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**Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal**

## **Policy for the Protection of Human Subjects**

**AGENCIES:** 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 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:** Interim final rule; delay of effective and compliance dates; request for comments.

**SUMMARY:** In a final rule published on January 19, 2017, federal departments and agencies listed in this document made revisions to the Federal Policy for the Protection of Human Subjects. The Consumer Product Safety Commission (CPSC) adopted the same regulatory changes in a separate final rule published on September 18, 2017. The revised policy, reflected in both final rules, is described here as the “2018 Requirements.” The 2018 Requirements are 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).

This interim final rule delays the effective date and general compliance date of the 2018 Requirements to July 19, 2018. The federal departments and agencies listed in this document are in the process of developing a proposed rule to further delay implementation of the 2018 Requirements. The limited implementation delay accomplished by this interim final rule both

provides additional time to regulated entities for the preparations necessary to implement the 2018 Requirements, and additional time for the departments and agencies listed in this document to seek input from interested stakeholders through a notice and comment rulemaking process that allows for public engagement on the proposal for a further implementation delay.

**DATES:** This interim final rule is effective on July 19, 2018. This interim final rule delays until July 19, 2018, the effective date and general compliance date of the final rule published in the Federal Register (82 FR 7149, Jan. 19 2017) and of the final rule published by the Consumer Product Safety Commission in the Federal Register (82 FR 43459, Sept. 18, 2017). 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 [FEDERAL REGISTER insert date 60 days after display at the Office of Federal Register].

**ADDRESSES:** You may submit comments, identified by docket ID number HHS–OPHS–2017–0001 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-2017-0001>*.
  - 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](mailto: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 revised policy is hereafter referred to as the "2018 Requirements." The 2018 Requirements are 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, 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.<sup>1</sup> Some of these stakeholders asked for a delay in the general compliance date of the 2018 Requirements with the exception of certain burden-reducing provisions of the 2018 Requirements, 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 implementation of the 2018 Requirements should be delayed.<sup>2</sup>

## **II. DELAY OF THE EFFECTIVE DATE AND GENERAL COMPLIANCE DATE**

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<sup>1</sup>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%2006-21-2017.pdf](http://www.cogr.edu/sites/default/files/AAMC_AAU_APLU_COGR%20Common%20Rule%20Delay%20Letter%2006-21-2017.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>.  
<sup>2</sup> SACHRP Recommendations of August 2, 2017, Attachment A: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-august-2-2017/index.html>

Through this interim final rule, we are delaying the effective date and the general compliance date of the 2018 Requirements for six months, until July 19, 2018. As described below, we revise §\_\_.101(l)(3)-(4) to specify that the general compliance date for the 2018 Requirements is July 19, 2018.

Prior to July 19, 2018, regulated entities will continue to comply with the pre-2018 Requirements and those requirements will be enforced by the Common Rule departments and agencies. To clarify, regulated entities are not allowed, prior to July 19, 2018, to comply with the 2018 Requirements in lieu of the pre-2018 Requirements. Unless further regulatory action is taken, studies initiated on or after July 19, 2018, will be required to comply with the 2018 Requirements. Studies initiated prior to July 19, 2018 (i.e., studies initially approved by an IRB, studies for which IRB review was waived pursuant to §\_.101(i), or studies determined to be exempt, before July 19, 2018) 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. However, on or after July 19, 2018, institutions may elect instead to conduct such studies in compliance with the 2018 Requirements, as set forth in §\_.101(l)(3).

This interim final rule does not delay the compliance date for the cooperative research provision of the 2018 Requirements (§\_\_.114(b)), which remains January 20, 2020.

### **III. GOOD CAUSE FOR INTERIM FINAL RULE**

Under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), a notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

Pursuant to 5 U.S.C. 553(b)(3)(B), we find that good cause exists to waive normal rulemaking requirements for the delay of the effective date and general compliance date to July 19, 2018.

We believe that a notice-and-comment procedure, in this limited instance, is impracticable, unnecessary, or contrary to the public interest.

Representatives of the regulated community, and HHS's own advisory committee, have requested a delay in implementation of the 2018 Requirements, citing the final rule's complexity, the absence of needed guidance, and the need to revamp institutional procedures and electronic systems in order to come into compliance with the requirements of the rule. We agree that regulated entities need additional time for implementation and compliance, which would be furthered by the issuance of guidance by the Common Rule agencies. Without a delay, and without guidance, institutions that have expected a delay who hastily attempt to implement the revised rule without adequate preparation are bound to make mistakes, the consequences of which may jeopardize the proper conduct of research and the safety and wellbeing of human subjects. At this point, it is impracticable to gather comments on an implementation delay prior to January 19, 2018, the scheduled effective date of the 2018 Requirements.

In addition, the benefits underlying this interim final rule, i.e., providing certainty to entities in the regulated community that they will be afforded additional time before being subject to compliance with the 2018 Requirements prior to the date such requirements are scheduled to go into effect, would be substantially undermined if a notice and comment process were to occur before the delay set forth in this interim final rule was finalized. For example, we understand that regulated entities may need to devise new policies and procedures and new information technology systems to accommodate the 2018 Requirements in advance of the applicable effective and compliance date. In addition, the effect of this interim final rule is simply to maintain the status quo by continuing to require compliance with the pre-2018 Requirements for several months.

Further, the federal departments and agencies named in this interim final rule are developing a notice of proposed rulemaking in order to fully engage regulated entities and the public regarding further delay of the 2018 Requirements until January 21, 2019. The additional time provided by the six month delay in this interim final rule will allow sufficient time for the notice and comment rulemaking process to be completed. Issuance of this interim final rule avoids the possible result of having the federal departments and agencies propose an implementation delay but be unable to complete the rulemaking process and publish a final rule that would be effective by January 19, 2018. This could have resulted in the absurd circumstance in which regulated entities would be technically required to come into compliance with the 2018 Requirements on January 19, 2018, only until the date a final rule implementing the delay became effective. In this unique circumstance, allowing the regulation to become effective while further rulemaking

for delay is ongoing would create confusion for, and impose unnecessary burdens on, the regulated community.

We also find that good cause exists for immediate implementation of this interim final rule and waiver of the 30-day delay in the effective date generally required by the APA. The APA provides that an agency is not required to delay the effective date when the agency, for good cause, finds that the requirement is impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(d)(3)). Given the reasons identified above for the good cause to dispense with notice and comment, we believe that this requirement is also met here. Further, the 30-day delay in the effective date is normally intended to give affected parties time to adjust their business practices and make preparations before a final rule takes effect. Because the action being taken delays the effective date to July 19, 2018 and thus maintains the status quo, an additional 30-day delay of this action is unnecessary.

#### Department of Homeland Security

The rule issued by the Department of Homeland Security (DHS) is consistent with section 8306 of P.L. 108-458, the Intelligence Reform and Terrorism Prevention Act of 2004, under which DHS shall comply with 45 CFR part 46 or equivalent regulations issued by DHS; continued adherence to the HHS standard best ensures that DHS does not lose critical research opportunities as a result of inconsistent federal standards. The DHS rule is also consistent with DHS's waiver authority under forthcoming 6 CFR 46.101(i), as well as the exemption at 5 U.S.C. 553(a)(2) for rules related to "loans, grants, benefits, or contracts."

## Department of Education

Continued adherence to the HHS standard protects the Department of Education (ED) from the potential loss of critical research opportunities as a result of inconsistent federal standards. The ED rule is also consistent with ED's waiver authority under 34 CFR 97.101(i).

## **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; P.L. 107-296, sec. 102, 306(c); P.L. 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 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, Pub. L. 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 interim final 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 interim final rule has been determined to be a “significant” regulatory action and was submitted to the Office of Management and Budget (OMB) for review.

Executive Order 13771 directs Agencies to identify at least two existing regulations to be repealed for every new regulation unless prohibited by law. The total incremental cost of all regulations issued in a given fiscal year must have costs within the amount of incremental costs allowed by the Director of the Office of Management and Budget, unless otherwise required by law or approved in writing by the Director of the Office of Management and Budget. This action’s designation as regulatory or deregulatory will be informed by comments received in response to this interim final rule. Details on the interim estimates of costs and cost savings of this rule can be found in the economic analysis below.

## **1. Need for Final Rule and Summary**

This interim final rule is intended to provide additional time to regulated entities for the preparations necessary to implement the 2018 Requirements. This interim final rule further allows time for the federal departments and agencies named in this interim final rule to conduct a notice and comment rulemaking process that will allow for public engagement as to whether a further delay in the implementation of the 2018 Requirements would be desirable.

## 2. Analysis of Benefits (Cost-savings) and Costs (Foregone Benefits)<sup>3</sup>

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

Table 1 summarizes the quantified costs and cost savings of delaying implementation of 2018 Requirements. Over the period of January 2018 to July 2018, annualized cost savings of \$7.4 million are estimated using a 3 percent discount rate; and \$6.9 million using a 7 percent discount rate. Annualized costs of \$49.5 million are estimated using a 3 percent discount rate; and \$45.9 million 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 2018 Requirements by Six Months**

	Annualized Value by Discount Rate	
	(Millions of 2016 Dollars)	
<b>BENEFITS (COST-SAVINGS)</b>	<b>3 Percent</b>	<b>7 Percent</b>
Quantified Benefits	7.4	6.9
<b>COSTS (FOREGONE BENEFITS)</b>	<b>3 Percent</b>	<b>7 Percent</b>
Quantified Costs	49.5	45.9

<sup>3</sup> 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.

The estimated benefits and costs of delaying 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 2018 Requirements.

**Table 2. Accounting Table of Quantified Benefits (Cost-savings) and Costs (Foregone Benefits) of Delaying the 2018 Requirements by Six Months<sup>4</sup>**

2018 Requirement RIA Category	Annualized Value over 1 Year by Discount Rate (Millions of 2016 dollars)			
	Benefits (Cost-savings)		Costs (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	-	-	0.94	0.88
Clarifying and Harmonizing Regulatory Requirements and Agency Guidance	-	-	-	-
Modifying the Assurance Requirements	-	-	0.31	0.29

<sup>4</sup> 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.

**Table 2. Accounting Table of Quantified Benefits (Cost-savings) and Costs (Foregone Benefits) of Delaying the 2018 Requirements by Six Months<sup>4</sup>**

2018 Requirement RIA Category	Annualized Value over 1 Year by Discount Rate (Millions of 2016 dollars)			
	Benefits (Cost-savings)		Costs (Foregone Benefits)	
	3%	7%	3%	7%
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	-	-	17.0	15.7
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	2.07	1.92	7.73	7.17
Amending the Expedited Review Procedures	-	-	2.66	2.47
Cooperative Research (single IRB mandate in multi-institutional research) <sup>5</sup>	-	-	-	-
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

<sup>5</sup> Because compliance with this provision is not required until 2020, benefits and costs here are not included.

**Table 2. Accounting Table of Quantified Benefits (Cost-savings) and Costs (Foregone Benefits) of Delaying the 2018 Requirements by Six Months<sup>4</sup>**

2018 Requirement RIA Category	Annualized Value over 1 Year by Discount Rate (Millions of 2016 dollars)			
	Benefits (Cost-savings)		Costs (Foregone Benefits)	
	3%	7%	3%	7%
Requirement for Posting of Consent Forms for Clinical Trials Conducted or supported by Common Rule Department or Agencies	0.85	0.79	-	-
Alteration in Waiver for Documentation of Informed Consent in Certain Circumstances	-	-	-	-

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 January through July of 2018. 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 January through July of 2018. We assume this because these categories generally would not have required significant guidance from Common Rule departments or agencies in order to implement the provisions, and thus could have been implemented as assumed in the economic analysis contained in the RIA for the 2018 Requirements.

The exceptions to the above assumption relate to two RIA categories: (1) excluding activities from the Common Rule because they are not research; and (2) the expansion of research

activities exempt from full IRB review. The 2018 Requirements include four explicit categories of activities that have been deemed not research for the purposes of the Common Rule. In the absence of guidance, it would be difficult for institutions to fully take advantage of the exclusion of activities from the definition of research; therefore we now assume that many institutions would not have used these categories without guidance.

The 2018 Requirements also include five new exemption categories, and modify all but one exemption that exists in the pre-2018 Requirements. We have received feedback from SACHRP that many of the exemption categories will require significant guidance in order to be implemented.<sup>6</sup> Areas where significant guidance is needed 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 necessary to implement these provisions has not yet been developed, we now assume that 50 percent of the regulated entities would not have taken advantage of the expansion in exemptions or the revised definition of research during the 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

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<sup>6</sup>SACHRP Recommendations of August 2, 2017: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html>.

during the six-month delay of this interim final rule. We are seeking comment on these assumptions.

### **B. Paperwork Reduction Act (PRA)**

This interim final rule does not impose any additional information collection burden under the PRA, and does not contain any information collection activities beyond the information collection already approved by OMB under control number 0990–0260.

### **C. Regulatory Flexibility Act (RFA)**

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) and the Small Business Regulatory Enforcement 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 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.

This action does 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 interim final rule does not impose a regulatory burden for regulated small entities because it delays the effective date and general compliance date of the 2018 Requirements, allowing the status quo to be retained for the period of delay. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

#### **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 interim final 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 interim final rule does not contain policies that 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 to the 2018 Requirements contained in this interim final rule represent the Federal Government regulating its own program. Accordingly, we conclude that the interim final rule does not contain 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), this common rule is further amended as follows:

**Text of the Amended Common Rule**

**PART \_\_—PROTECTION OF HUMAN SUBJECTS**

1. Amend §\_\_.101 by revising paragraphs (l)(3) and (4) to read as follows:

**§\_\_.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §\_\_.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §\_\_.101(i), or for which a determination was made that the research was exempt on or after

July 19, 2018, shall comply with the 2018 Requirements.

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## DEPARTMENT OF HOMELAND SECURITY

### List of Subjects in 6 CFR Part 46:

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Homeland Security further amends 6 CFR part 46 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

### PART 46—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(1), (2), (3), and (4) to read as follows:

#### **§46.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(1) For purposes of this section, the *pre-2018 Requirements* means Subpart A to 45 CFR part 46, as published in the 2016 edition of the Code of Federal Regulations, which is the rule that DHS applied before it first promulgated this subpart.

(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 July 19, 2019. The compliance date for §46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) Research initially approved by an IRB, for which such review was waived pursuant to §46.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §46.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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William Bryan

Deputy Under Secretary for Science & Technology

**DEPARTMENT OF AGRICULTURE**

**List of Subjects in 7 CFR Part 1c:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Agriculture further amends 7 CFR part 1c as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 1c—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

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

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §1c.101(i), or for which a determination was made that the research was exempt before

July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §1c.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Dr. 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 record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Energy further amends 10 CFR part 745 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 745—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

**§745.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §745.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §745.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Dan Brouillette

Deputy Secretary of Energy

# NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

## List of Subjects in 14 CFR Part 1230:

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the National Aeronautics and Space Administration further amends 14 CFR part 1230 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

## PART 1230—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(3) and (4) to read as follows:

### **§1230.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §1230.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §1230.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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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 record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Commerce further amends 15 CFR part 27 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

### PART 27—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(3) and (4) to read as follows:

#### **§27.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §27.101(i), or for which a determination was made that the research was exempt before

July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §27.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Wilbur L. Ross

The Secretary of Commerce

## CONSUMER PRODUCT SAFETY COMMISSION

### List of Subjects in 16 CFR Part 1028:

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Consumer Product Safety Commission further amends 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) as follows:

### PART 1028—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(3) and (4) to read as follows:

#### **§1028.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §1028.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §1028.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Alberta E. Mills

Acting Secretary,

Consumer Product Safety Commission

## **SOCIAL SECURITY ADMINISTRATION**

### **List of Subjects in 20 CFR Part 431:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Social Security Administration further amends 20 CFR part 431 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

### **PART 431—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

#### **§431.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §431.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §431.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Nancy Berryhill

Acting Commissioner

Social Security Administration

**AGENCY FOR INTERNATIONAL DEVELOPMENT**

**List of Subjects in 22 CFR Part 225:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Agency for International Development further amends 22 CFR part 225 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 225—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

**§225.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §225.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §225.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Irene Koek,

Senior Deputy Assistant Administrator for Global Health

U.S. Agency for International Development

**DEPARTMENT OF LABOR**

**List of Subjects in 29 CFR Part 21:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Labor further amends 29 CFR part 21 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 21—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

**§21.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §21.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §21.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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R. Alexander Acosta

Secretary of Labor

**DEPARTMENT OF DEFENSE**

**List of Subjects in 32 CFR Part 219:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Defense further amends 32 CFR part 219 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 219—PROTECTION OF HUMAN SUBJECTS**

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

**Authority:** 5 U.S.C. 301.

2. Amend §219.101 by revising paragraphs (l)(3) and (4) to read as follows:

**§219.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §219.101(i), or for which a determination was made that the research was exempt before

July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §219.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Mary J. Miller

Principal Deputy, Assistant Secretary of Defense  
for Research and Engineering

**DEPARTMENT OF EDUCATION**

**List of Subjects in 34 CFR Part 97:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Education further amends 34 CFR part 97 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 97—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

**§97.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §97.101(i), or for which a determination was made that the research was exempt before

July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §97.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Betsy DeVos,

Secretary of Education

## DEPARTMENT OF VETERANS AFFAIRS

### List of Subjects in 38 CFR Part 16:

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Veterans Affairs further amends 38 CFR part 16 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

### PART 16—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(3) and (4) to read as follows:

#### **§16.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §16.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §16.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Gina S. Farrisee

Deputy Chief of Staff

Department of Veterans Affairs

**ENVIRONMENTAL PROTECTION AGENCY**

**List of Subjects in 40 CFR Part 26:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Environmental Protection Agency further amends 40 CFR part 26 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 26—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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; and 42 U.S.C. 300v-1(b).

2. Amend §26.101 by revising paragraphs (l)(3) and (4) to read as follows:

**§26.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §26.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §26.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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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 record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Health and Human Services further amends 45 CFR part 46 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

**PART 46—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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)(3) and (4) to read as follows:

**§46.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §46.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §46.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Eric D. Hargan,

Acting Secretary, Department of Health and Human Services

## **National Science Foundation**

### **List of Subjects in 45 CFR Part 690:**

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the National Science Foundation further amends 45 CFR part 690 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

### **PART 690—PROTECTION OF HUMAN SUBJECTS**

1. The authority citation for 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 (1)(3) and (4) to read as follows:

#### **§690.101 To what does this policy apply?**

\* \* \* \* \*

(1) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §690.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §690.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Lawrence Rudolph

General Counsel

## DEPARTMENT OF TRANSPORTATION

### 49 CFR Part 11

#### List of Subjects in 49 CFR Part 11:

Human research subjects, Reporting and record-keeping requirements, Research.

For the reasons stated in the preamble, the Department of Transportation further amends 49 CFR part 11 as published in the Federal Register on January 19, 2017 (82 FR 7149) as follows:

#### PART 11—PROTECTION OF HUMAN SUBJECTS

1. The authority citation for 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)(3) and (4) to read as follows:

#### **§11.101 To what does this policy apply?**

\* \* \* \* \*

(l) \* \* \*

(3) Research initially approved by an IRB, for which such review was waived pursuant to §11.101(i), or for which a determination was made that the research was exempt before July 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after July 19, 2018 may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to §11.101(i), or for which a determination was made that the research was exempt on or after July 19, 2018, shall comply with the 2018 Requirements.

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Elaine L. Chao,

Secretary of Transportation

[FR Doc. 2018-00997 Filed: 1/17/2018 4:15 pm; Publication Date: 1/22/2018]