federal Policy for the Protection of Human Subjects (hereafter the ''2018 Requirements''). The Consumer Product Safety Commission (CPSC) adopted the same regulatory changes in a separate final rule published on September 18, 2017. The 2018 Requirements were scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018 (with the exception of the revisions to the cooperative research provision). The departments and agencies listed in this document have also published an interim final rule delaying the effective date and general compliance date for the 2018 Requirements for six months, to cover the time period of January 19, 2018 until July 19, 2018.

As per the interim final rule, the effective date of the 2018 Requirements is now July 19, 2018. The departments and agencies listed in this document propose delaying the general compliance date for the 2018 Requirements for an additional six months, for the time period of July 19, 2018 until January 21, 2019. This proposed rule is intended to provide additional time to regulated entities for the preparations necessary to implement the 2018 Requirements. This proposed rule, if finalized, would require regulated entities to continue to comply with the requirements of the current Federal Policy for the Protection of Human Subjects (hereafter the ''pre-2018 Requirements'') until January 21, 2019.

This proposal also takes comment on whether to permit institutions to implement, for certain research studies, the following provisions in the 2018 Requirements during the period from July 19, 2018, until January 21, 2019, that the general compliance date is delayed. Those three provisions, intended to reduce burdens on regulated entities, are the 2018 Requirements' definition of ''research,'' which deems certain activities not to be research, the allowance for no annual continuing review of certain categories of research, and the elimination of the requirement that institutional review boards (IRBs) review grant applications related to the research. The way that this option is proposed, regulated entities would be required to comply with all pre-2018 Requirements during the period that the general compliance date is delayed, except for provisions substituted by the three burden-reducing provisions of the 2018 Requirements.

As described in section III, below, this flexibility is proposed only for studies for which an institution makes a choice to transition to comply with the 2018 Requirements, beginning on July 19, 2018. In order to clearly describe this proposed flexibility, including how it would impact institutions choosing to transition research to comply with the 2018 Requirements, this document proposes a redrafted transition provision.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 11:59 p.m. Eastern Standard Time on May 21, 2018.

ADDRESSES: You may submit comments, identified by docket ID number HHS–OPHS–2018–0007 by one of the following methods:

- *Federal eRulemaking Portal* (*http://www.regulations.gov*):
  - Enter the following link into your web browser's address bar: *https://www.regulations.gov/document?D=HHS-OPHS-2018-0007*.
  - Click the blue ''Comment Now!'' button in the upper right hand corner and follow the instructions on how to submit a comment.
  - Alternatively, you can enter the docket ID number into the ''search'' box on the main page of the Federal eRulemaking Portal (*http://www.regulations.gov*) to find the electronic docket.

• *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions] to:* Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

• Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240–453–6900 or 1–866–447–4777; facsimile: 301–402–2071; email *Jerry.Menikoff@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 8, 2015, HHS and 15 other federal departments and agencies published a notice of proposed rulemaking (NPRM) proposing revisions to each agency's codification of the Federal Policy for the Protection of Human Subjects, originally promulgated as a Common Rule in 1991. 80 FR 53931. On January 19, 2017, HHS and other federal departments and agencies published a final rule revising the Federal Policy for the Protection of Human Subjects. 82 FR 7149. The CPSC adopted the same regulatory changes, also with a scheduled effective date of January 19, 2018, in a separate final rule published on September 18, 2017. 82 FR 43459. For this reason, references in this document to the January 2017 final rule also extend to the CPSC's September 2017 final rule. The revised policy, reflected in both final rules, is hereafter referred to as the ''2018 Requirements.'' The 2018 Requirements were originally scheduled to become effective on January 19, 2018, with a general compliance date of January 19, 2018 (with the exception of the revisions to the cooperative research provision at § ____.114(b), for which the compliance date is January 20, 2020).

After publication of the 2018 Requirements, some representatives of the regulated community, including organizations representing recipients of federal human subjects research awards, expressed concern regarding the regulated community's ability to implement all of the 2018 Requirements by the scheduled general compliance date.[1] One of the two letters asked for a delay in the general compliance date of the 2018 Requirements, with the option to adopt burden-reducing provisions of the 2018 Requirements during the delay period, including certain carve-outs from the definition of ''research,'' exemptions, elimination of the continuing review requirement for certain categories of research, and the elimination of the requirement that institutional review boards (IRBs) review grant applications. The HHS Secretary's Advisory Committee on Human Research Protections (SACHRP) also recommended in August 2017 that the required implementation of the 2018 Requirements should be delayed.[2] On January 17, 2018, HHS and other federal departments and agencies placed on display in the **Federal Register** an interim final rule delaying the effective date and general compliance date of the 2018 requirements to July 19, 2018. 83 FR 2885 (published January 22, 2018). On January 26, 2018, HUD published an interim final rule adopting the January 17, 2018 interim final rule. 83 FR 3589.

This NPRM proposes to delay the general compliance date of the 2018 Requirements by an additional six months, during the time period of July 19, 2018 to January 21, 2019.

II. Proposed Delay of the General Compliance Date

We propose to delay the general compliance date of the 2018 Requirements for six months after the effective date of July 19, 2018 until January 21, 2019. Given the degree of complexity involved with implementing the revised rule, we believe the delay we are proposing in this action is both an appropriate action to take at this juncture, and a reasonable time period to allow the regulated community to be prepared for compliance with the 2018 Requirements and for HHS and the other Common Rule agencies to develop implementation guidance. The 2018 requirements include new exemptions, new IRB review procedures, and new provisions pertaining to informed consent, among other revisions, and guidance would be helpful to the regulated community in understanding and complying with these requirements. As described below, we propose to revise § ____.101(l)(2) to specify that the general compliance date for the 2018 Requirements is January 21, 2019. We also propose to revise the dates in the transition provision at § ____.101(l)(3),(4) and (5) to reflect this revised general compliance date.

As proposed, regulated entities would be required to comply with the pre-2018 Requirements prior to January 21, 2019, and the pre-2018 Requirements would be applied by the Common Rule departments and agencies during this period. To clarify, under this proposal, regulated entities would not be allowed, prior to January 21, 2019, to comply with all provisions of the 2018 Requirements in lieu of all provisions of the pre-2018 Requirements. As described below in section III, an exception would exist during the six-month period between July 19, 2018, and January 21, 2019, with respect to three specified burden-reducing provisions contained in the 2018 Requirements.

Research initiated (*i.e.,* initially approved by an IRB, or for which IRB review was waived pursuant to § ____.101(i), or determined to be exempt) before the general compliance date of the 2018 Requirements (which would now become January 21, 2019) would, as a default, continue to be subject to the pre-2018 Requirements for their duration. This will maintain the ability of institutions to hold such studies to the same set of standards throughout the studies' duration, and will avoid a requirement that such research be subject to two sets of rules.

Research initiated (*i.e.,* initially approved by an IRB, or for which IRB review was waived pursuant to § ____.101(i), or determined to be exempt) on or after January 21, 2019 (proposed as the new general compliance date), would need to be conducted entirely in compliance with the 2018 Requirements. This document proposes to restructure § ____.101(1)(3) and (4) (now numbered (5)) to aid readability. A new section § ____.101(l)(4) is proposed to be inserted to explain how the requirements would apply to research transitioning to take advantage of the burden-reducing provisions.

We do not propose delaying the compliance date for the cooperative research provision of the 2018 Requirements (§ __.114(b)), which will remain January 20, 2020.

[1] Two unsolicited comments were received. See the June 21, 2017 letter to Jerry Menikoff from the Association of American Medical Colleges, Association of American Universities, Association of Public & Land-grant Universities, and Council on Governmental Relations, available at *http://www.cogr.edu/sites/default/files/AAMC_AAU_APLU_COGR%20Common%20Rule%20Delay%20Letter%206-21-2017.pdf.* See the June 9, 2017 letter to Secretary Thomas Price from the American Medical Informatics Association at *https://www.amia.org/sites/default/files/AMIA%20Letter%20Regarding%20the%20Common%20Rule.pdf.*

[2] August 2, 2017 SACHRP Letter to HHS Secretary, Attachment A-Recommendations on Compliance Dates and Transition Provisions, *https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-august-2-2017/index.html.*

III. Proposed Flexibility for Taking Advantage of Certain Burden-Reducing Provisions Without a Delay

This proposed rule also proposes to permit institutions, during the period from July 19, 2018, until January 21, 2019, that the general compliance date is proposed to be delayed, to take advantage of three provisions in the 2018 Requirements intended to minimize burdens on regulated entities (hereinafter ''three burden-reducing 2018 Requirements'').

As under the January 2017 final rule, under this proposed rule, studies initiated prior to the general compliance date of the 2018 Requirements, would, as a default, remain subject to the pre-2018 Requirements for their duration unless and until a decision to transition to the 2018 Requirements (*i.e.,* the institution chooses to have a study be subject to the 2018 Requirements) is made and documented.

The January 2017 final rule provided an option for institutions to transition ongoing studies from compliance with the pre-2018 Requirements to compliance with the 2018 Requirements for the studies' duration. This proposed rule would preserve that option, and proposes an additional flexibility for ongoing studies to transition to the 2018 Requirements if the decision to transition is documented prior to January 21, 2019, which would be the new general compliance date of the 2018 Requirements. Between July 19, 2018 and January 21, 2019, institutions that elect to transition studies to the 2018 Requirements would, after the decision to transition has been documented, be able to take advantage of the three burden-reducing 2018 Requirements. This option is available for ongoing studies, as well as for studies newly initiated after July 19, 2018.

This option is described in a proposed revision to § ____.101(l). In order to clearly outline the operation of this proposed flexibility, we propose to redraft § ____.101(l) to describe how the transition provision applies to research subject to the pre-2018 Requirements, research transitioned from the pre-2018 Requirements to the 2018 Requirements, and research subject to the 2018 Requirements. The revised § ____.101(l) describes how the pre-2018 Requirements and the 2018 Requirements apply to research initiated (*i.e.,* initially approved by an IRB, waived under § ____.101(i), or determined to be exempt), during three time periods: Prior to July 19, 2018, between July 19, 2018 and January 21, 2019, and on or after January 21, 2019.

As described, studies taking advantage of this option would be subject to the three burden-reducing 2018 Requirements instead of, or in addition to, the comparable provisions of the pre-2018 Requirements. The three burden-reducing 2018 Requirements are (1) the 2018 Requirements' definition of ''research'' at § ____.102(l) (instead of § ____.102(d) of the pre-2018 Requirements), which deems certain activities not to be research, (2) the elimination of the requirement that an IRB review the grant application related to the research at § ____.103(d) of the 2018 Requirements (instead of § ____.103(f) of the pre-2018 Requirements), and (3) the allowance for no annual continuing review of certain categories of research at § ____.109(f)(1)(i) and (iii) of the 2018 Requirements (instead of § ____.103(b), as related to the requirement for continuing review, and in addition to § ____.109, of the pre-2018 Requirements).

Given that studies taking advantage of this flexibility would, if this proposal is adopted, temporarily be subject to the three burden-reducing 2018 Requirements, but not other provisions in the 2018 Requirements, we are clarifying our intended interpretations of these provisions during a transition period. First, the definition of ''research'' in the 2018 Requirements references a ''public health authority,'' a term defined in the 2018 Requirements, but not included in the pre-2018 Requirements. The reference to a ''public health authority'' in § ____.102(l)(3) of the 2018 Requirements would be interpreted consistent with the definition of ''public health authority'' included in the 2018 Requirements (§ ____.102(k)). Second, § ____.103(d) of the 2018 Requirements refers to research ''exempted under § ____.104.'' Because the exemptions that will be in place during any transition period are set forth in § ____.101(b) of the pre-2018 Requirements, this reference to research ''exempted under § ____.104'' would be interpreted, during this transition period and prior to the general compliance date of the 2018 Requirements, as a reference to research exempted under § ____.101(b) of the pre-2018 Requirements. Third, the reference in § ____.109(f)(1)(i) of the 2018 Requirements to research eligible for expedited review under § ____.110 would be interpreted as a reference to that section in the pre-2018 Requirements. Moreover, the documentation requirements set forth in § ____.115(a)(3) of the 2018 Requirements (documenting an IRB's rationale for conducting continuing review that would not otherwise be required under § ____.109(f)(1) of the 2018 Requirements) would not be applicable during this transition period as proposed.

As proposed above, for institutions electing to transition a research study to compliance with the 2018 Requirements in order to take advantage of the three burden-reducing provisions, § ____.103(d) of the 2018 Requirements would be substituted for § ____.103(f) of the pre-2018 Requirements. Both sections address the requirement for certification of research supported by a Federal department or agency. In addition to removing the requirement that IRBs review grant applications or proposals, § ____.103(d) of the 2018 Requirements reflects other minor wording changes necessary to accommodate the removal of the grant application or proposal review requirement or to provide additional clarifications.

Except for the three burden-reducing 2018 Requirements identified in proposed § ____.101(l)(4)(i)(A), institutions that elect to transition a research study to comply with the 2018 Requirements and document that decision, at any time between July 19, 2018, and January 21, 2019, would be required to comply with the pre-2018 Requirements until January 21, 2019. This approach would afford institutions additional time before they are required to comply with all provisions of the 2018 Requirements, while enabling them to take advantage of the three burden-reducing 2018 Requirements more quickly. The option of applying the three burden-reducing 2018 Requirements would only be available for studies that institutions decided to transition to comply with the 2018 Requirements on or after July 19, 2018. If an institution so chooses to apply the three burden-reducing 2018 Requirements to certain research, those studies would be required to comply with all of the 2018 Requirements beginning on January 21, 2019.

An institution's decision about whether to transition a study to the 2018 requirements to take advantage of the three burden-reducing provisions might vary depending on the nature and progress of the study, including any elements of the study to be conducted on or after January 21, 2019. For example, studies planning to recruit some subjects on or after January 21, 2019 would have to meet the new requirements for obtaining the informed consent of those subjects. In contrast, for studies whose remaining activities

consist only of completing data analyses, the new requirements for informed consent generally would not be applicable.

We considered stakeholder suggestions to extend this approach to other burden-reducing sections of the 2018 Requirements, such as the revised exemption categories. We do not propose adding the revised exemption categories to § ____.101(l)(4)(i)(A) because implementation of these categories would involve significantly greater complications. For example, these categories use terms that are newly defined or for which revised definitions have been included in the 2018 Requirements, and permitting compliance with these categories without also selectively adopting revised definitions could be problematic. To minimize confusion, this proposed rule limits those provisions for which early adoption would be permitted to those that would minimize burdens without creating significant complexities. We also considered a delay to the effective and general compliance dates without proposing this additional option in the interim period. Such an approach would be simple to implement. We decided against proposing this alternative to be responsive to public comments received and in an effort to minimize burdens with respect to new provisions that will not be difficult to implement prior to the general compliance date of the 2018 Requirements.

As proposed for § ____.101(l)(4)(ii), if the determination to transition previously initiated studies to the 2018 Requirements is not made until on or after January 21, 2019, such studies would not benefit from the additional flexibilities created for the period between July 19, 2018 and January 21, 2019. Such studies would be required to comply with the 2018 Requirements after the date of transition.

The regulatory provisions are not prescriptive regarding how an institution chooses to make its transition decisions. An institution may elect to transition research protocols to the 2018 Requirements on a protocol-by-protocol basis, or for a class of protocols (*e.g.,* all minimal risk research), or for the institution's entire research portfolio. While these three burden reducing provisions are a regulatory package, an institution that took advantage of the flexibility proposed in this NPRM, as a matter of institutional policy, could adopt a more stringent standard (such as that of the pre-2018 rule) for any or all of these three provisions.

We also propose a revision to § ____.101(l)(4) regarding documentation of an institution's decision to transition research begun under the pre-2018 Requirements to the 2018 Requirements. This proposal is intended to offer institutions greater flexibility regarding who documents that decision. Under the January 19, 2017, final rule, if an institution determines that ongoing research will transition to comply with the 2018 Requirements, this determination must be documented by an IRB before the transition can take effect. We now propose that, to allow ease in implementing this documentation requirement, the documentation of an institution's transition determination may be performed either by an institution (through officials who have the authority to make such determinations on behalf of the institution) or an IRB. As proposed, this documentation must include the date of the transition determination. Records documenting the transition decision must be retained as per § ____.115(b).

Once the institution makes the determination to transition the research to the revised rule and that determination is documented, the date of documentation will serve as the de facto compliance date as applied to the research. For a study that is transitioned in accordance with § ____.101(l)(4)(i), between July 19, 2018, and January 20, 2019, one set of rules would apply until the general compliance date of the final rule and another would apply beginning on such general compliance date. As of the date the decision to transition is documented until January 20, 2019, the pre-2018 Requirements would be applicable, except that the three burden-reducing 2018 Requirements would apply instead of or in addition to the pre-2018 Requirements specified in § ____.101(l)(4)(i)(A). Beginning on January 21, 2019, the 2018 Requirements would apply for the duration of the study.

As proposed, all studies that are transitioned in accordance with § ____.101(l)(4)(ii) on or after January 21, 2019, and all studies that are newly initiated on and after January 21, 2019, would be required to follow all of the 2018 Requirements.

In summary, the proposed rule would create three options that would be available beginning July 19, 2018, that institutions may choose to follow for research studies initiated before January 21, 2019. The first option, and default, is to continue to follow all of the pre-2018 Requirements for the duration of the study. The second option is to choose to follow the pre-2018 Requirements, except for the three burden-reducing 2018 Requirements, until January 21, 2019, when all of 2018 Requirements would become applicable. The third option would be to follow the pre-2018 requirements until January 21, 2019, and at some point thereafter choose to follow all of the 2018 Requirements for the duration of the study.

We also solicit comments about the advisability of the alternative of delaying the effective date and general compliance date until January 21, 2019, but without the option to implement certain 2018 Requirements during that delay period.

In addition, we solicit comments on the desirability of the alternative of delaying the effective date and general compliance date beyond January 21, 2019. We do not believe the regulated community will require this additional time to come into compliance with the revised rule, but we are interested in receiving public comments on this alternative.

While we considered the alternative of proposing to amend the transition provision to permit institutions to voluntarily comply with the revised rule beginning on July 19, 2018, and not requiring compliance with the new rule until January 21, 2019 or later, we believe this approach could result in confusion regarding implementation of the revised Common Rule that could be minimized with the issuance of guidance from the Common Rule departments and agencies. By making the changes proposed above, we believe the Common Rule departments and agencies will be able to issue relevant guidance documents that will better enable the regulated community to comply with the revised rule.

We also solicit comments about the advisability of not making the changes proposed in this NPRM (*i.e.,* allowing the effective date and general compliance date to remain as July 19, 2018). Finally, we note that we will consider public comments submitted in response to the interim final rules described above.

IV. Legal Authorities

The legal authorities for the departments and agencies that are signatories to this action are as follows:

Department of Homeland Security, 5 U.S.C. 301; Public Law 107–296, sec. 102, 306(c); Public Law 108–458, sec. 8306. Department of Agriculture, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Department of Energy, 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b). National Aeronautics and Space Administration, 5 U.S.C. 301; 42 U.S.C.

300v–1(b). Department of Commerce, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Consumer Product Safety Commission, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Social Security Administration, 5 U.S.C. 301; 42 U.S.C. 289(a). Agency for International Development, 5 U.S.C. 301; 42 U.S.C. 300v–1(b), unless otherwise noted. Department of Housing and Urban Development, 5 U.S.C. 301; 42 U.S.C. 300v–1(b); 3535(d). Department of Labor, 5 U.S.C. 301; 29 U.S.C. 551. Department of Defense, 5 U.S.C. 301. Department of Education, 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474. Department of Veterans Affairs, 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v–1(b). Environmental Protection Agency, 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Public Law 109–54, 119 Stat. 531; and 42 U.S.C. 300v–1(b). Department of Health and Human Services, 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b). National Science Foundation, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Department of Transportation, 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

V. Regulatory Impact Analyses

We have examined the effects of this proposed rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017), the Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Regulatory Flexibility Act, (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

A. Executive Orders 12866, 13563, and 13771

Executive Orders 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). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. In accordance with the provisions of Executive Order 12866, this proposed rule was submitted to the Office of Management and Budget (OMB) for review, and has been determined to be a ''significant'' regulatory action. The designation, as regulatory or deregulatory under Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs, issued on January 30, 2017), of any final rule resulting from this notice of proposed rulemaking will be informed by comments received on the costs and cost savings of delaying the 2018 Requirements. Details on the preliminary estimated costs of this proposed rule can be found in the economic analysis below.

1. Need for This NPRM and Summary

On January 19, 2017, HHS and 15 other federal departments and agencies published the 2018 Requirements designed to more thoroughly address the broader types of research conducted or otherwise supported by all of the Common Rule departments and agencies. In addition, the CPSC adopted the same regulatory changes on September 18, 2017.

This proposed rule, if finalized, would allow regulated entities to continue to comply with the pre-2018 requirements until January 21, 2019. As discussed above, this proposed rule also proposes to permit institutions, during the period between July 19, 2018, and January 21, 2019, to take advantage of three provisions in the 2018 Requirements intended to minimize burdens on regulated entities. Those three burden-reducing 2018 Requirements are (1) the 2018 Requirements' definition of ''research,'' which deems certain activities not to be research, (2) the allowance for no annual continuing review of certain categories of research, and (3) the elimination of the requirement that IRBs review grant applications related to the research. As described in section III above, this flexibility is proposed for studies for which an institution makes a choice to have those studies be subject to the 2018 Requirements.

2. Analysis of Benefits (Cost-Savings) and Costs (Foregone Benefits) [3]

The RIA for the 2018 Requirements described the benefits and costs of 16 broad categories of changes finalized. The RIA for this NPRM uses the information and calculations described in the preamble to the 2018 Requirements as a base for estimating benefits and costs of delaying the general implementation of the 2018 Requirements by six months. The time period for the analysis in this RIA is the six month period from July 2018 to January 2019.

Table 1 summarizes the quantified benefits and costs of delaying the general implementation of 2018 Requirements. Over the period of July 2018 to January 2019, annualized benefits of $6.4 million are estimated using a 3 percent discount rate; annualized benefits of $5.9 million are estimated using a 7 percent discount rate. Annualized costs of $37.2 million are estimated using a 3 percent discount rate; annualized costs of $34.4 million are estimated using a 7 percent discount rate. Note that all values are represented in millions of 2016 dollars, and 2016 is used as the frame of reference for discounting.

TABLE 1—ALL BENEFITS AND COSTS OF DELAYING THE GENERAL COMPLIANCE DATE OF THE 2018 REQUIREMENTS BY SIX MONTHS

[From July 19, 2018 to January 21, 2019]

	Annualized value by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent
Benefits (Cost–Savings):		
Quantified Benefits	6.4	5.9
Costs (Foregone Benefits):		

[3] Note, that the terms ''benefits'' and ''cost-savings'' are used interchangeably in this RIA. Similarly, the terms ''costs'' and ''foregone benefits'' are also used interchangeably.

TABLE 1—ALL BENEFITS AND COSTS OF DELAYING THE GENERAL COMPLIANCE DATE OF THE 2018 REQUIREMENTS BY SIX MONTHS—Continued

[From July 19, 2018 to January 21, 2019]

	Annualized value by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent
Quantified Costs	37.4	34.7

The estimated benefits and costs of delaying the general implementation date of the 2018 Requirements by six months are shown in Table 2 below. Note that the categorization shown below includes the same 16 categories used in the RIA of the 2018 Requirements.

TABLE 2—ACCOUNTING TABLE OF QUANTIFIED BENEFITS (COST-SAVINGS) AND COSTS (FOREGONE BENEFITS) OF DELAYING COMPLIANCE WITH THE 2018 REQUIREMENTS BY SIX MONTHS [4]

2018 Requirement RIA Category	Annualized value over 1 year by discount rate (millions of 2016 dollars)			
	Benefits (cost-savings)		(Foregone benefits)	
	3%	7%	3%	7%
Regulated Community Learning New Requirements and Developing Training Materials; OHRP Developing Training and Guidance Materials, and Implementing the 2018 Requirements	—	—	—	—
Extending Oversight to IRBs Unaffiliated with an Institution Holding an FWA (impact to IRBs not operated by an FWA-holding institution)	4.47	4.14	—	—
Excluding Activities from the Requirements of the Common Rule because They are not Research	—	—	0.95	0.88
Clarifying and Harmonizing Regulatory Requirements and Agency Guidance	—	—	—	—
Modifying the Assurance Requirements	—	—	0.31	0.29
Requirement for Written Procedures and Agreements for Reliance on IRBs Not Operated by the Engaged Institution (impact to FWA-holding institutions)	—	—	—	—
Eliminating the Requirement that the Grant Application Undergo IRB Review and Approval	—	—	8.5	7.9
Expansion of Research Activities Exempt from Full IRB Review	0.01	0.01	20.8	19.3
Elimination of Continuing Review of Research Under Specific Conditions	1.04	0.96	4.10	3.80
Amending the Expedited Review Procedures	—	—	2.66	2.47
Cooperative Research (single IRB mandate in multi-institutional research) [5]	—	—	—	—
Changes in the Basic Elements of Consent, Including Documentation	—	—	—	—
Obtaining Consent to Secondary Use of Identifiable biospecimens and Identifiable private information	—	—	—	—
Elimination of Pre-2018 Rule Requirement to Waive Consent in Certain Subject Recruitment Activities	—	—	0.07	0.06
Requirement for Posting of Consent Forms for Clinical Trials Conducted or supported by Common Rule Departments or Agencies	0.85	0.79	—	—
Alteration in Waiver for Documentation of Informed Consent in Certain Circumstances	—	—	—	—
Cost Savings, as indicated by public comments (unable to attribute to particular provisions)	unquantified		—	—

We assume that, in almost all categories described in the RIA for the 2018 Requirements, the foregone benefits (costs) of delaying the 2018 Requirements by six months are what would have been the benefits of implementing the 2018 Requirements during the period of July 2018 through January of 2019. Similarly, we assume that, in almost all categories described in the RIA for the 2018 Requirements, the benefits (cost-savings) associated with delaying the 2018 Requirements by six months are what would have been the costs of implementing the 2018 Requirements during the period of July 2018 through January of 2019. We assume this because regulated entities likely would not have difficulty implementing these provisions in the absence of guidance from Common Rule departments or agencies, and thus could have been implemented as assumed in the economic analysis contained in the RIA for the 2018 Requirements. We seek comment on these assumptions.

Categories with different assumptions are described below:

[4] Zeroes in Table 2 (represented by ''—'') signify that the category has been unaffected by the six month delay of the 2018 Requirements. The category could be unaffected for one of two reasons: (1) No costs or benefits were associated with the category in the RIA for the 2018 Requirements; or (2) the costs and benefits of the provision during the six month delay are the same as those estimated in the RIA for the 2018 Requirements.

[5] Because compliance with this provision is not required until 2020, benefits and costs here are not included.

a. Regulated Community Learning New Requirements and Developing Training Materials; OHRP Developing Training and Guidance Materials, and Implementing the 2018 Requirements

We assume that even with the proposed six month delay, regulated entities and OHRP would still assume costs related to learning the new requirements and developing training materials. Thus, there are no effects estimated here.

We expect that some entities would experience cost savings as a result of this proposed rule, and some entities would experience costs as a result of this proposed rule, but we lack data to quantify these effects. We request comments which provide data that can be used to quantify these effects.

b. Early Implementation of the Three Burden-Reducing Provisions of the 2018 Requirements (Explicit Carve-Outs of Activities From the Definition of Research [§ ____.102(l)]; Eliminating the Requirement That the Grant Application Undergo IRB Review and Approval [Pre-2018 Rule at § ____.103(f)]; Elimination of Continuing Review of Research Under Specific Conditions [§§ ____.109(f) and ____.115(a)(3)]

We assume that 50 percent of regulated entities will take advantage of the option proposed in this NPRM to implement three burden-reducing provisions of the 2018 Requirements early. We assume this because an institution's decision about whether to transition a study to the 2018 requirements to take advantage of the three burden-reducing provisions might vary depending on the nature and progress of the study, including any elements of the study to be conducted after January 21, 2019. For example, studies planning to recruit some subjects after January 21, 2019 would have to meet the new requirements for obtaining the informed consent of those subjects. In contrast, for studies whose remaining activities consist only of completing data analyses, the new requirements for informed consent would generally not be applicable. Therefore, we assume that there are situations where an institution would want to take advantage of the three burden-reducing provisions, and situations where an institution would not want to take advantage of this flexibility. We note that we intend to publish guidance on the carve-outs from the definition of research prior to July 2018, which may also impact an institution's decision to elect to implement the three burden-reducing provisions or not.

Thus, these entities will still obtain the benefits and costs described in the RIA for the 2018 Requirements, implying no effects of this rule for 50 percent of regulated entities. For the regulated entities that do not take advantage of these flexibilities, we assume that the foregone benefits (costs) of delaying implementation of these provisions are what would have been the benefits of implementing these provisions in January of 2018. Similarly, we assume that the benefits (cost-savings) associated with delaying the implementation of these provisions are what would have been the costs of implementing these provisions in July of 2018. We assume that these regulated entities account for 50 percent of the costs and benefits that would have been experienced in 2018 absent this delay.

We also assume that institutional staff at the IRB Administrative staff level [6] will spend 5 minutes per protocol documenting the voluntary election to use the three burden-reducing 2018 provisions during the time period of July 19, 2018 to January 21, 2019.

We request comment on our assumption that 50 percent of regulated entities will take advantage of the option proposed in this NPRM to implement three burden-reducing provisions of the 2018 Requirements early.

Some members of the regulated community have indicated that even though the 2018 Requirements yield cost savings, these institutions are still hesitant to transition ongoing research to the 2018 Requirements, largely because of the burden of making studies already in compliance with the pre-2018 requirements comply with the 2018 requirements. Also, some institutions seem inclined to make all of the transitions at once. This interconnectedness is key to some of the assumptions noted elsewhere in this analysis. For example, if the three burden-reducing provisions are considered on their own, a reasonable assumption would be that 100 percent of affected entities would realize the associated cost savings as soon as possible. The use, instead, of a 50 percent estimate reflects entities' possible inclinations to make all transitions at once. We request comment that would provide insight into entities' views regarding the interconnectedness of the 2018 Requirements' provisions and thus allow for refinement of the 50 percent estimate.

[6] See the RIA to the 2018 Requirements (82 FR 7149) for more information about the labor categories used in this analysis.

c. Expansion of Research Activities Exempt From Full IRB Review (§ ____.104(d))

The 2018 Requirements include five new exemption categories, and modify all but one exemption that exist in the pre-2018 Requirements. We have received feedback from SACHRP that guidance will be useful for regulated entities to implement many of the exemption categories.[7] Areas where significant guidance will be helpful include: Applying the categories of the new exemptions themselves, conducting limited IRB review (as required in four exemptions), developing and using broad consent (as required in two exemptions), utilizing the exemption for certain HIPAA covered activities, and understanding which federally supported or conducted nonresearch information collections qualify for exemption.

Because the guidance documents that would be helpful to assist regulated entities in implementing these 2018 Common Rule provisions have not yet been developed, we assume that 50 percent of the regulated entities would not have taken advantage of the expansion in exemptions during this six month-delay. For these entities, we assume that there are no benefits and costs of the proposed delay, because they would not have changed their operations. We assume that 50 percent of the regulated entities would have gone forward with using the new or expanded exemption categories under the 2018 Requirements; for these entities, there are costs of delaying the implementation of this provision during the six-month delay proposed in this NPRM.

We do not have data to support our assumption of what percent of regulated entities would have gone forward with the implementation of these provisions in the absence of additional guidance, and what percent would not have gone forward. We request comments on these assumptions and solicit data that can be used to quantify these effects.

3. Analysis of NPRM Alternative

This NPRM includes a primary alternative proposal of delaying the general effective and compliance date to January 2019.

Table 3 summarizes the quantified benefits and costs of the alternative proposal of delaying the general implementation of 2018 Requirements without the option to implement certain

[7] See for example, SACHRP Recommendations of August 2, 2017: *https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html.*

2018 Requirements. Over the period of July 2018 to January 2019, annualized benefits of $7.4 million are estimated using a 3 percent discount rate; annualized benefits of $6.9 million are estimated using a 7 percent discount rate. Annualized costs of $50.8 million are estimated using a 3 percent discount rate; annualized costs of $47.0 million are estimated using a 7 percent discount rate. Note that all values are represented in millions of 2016 dollars, and 2016 is used as the frame of reference for discounting.

TABLE 3—ALL BENEFITS AND COSTS OF DELAYING COMPLIANCE WITH THE 2018 REQUIREMENTS UNDER THE ALTERNATIVE PROPOSAL

	Annualized value by discount rate (millions of 2016 dollars)	
	3 Percent	7 Percent
Benefits (Cost–Savings):		
Quantified Benefits	7.4	6.9
Costs (Foregone Benefits):		
Quantified Costs	50.8	47.0

B. Paperwork Reduction Act (PRA)

This proposed rule contains collections of information that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), as amended (44 U.S.C. 3501–3520). A description of these provisions is given in this document with an estimate of the annual reporting and recordkeeping burden.

Title: Federal Policy for the Protection of Human Subjects.

Description: In this document is a discussion of the regulatory provisions we believe are subject to the PRA and the probable information collection burden associated with these provisions. In general, the following actions trigger the PRA: (i) Reporting; (ii) Recordkeeping.

Description of Respondents: The reporting and recordkeeping requirements in this document are imposed on institutions, institutional review boards, and investigators involved in human subjects research conducted or supported or otherwise subject to regulation by any federal department or agency that takes administrative action that makes the policy applicable to such research.

§ ____.101(l)(4). Compliance Date and Transition Provision (OMB Control No 0990–0260)

Section 101(l)(4)(i) would permit studies to transition to the 2018 Requirements between July 19, 2018 and January 21, 2019 (which would be the new general compliance date of the 2018 Requirements). Between July 19, 2018 and January 21, 2019, institutions that elect to transition studies to the 2018 Requirements would, after the decision to transition has been documented, be able to take advantage of the three burden-reducing 2018 Requirements.

This option is described in a proposed revision to § ____.101(l)(4)(i). As described, studies taking advantage of this option would be subject to the three burden-reducing 2018 Requirements instead of, or in addition to, the comparable provisions of the pre-2018 Requirements. As discussed above, the three burden-reducing 2018 Requirements are (1) the 2018 Requirements' definition of ''research'' at § ____.102(l) (instead of § ____.102(d) of the pre-2018 Requirements), which deems certain activities not to be research, (2) the elimination of the requirement that an IRB review the grant application or proposal related to the research at § ____.103(d) of the 2018 Requirements (instead of § ____.103(f) of the pre-2018 Requirements), and (3) the allowance for no annual continuing review of certain categories of research at § ____.109(f)(1)(i) and (iii) of the 2018 Requirements (instead of § ____.103(b), as related to the requirement for continuing review, and in addition to § ____.109 of the pre-2018 Requirements).

We estimate that approximately 92,084 protocols would take advantage of the voluntary election described in § ____.101(l)(4)(i). We estimate that institutional staff would spend 5 minutes per protocol documenting that the study will be subject to the three burden-reducing 2018 Requirements during the time period of July 19, 2018 through January 21, 2019. We estimate that this provision includes 7,673 burden hours.

C. Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies that issue a regulation to analyze options for regulatory relief for small businesses. If a rule has a significant economic impact on a substantial number of small entities, agencies must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of ''small entity''). HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue.

If finalized, this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This proposed rule would not impose a regulatory burden for regulated small entities because it would delay the general compliance date of the 2018 Requirements, allowing the status quo to be retained for the period of delay, and also would allow regulated small entities to elect to implement the 2018 Requirements as scheduled if the entities so choose. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities. We request

comment on this conclusion, including specific data and information to support commenters' views.

D. Unfunded Mandates Reform Act (UMRA)

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 $148 million, using the most current (2016) implicit price deflator for the gross domestic product. We do not expect this rule to result in expenditures that will exceed this amount. This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. We have determined that the proposed rule would not contain policies that would have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The changes in the proposed rule represent the Federal Government regulating its own program. Accordingly, we conclude that the rule does not propose policies that have federalism implications as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

For the reasons set forth in the preamble, the Federal Policy for the Protection of Human Subjects, as published in the **Federal Register** on January 19, 2017 (82 FR 7149) and as adopted in a final rule published by the CPSC on September 18, 2017 (82 FR 43459), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885) and adopted by HUD through a final rule published on January 26, 2018 (83 FR 3589), is proposed to be amended as follows:

Text of the Amended Common Rule

PART ____—PROTECTION OF HUMAN SUBJECTS

■ 1. Amend § ____.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ ____.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part/subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § ____.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § ____.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § ____.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section ____.102(l) of the 2018 Requirements (definition of research) (instead of § ____.102(d) of the pre-2018 Requirements),

(*2*) Section ____.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § ____.103(f) of the pre-2018 Requirements), and

(*3*) Section ____.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § ____.103(b), as related to the requirement for continuing review, and in addition to § ____.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

Department of Homeland Security

List of Subjects in 6 CFR Part 46

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Homeland Security proposes to further amend 6 CFR part 46 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 46—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 46 continues to read as follows:

Authority: 5 U.S.C. 301; P.L. 107–296, sec. 102, 306(c); P.L. 108–458, sec. 8306.

■ 2. Amend § 46.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 46.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the

following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 46.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 46.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 46.102(l) of the 2018 Requirements (definition of research) (instead of § 46.102(d) of the pre-2018 Requirements),

(*2*) Section 46.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 46.103(f) of the pre-2018 Requirements), and

(*3*) Section 46.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 46.103(b), as related to the requirement for continuing review, and in addition to § 46.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Elaine C. Duke,

Deputy Secretary, Department of Homeland Security.

Department of Agriculture

List of Subjects in 7 CFR Part 1c

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Agriculture proposes to further amend 7 CFR part 1c as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 1c—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 1c continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 1c.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 1c.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 1c.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 1c.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 1c.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 1c.102(l) of the 2018 Requirements (definition of research) (instead of § 1c.102(d) of the pre-2018 Requirements),

(*2*) Section 1c.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 1c.103(f) of the pre-2018 Requirements), and

(*3*) Section 1c.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 1c.103(b), as related to the requirement for continuing review, and in addition to § 1c.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Chavonda Jacobs-Young,

Acting Deputy Under Secretary for Research, Education, and Economics, USDA.

Department of Energy

List of Subjects in 10 CFR Part 745

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Energy proposes to further amend 10 CFR part 745 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 745—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 745 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b).

■ 2. Amend § 745.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 745.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 745.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 745.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 745.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 745.102(l) of the 2018 Requirements (definition of research) (instead of § 745.102(d) of the pre-2018 Requirements),

(*2*) Section 745.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 745.103(f) of the pre-2018 Requirements), and

(*3*) Section 745.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 745.103(b), as related to the requirement for continuing review, and in addition to § 745.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Dan Brouillette,

Deputy Secretary of Energy.

National Aeronautics and Space Administration

List of Subjects in 14 CFR Part 1230

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, National Aeronautics and Space Administration proposes to further amend 14 CFR part 1230 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 1230—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 1230 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 1230.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 1230.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 1230.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 1230.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 1230.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 1230.102(l) of the 2018 Requirements (definition of research) (instead of § 1230.102(d) of the pre-2018 Requirements),

(*2*) Section 1230.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 1230.103(f) of the pre-2018 Requirements), and

(*3*) Section 1230.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 1230.103(b), as related to the requirement for continuing review, and in addition to § 1230.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

James D. Polk,

Chief Health & Medical Officer, National Aeronautics and Space Administration.

Department of Commerce

List of Subjects in 15 CFR Part 27

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Commerce proposes to further amend 15 CFR part 27 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 27—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 27 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 27.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 27.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 27.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 27.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 27.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 27.102(l) of the 2018 Requirements (definition of research) (instead of § 27.102(d) of the pre-2018 Requirements),

(*2*) Section 27.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 27.103(f) of the pre-2018 Requirements), and

(*3*) Section 27.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 27.103(b), as related to the requirement for continuing review, and in addition to § 27.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Wilbur L. Ross,

Secretary of Commerce.

Consumer Product Safety Commission

List of Subjects in 16 CFR Part 1028

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Consumer Product Safety Commission proposes to further amend 16 CFR part 1028 as published in the **Federal Register** on January 19, 2017 (82 FR 7149) and as adopted in a final rule published by the CPSC on September 18, 2017 (82 FR 43459), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 1028—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 1028 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 1028.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 1028.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 1028.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 1028.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 1028.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 1028.102(l) of the 2018 Requirements (definition of research) (instead of § 1028.102(d) of the pre-2018 Requirements),

(*2*) Section 1028.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of

§ 1028.103(f) of the pre-2018 Requirements), and

(*3*) Section 1028.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 1028.103(b), as related to the requirement for continuing review, and in addition to § 1028.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

Social Security Administration

List of Subjects in 20 CFR Part 431

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Social Security Administration proposes to further amend 20 CFR part 431 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 431—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 431 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

■ 2. Amend § 431.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 431.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 431.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 431.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 431.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 431.102(l) of the 2018 Requirements (definition of research) (instead of § 431.102(d) of the pre-2018 Requirements),

(*2*) Section 431.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 431.103(f) of the pre-2018 Requirements), and

(*3*) Section 431.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 431.103(b), as related to the requirement for continuing review, and in addition to § 431.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Nancy Berryhill,

Deputy Commissioner for Operations, performing the duties and functions not reserved to the Commissioner of Social Security.

Agency for International Development

List of Subjects in 22 CFR Part 225

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Agency for International Development proposes to further amend 22 CFR part 225 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 225—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 225 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b), unless otherwise noted.

■ 2. Amend § 225.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 225.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 225.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 225.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the

research was exempt under § 225.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 225.102(l) of the 2018 Requirements (definition of research) (instead of § 225.102(d) of the pre-2018 Requirements),

(*2*) Section 225.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 225.103(f) of the pre-2018 Requirements), and

(*3*) Section 225.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 225.103(b), as related to the requirement for continuing review, and in addition to § 225.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Kerry Pelzman,

Acting Senior Deputy Assistant Administrator for Global Health, U.S. Agency for International Development.

Department of Housing and Urban Development

List of Subjects in 24 CFR Part 60

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Housing and Urban Development proposes to further amend 24 CFR part 60 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885) and adopted by HUD through a final rule published on January 26, 2018 (83 FR 3589), as follows:

PART 60—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 60 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b) and 3535(d).

■ 2. Amend § 60.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 60.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 60.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 60.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 60.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 60.102(l) of the 2018 Requirements (definition of research) (instead of § 60.102(d) of the pre-2018 Requirements),

(*2*) Section 60.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 60.103(f) of the pre-2018 Requirements), and

(*3*) Section 60.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 60.103(b), as related to the requirement for continuing review, and in addition to § 60.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Todd M. Richardson,

Acting General Deputy Assistant Secretary for Policy Development and Research, U.S. Department of Housing and Urban Development.

Department of Labor

List of Subjects in 29 CFR Part 21

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Labor proposes to further amend 29 CFR part 21 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 21—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 21 continues to read as follows:

Authority: 5 U.S.C. 301; 29 U.S.C. 551.

■ 2. Amend § 21.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 21.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 21.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 21.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 21.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 21.102(l) of the 2018 Requirements (definition of research) (instead of § 21.102(d) of the pre-2018 Requirements),

(*2*) Section 21.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 21.103(f) of the pre-2018 Requirements), and

(*3*) Section 21.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 21.103(b), as related to the requirement for continuing review, and in addition to § 21.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Dated: April 2, 2018.

R. Alexander Acosta,

Secretary of Labor.

Department of Defense

List of Subjects in 32 CFR Part 219

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Defense proposes to further amend 32 CFR part 219 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 219—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 219 continues to read as follows:

Authority: 5 U.S.C. 301.

■ 2. Amend § 219.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 219.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 219.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 219.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 219.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 219.102(l) of the 2018 Requirements (definition of research) (instead of § 219.102(d) of the pre-2018 Requirements),

(*2*) Section 219.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 219.103(f) of the pre-2018 Requirements), and

(*3*) Section 219.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 219.103(b), as related to the requirement for continuing review, and in addition to § 219.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Mary J. Miller,

Principal Deputy, Assistant Secretary of Defense for Research and Engineering, U.S. Department of Defense.

Department of Education

List of Subjects in 34 CFR Part 97

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Education proposes to further amend 34 CFR part 97 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 97—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 97 continues to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474.

■ 2. Amend § 97.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 97.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 97.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 97.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 97.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 97.102(l) of the 2018 Requirements (definition of research) (instead of § 97.102(d) of the pre-2018 Requirements),

(*2*) Section 97.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 97.103(f) of the pre-2018 Requirements), and

(*3*) Section 97.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 97.103(b), as related to the requirement for continuing review, and in addition to § 97.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Betsy DeVos,

Secretary of Education.

Department of Veterans Affairs

List of Subjects in 38 CFR Part 16

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Veterans Affairs proposes to further amend 38 CFR part 16 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 16—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 16 continues to read as follows:

Authority: 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v–1(b).

■ 2. Amend § 16.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 16.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 16.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 16.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 16.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 16.102(l) of the 2018 Requirements (definition of research) (instead of § 16.102(d) of the pre-2018 Requirements),

(*2*) Section 16.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 16.103(f) of the pre-2018 Requirements), and

(*3*) Section 16.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 16.103(b), as related to the requirement for continuing review, and

in addition to § 16.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

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Jacquelyn Hayes-Byrd,

Deputy Chief of Staff, Department of Veterans Affairs.

Environmental Protection Agency

List of Subjects in 40 CFR Part 26

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Environmental Protection Agency proposes to further amend 40 CFR part 26 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 26—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 26 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109–54, 119 Stat. 531; 42 U.S.C. 300v–1(b).

■ 2. Amend § 26.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 26.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 26.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 26.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 26.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 26.102(l) of the 2018 Requirements (definition of research) (instead of § 26.102(d) of the pre-2018 Requirements),

(*2*) Section 26.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 26.103(f) of the pre-2018 Requirements), and

(*3*) Section 26.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 26.103(b), as related to the requirement for continuing review, and in addition to § 26.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

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E. Scott Pruitt,

Administrator, Environmental Protection Agency.

Department of Health and Human Services

List of Subjects in 45 CFR Part 46

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Health and Human Services proposes to further amend 45 CFR part 46 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 46—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 46 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b).

■ 2. Amend § 46.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 46.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 46.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 46.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution

engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 46.102(l) of the 2018 Requirements (definition of research) (instead of § 46.102(d) of the pre-2018 Requirements),

(*2*) Section 46.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 46.103(f) of the pre-2018 Requirements), and

(*3*) Section 46.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 46.103(b), as related to the requirement for continuing review, and in addition to § 46.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

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Alex M. Azar II,

Secretary, U.S. Department of Health and Human Services.

National Science Foundation

List of Subjects in 45 CFR Part 690

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, National Science Foundation proposes to further amend 45 CFR part 690 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 690—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 690 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 690.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 690.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for § 690.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 690.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 690.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 690.102(l) of the 2018 Requirements (definition of research) (instead of § 690.102(d) of the pre-2018 Requirements),

(*2*) Section 690.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 690.103(f) of the pre-2018 Requirements), and

(*3*) Section 690.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 690.103(b), as related to the requirement for continuing review, and in addition to § 690.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

* * * * *

Lawrence Rudolph,

General Counsel, National Science Foundation.

Department of Transportation

List of Subjects in 49 CFR Part 11

Human research subjects, Reporting and recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Transportation proposes to further amend 49 CFR part 11 as published in the **Federal Register** on January 19, 2017 (82 FR 7149), and as amended in a final rule published in the **Federal Register** on January 22, 2018 (83 FR 2885), as follows:

PART 11—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for Part 11 continues to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

■ 2. Amend § 11.101 by revising paragraphs (l)(2), (3), and (4), and adding paragraph (l)(5), to read as follows:

§ 11.101 To what does this policy apply?

* * * * *

(l) * * *

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this part. The general compliance date for the 2018 Requirements is January 21, 2019. The compliance date for

§ 11.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (l)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 11.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 11.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution engaged in research otherwise covered by paragraph (l)(3) of this section determines that such ongoing research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation until January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(*1*) Section 11.102(l) of the 2018 Requirements (definition of research) (instead of § 11.102(d) of the pre-2018 Requirements),

(*2*) Section 11.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 11.103(f) of the pre-2018 Requirements), and

(*3*) Section 11.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 11.103(b), as related to the requirement for continuing review, and in addition to § 11.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019,

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019, and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

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Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2018–08231 Filed 4–19–18; 8:45 am]

BILLING CODE 4150–36–P