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

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 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: Final rule.

SUMMARY: In a final rule published on January 19, 2017, a number of federal departments and agencies revised to the Federal Policy for the Protection of Human Subjects (often referred to as the "Common Rule"), which each department and agency adopted into regulations in its part of the Code of Federal Regulations (CFR). The Consumer Product Safety Commission (CPSC) adopted the same changes in a final rule published on September 18, 2017. The revised Common Rule was scheduled to become effective on January 19, 2018, with a general compliance date of the same date. By an interim final rule issued on January 17, 2018 and published in the *Federal Register* on January 22, 2018, federal departments and agencies delayed the effective date and the general compliance date for the revised Common Rule for a 6-month period, until July 19, 2018. The Department of Housing and Urban Development (HUD) published an interim final rule adopting the same regulatory changes on January 26, 2018. The revised Common Rule, including technical amendments made by the January 22, 2018 interim final rule, is referred to here as the "2018 Requirements."

On April 20, 2018, the federal departments and agencies listed here published a notice of proposed rulemaking (NPRM) proposing and seeking comments as to whether the general compliance date for the 2018 Requirements should be delayed for an additional 6-month period. The NPRM also proposed and sought comments on whether to allow regulated entities to

implement certain burden-reducing provisions of the 2018 Requirements in specified circumstances during such continued delay period.

Through this final rule, we are adopting the proposals described in the April 20, 2018 NPRM. This rule delays the general compliance date for the 2018 Requirements for an additional 6-month period, until January 21, 2019. As a result of this delay, regulated entities will be required, with an exception, to continue to comply with the requirements of the pre-2018 version of the Federal Policy for the Protection of Human Subjects (the "pre-2018 Requirements") until January 21, 2019. The one exception to this general rule is that institutions will be permitted (but not required) to implement, for certain research, three burden-reducing provisions of the 2018 Requirements during the delay period (July 19, 2018, through January 20, 2019). Those three provisions are: the revised definition of "research," which deems certain activities not to be research covered by the Common Rule; the elimination of the requirement for annual continuing review with respect to certain categories of research; and the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research. Institutions taking advantage of the three-burden reducing provisions must comply with all other pre-2018 Requirements during the delay period. The three burden-reducing provisions of the 2018 Requirements can only be implemented during the delay period with respect to studies initiated prior to January 21, 2019 that will transition to compliance with the revised Common Rule. Any study that implements these three burden-reducing provisions during the delay period must, beginning on January 21, 2019, comply with all of the 2018 Requirements for the balance of the study's duration.

DATES: *Effective date*: This rule is effective on July 19, 2018. *Compliance dates*: The general compliance date for the 2018 Requirements in 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), which were delayed in the interim final rule published in the Federal Register (83 FR 2885, Jan. 22, 2018), and adopted by HUD through an interim final rule published in the Federal Register (83 FR 3589, Jan. 26, 2018), with the exception of §__.114(b), is further delayed until January 21, 2019. The compliance date for §__.114(b) (cooperative research) remains January 20, 2020.

ADDRESSES: Jerry Menikoff, M.D., J.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

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 January 19, 2017, the Department of Health and Human Services (HHS) and other federal departments and agencies published a final rule revising the Federal Policy for the Protection of

Human Subjects (generally referred to as "the Common Rule"). 82 FR 7149. The CPSC adopted the same regulatory changes in a separate final rule published on September 18, 2017. 82 FR 43459. The revised Common Rule was 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), which has a compliance date of January 20, 2020).

Some representatives of the regulated community expressed concern regarding their ability to implement all of the 2018 Requirements by the scheduled general compliance date.[1]

On January 17, 2018, HHS and other federal departments and agencies placed on display at the Office of 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). This rule did not impact the compliance date for the cooperative research provision at §__.114(b), which remained January 20, 2020. On January 26, 2018, HUD published an interim final rule adopting the interagency interim final rule. 83 FR 3589.

[1]See, e.g., 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 https://www.aamc.org/download/480840/data/aamcissuesjointletteroncommonrule.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.

See also 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.

On April 20, 2018, federal departments and agencies published a notice of proposed rulemaking (NPRM) soliciting comments on two proposals. 83 FR 17595. The first proposed an additional 6-month delay for the general compliance date for the 2018 Requirements (from July 19, 2018 to January 21, 2019). The second proposed a flexibility that would allow regulated entities to take advantage of three burden-reducing provisions of the 2018 Requirements during the delay period. Both proposals are described more fully below, together with a discussion of the public comments submitted, and our response to public comments. For the reasons provided below, this final rule adopts the proposals set forth in the NPRM.

II. Public Comments and Response to Comments

A. 2018 Interim Final Rule and 2018 NPRM Public Comment Summary

Public comment was solicited on the interim final rule between January 22, 2018 and March 19, 2018. Public comment was solicited on the NPRM to delay the implementation of the 2018 Requirements while permitting the use of three burden-reducing provisions of the 2018 Requirements between April 20, 2018 and May 21, 2018.

We received 62 public comments on the interim final rule. Of these, 36 comments were related to the Common Rule. The remaining 26 comments were not related to the Common Rule in any way. We received 73 comments on the NPRM. Five of these comments were not related to the Common Rule.

Several common themes emerged from the public comments on the interim final rule and the NPRM. These included:

- The need for the regulated community to have as much advance notice as possible about any delay in implementing the 2018 Requirements.
- The need for guidance to be issued promptly.
- General support for a delay of the general compliance date, with more limited support for a delay beyond January, 2019. This support, however, was generally tied to concern with whether Common Rule departments and agencies will be able to issue guidance in a timely fashion prior to the new general compliance date of January 21, 2019.

Both sets of comments tended to endorse some type of delay beyond July 19, 2018 in the general compliance date for the 2018 Requirements. Comments on the interim final rule tended to suggest that institutions be permitted to voluntarily implement the 2018 Requirements in their entirety at any time after July 19, 2018, while comments on the NPRM indicated broad support for the narrower approach of permitting the voluntary use of three burden-reducing provisions during the delay period.

B. Public Comments on the January 22, 2018 Interim Final Rule and Response to Comments

As well as soliciting comments on the delay of the implementation of the 2018 Requirements, the interim final rule solicited comments on the following:

- Whether or not the interim final rule should be considered regulatory or de-regulatory.
- Whether or not our assumption that 50 percent of regulated entities would have gone forward using the new or expanded exemption categories, had the implementation date of the 2018 Requirements remained January 19, 2018, was correct.

We received no comments on our assumption that 50 percent of regulated entities would have gone forward using the new or expanded exemption categories had the implementation date of the 2018 Requirements remained January 19, 2018. We received one comment addressing whether or not the interim final rule should be considered regulatory or de-regulatory. This comment indicated that the 2018 Requirements should be considered de-regulatory, without commenting on the regulatory or de-regulatory status of the interim final rule.

Of the 36 comments received on the interim final rule related to the Common Rule (and more specifically on delaying the effective and general compliance dates of the 2018 Requirements to July 19, 2018), several themes were present. Many of these comments discussed issues with the timing and issuance of the interim final rule, claiming that the fact that it was put on public display in the *Federal Register* 48 hours before the original implementation date caused chaos and confusion in the regulated community. Several commenters described what they categorized as chaos that ensued when the interim final rule was put on public display 48 hours before the original effective date and general compliance date for the 2018 Requirements. This rollout created administrative burdens for institutions, as many had changed IT systems, training programs, and other operational tasks and then had to hastily undo these changes. Another

commenter described the issuance of the interim final rule and the relative silence from Common Rule departments and agencies in the period since publication of the 2018 Requirements (in the January 19, 2017 final rule) as a betrayal of IRBs.

Additionally, commenters expressed concern that given the short timeline between the closing of the comment period and the new general implementation date of July 19, 2018, any further delay of the 2018 Requirements would similarly create chaos and confusion in the regulated community. Commenters also generally expressed that the 6-month delay granted by the interim final rule created a situation in which regulated entities that were ready to implement the 2018 Requirements in January 2018 had to spend the personnel hours to "undo" these changes, which seemed contradictory to the overall goal of the revisions to the Common Rule of reducing administrative burden. A few commenters focused entirely on how the relative silence by Common Rule departments and agencies since publication of the 2018 Requirements has created a confusing environment for this regulated community and requested more transparency from the regulating departments and agencies in the future.

[*Response:* We acknowledge that the timing of the interim final rule was not ideal and led to frustration within the regulated community. We believe that the 2018 NPRM and this final rule to delay the general compliance date for the 2018 Requirements while permitting the use of three burden-reducing provisions of the 2018 Requirements provides the regulated community with sufficient notice about when the 2018 Requirements will go into effect, and when regulated entities will be required to comply with the 2018 Requirements.]

Almost half of the comments related to the Common Rule advocated for the Common Rule departments and agencies to retain the July 19, 2018 effective date for the 2018 Requirements, and to delay the general compliance date. These commenters argued that during the period between the effective date and delayed general compliance date, institutions should be permitted to voluntarily comply (on a study-by-study basis) with the 2018 Requirements. A couple of these comments advocated for institutions to be able to implement select 2018 Requirements during this voluntary compliance period, as opposed to choosing to comply with the entirety of the 2018 Requirements, in order to provide institutions with the most flexibility. A majority of the comments described in this paragraph advocated for delaying the general compliance date to January 21, 2019, as these commenters did not believe that full compliance with the 2018 Requirements would be possible by July 19, 2018. A few commenters advocated delaying the general compliance date beyond January 21, 2019 to permit institutions as much time as possible to comply with the 2018 Requirements

One commenter suggested that both the effective and general compliance dates be delayed by 6 months to one year after Common Rule departments and agencies issue critical guidance documents. Other commenters suggested that Common Rule departments and agencies should be given a date by which they must publish key guidance documents. Several comments included a description of guidance documents that they would like for Common Rule departments and agencies to focus on initially. Suggestions included: OHRP's decision charts, key information in informed consent, broad consent, and continuing review (§__.109(f)).

Some of the comments relevant to the Common Rule advocated for no additional delay in the implementation of the 2018 Requirements beyond July 19, 2018. These comments argued that institutions and Common Rule departments and agencies have had sufficient time to prepare for the implementation of the Rule. One comment suggested that while guidance would certainly be helpful, it is possible to implement the Rule without such guidance, as evidenced by the fact that many institutions were ready to implement the 2018 Requirements before the publication of the interim final rule.

Several commenters also addressed whether certain aspects of the 2018 Requirements would be difficult to implement in the absence of agency guidance. These commenters acknowledged the importance of guidance to implement many areas of the 2018 Requirements but noted that the confusion and chaos created by late-breaking announcements of delays in the implementation of the 2018 Requirements ultimately caused more administrative burden within institutions. One large public university system in the United States indicated that if guidance is issued after institutions have revised their policies, procedures, and IT systems, it likely will create a burdensome situation where policies, procedures, and IT systems will need to be revised again to comport with department and agency guidance.

[*Response:* We agree with interim final rule comments suggesting that we keep the effective date of the 2018 Requirements as July 19, 2018, while delaying the general compliance date. While we considered the alternative of amending 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 adopting the changes proposed in the NPRM, 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 2018 Requirements. As described in the NPRM, 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 finalizing 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.

We recognize the difficulty in implementing the 2018 Requirements in the absence of guidance and will strive to issue guidance on key aspects of the 2018 Requirements as quickly as possible, while also engaging stakeholders.]

A small subset of comments suggested additional revisions to the Common Rule. For example, one commenter discussed the inclusion of a provision that would permit parents to decline certain procedures on behalf of their children.

[*Response:* This comment listed several clinical procedures done in the routine course of medical care. Such activities are outside of the scope of the Common Rule, and thus are outside of the scope of this rulemaking.]

Others discussed concerns with the waiver provision at §__.101(i) and suggested that this provision be strengthened such that departments and agencies are only permitted to waive the Common Rule with regard to certain research activities when such a waiver is consistent with the Belmont Report.[2] One commenter also suggested that the Clinton Memorandum[3] concerning requirements pertaining to classified research be fully implemented. These comments also referenced concerns with the carve-out form the definition of research pertaining to authorized operational activities in support of national security missions.

[*Response:* The January 19, 2017 final rule preamble stated "[t]hese authorized operational activities, as determined by each agency, do not include research activities as defined by the Common Rule, nor have they ever in the past been considered regulated by the Common Rule. This category of activity is removed from the definition of research to make explicit that the requirements of the final rule do not apply to authorized operational activities in support of national security missions. This clarification is not intended to narrow the scope of the Common Rule. We do not believe that this category contradicts President Clinton's Memorandum of 1997 regarding classified research, because this category is merely clarifying what activities are not considered to meet the definition of research. The Clinton Memorandum calls for a number of requirements to be added to protections for classified research activities, but it does not address activities that are not considered research."]

[2] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. April 18, 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.
[3] Clinton, WJ. Strengthened Protections for Human Subjects of Classified Research. 62 FR 26367-26372. May 13, 1997. https://www.gpo.gov/fdsys/pkg/FR-1997-05-13/pdf/97-12699.pdf.

Some commenters expressed concerns with how the transition provision essentially creates a dual regulatory system for human subjects protections. One commenter explicitly advocated for the Common Rule to require all research subject to the Common Rule to comply with the 2018 Requirements by a certain date given the additional protections to subjects that the revised Common Rule affords research participants.

[*Response:* We agree that the transition provision at §__.101(l) creates a system in which many institutions will need to be familiar with both versions of the Common Rule (if they elect to keep at least some previously initiated studies subject to the pre-2018 Requirements while their newly initiated studies are subject to the 2018 Requirements). However, we believe that the flexibility afforded by the transition provision is important for institutions to manage their operations while implementing the 2018 Requirements. We do not believe that this compromises the protection of human subjects.]

A few comments suggested that the general compliance date of the 2018 Requirements should coincide with FDA's revision of its human subjects protection regulations in order for there not to be a time period where FDA regulations are not harmonized with the other Common Rule departments and agencies.

[*Response:* With respect to the comments suggesting that the general compliance date of the 2018 Requirements should be tied to the FDA harmonization efforts with the Common Rule, we do not believe that this is necessary. FDA is currently working to harmonize its human subjects

regulations with the 2018 Requirements, to the extent permitted by FDA's statutory authority and mandate. We do not believe it is necessary to further delay the 2018 Requirements' general compliance date as a result of a separate rulemaking effort.]

One commenter argued that the 2018 Requirements should not be implemented at all, as in their view, the pre-2018 Requirements adequately protect human subjects.

[*Response:* We disagree. We believe that the 2018 Requirements will provide a meaningful improvement in human subjects protection, while reducing administrative burden on institutions.]

A couple of commenters argued that the general compliance date for the cooperative research provision (§__.114) should be delayed to 2022.

[*Response:* We disagree with the comments suggesting that the compliance date for the cooperative research provision (§__.114(b)) needs to be delayed beyond January 2020. Public comments requesting this change have not provided specific evidence for why such a delay is necessary, nor for the assertion that implementing the single IRB of record in cooperative research requirement will not result in a reduction in burden.]

C. Public Comments on the April 20, 2018 NPRM and Response to Comments

The April 20, 2018 NPRM sought comment on two primary proposals: (1) the proposal to delay the general compliance date for the 2018 Requirements to January 21, 2019; and (2) whether institutions should be allowed to implement three burden-reducing provisions in the 2018 Requirements during the delay period from July 19, 2018 to January 21, 2019. The NPRM also solicited comment on the advisability of two alternative approaches to delaying the 2018 Requirements: (1) 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; and (2) the alternative of delaying the effective date and general compliance date beyond January 21, 2019. The NPRM also solicited comment on whether the general compliance date for the 2018 Requirements should remain July 19, 2018.

The NPRM proposed to modify the transition provision at §__.101(l) to permit an institution or IRB (and not just an IRB) to document the institution's decision to transition a study to comply with the 2018 Requirements. (We received no public comments on this proposal.)

A majority of comments that discussed the NPRM proposals supported some kind of delay to the implementation of the 2018 Requirements. A majority supported the NPRM proposals as drafted but indicated that their support was contingent upon the Common Rule departments and agencies issuing the relevant guidance prior to July 19, 2018 for the three burden-reducing provisions, and all other key guidance documents before the January 2019 general compliance date. In particular, commenters noted that critical guidance documents would need to be available to the regulated community at least four months prior to the proposed general compliance date of January 21, 2019. These commenters specifically stated that if critical guidance documents were not

available by September 19, 2019, they would support an additional delay of the general compliance date.

Comments in response to the NPRM generally supported the position that many institutions need additional time to prepare to implement the 2018 Requirements, and that the Common Rule departments and agencies need more time to develop and issue guidance. Several commenters specifically noted that the Department of Veterans Affairs is not yet ready to implement the 2018 Requirements and needs more time.

Commenters suggested guidance documents that should be provided as quickly as possible to the regulated community. These suggestions included revising existing guidance, or issuing new guidance, as follows:

- Revised OHRP decision charts
- Information on the §__.116 clinical trial consent form posting location
- Limited IRB review
- Broad consent
- The new requirement that the informed consent give the prospective subject the information that a reasonable person would want to know in order to make an informed decision about research participation
- The new requirement that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or

legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

- Identifiability
- Privacy and confidentiality
- Benign behavioral interventions
- Continuing review

[*Response:* This final rule adopts the April 20, 2018 NPRM proposals, with minor changes made to the regulatory text for clarification and accuracy. As stated above, we agree with the comments that the issuance of guidance will be useful for institutions to be able to implement the 2018 Requirements, and are working to issue such guidance promptly. We appreciate the commenter input on topics for guidance to be issued by the departments and agencies.]

One commenter noted that if Common Rule departments and agencies envisioned a specific way that institutions or IRBs should document the use of the three burden-reducing provisions in the 2018 Requirements or document the fact that an ongoing study has transitioned to comply with the 2018 Requirements, that information must be communicated to the regulated community as soon as possible.

[*Response*: We do not believe that there is a need to prescribe how institutions document the decision to use the three burden-reducing provisions of the 2018 Requirements or the decision to transition a study to comply with the 2018 Requirements (on or after January 21, 2019), beyond the requirement that the institution or an IRB must document and date such determination. For

example, this institutional determination could be documented in IRB meeting minutes, or in an IRB reviewer checklist (if an institution uses a checklist system). This institutional determination could also be documented in an institution's existing electronic system, if one exists, or in a spreadsheet created and maintained by the institution to keep track of which studies have been transitioned to the 2018 Requirements.]

Several alternatives were suggested for how a delay might be structured. These included:

- Permitting voluntary compliance with the entirety of the 2018 Requirements between July 19, 2018 and January 21, 2019
- Keeping the NPRM proposals related to decoupling the effective and general compliance dates and the early implementation of the three burden-reducing provisions of the 2018 Requirements, but delaying the effective date of the 2018 Requirements until at least one year after Common Rule departments and agencies have issued key guidance documents
- Delaying both the effective and general compliance dates until January 21, 2019
- Delaying both the effective and general compliance dates beyond January 21, 2019
- Permitting the use of the three burden-reducing provisions of the 2018 Requirements, but not requiring that studies taking advantage of this flexibility comply with the entirety of the 2018 Requirements on and after January 21, 2019.

A minority of comments indicated concern that the NPRM proposals would be confusing for the regulated community to implement accurately. However, several of these comments indicated

that if the Common Rule departments and agencies determined that moving forward with a delay was still appropriate, the structure proposed in the NPRM would be acceptable.

Regardless of the delay structure endorsed, commenters noted that no matter the delay option chosen by Common Rule departments and agencies, guidance needed to be issued in order for the regulated community to make use of the delay period and prepare their institutions.

[*Response*: We acknowledge that there were multiple ways that an implementation delay of the 2018 Requirements could be structured. We believe that the approach proposed in the NPRM and adopted in this final rule is the best balance of permitting institutions to implement several of the more straightforward provisions of the 2018 Requirements before the general compliance date, while granting Common Rule departments and agencies additional time to develop and issue key guidance documents, and granting institutions additional time to ensure that their operations are ready to implement the 2018 Requirements.

We do not believe a delay of the general compliance date beyond January 21, 2019 is necessary. As discussed in the NPRM, we continue to believe that the regulated community will not need additional time beyond January 2019 to comply with the 2018 Requirements. Most NPRM comments supported the idea that January 2019 would be sufficient to allow for implementation of the 2018 Requirements, provided that the Common Rule departments and agencies issued key guidance.

We recognize that the implementation structure in this final rule might be confusing to some in the regulated community. We intend to engage in educational outreach to help the regulated community better understand what is permitted and what is not under the revised transition provision at §__. 101(l).]

Several commenters indicated that understanding OHRP's plan for modifying the Federalwide Assurance ("FWA") process to comport with the 2018 Requirements would also be helpful. Specific concerns were raised about the deletion of the option to "check the box" on the FWA and how the removal of this option will, in certain states with separate human subjects requirements, present administrative challenges for institutions. Another commenter expressed concern about whether, after January 21, 2019, FWAs would still be valid given that they would include statements and elections no longer required under the 2018 Requirements.

[*Response:* We intend to provide the regulated community with information about how the FWA process will change well in advance of any modifications that are implemented. The 2018 Requirements at §__.103(b) state that the "[assurance] shall be filed in such form and manner as the department or agency head prescribes." To that end, Common Rule departments and agencies have significant flexibility in what information is requested in the assurance process. Questions about non-OHRP assurances will be addressed by the relevant Common Rule departments and agencies. With respect to OHRP issued FWAs, OHRP wishes to make clear that assurances on file with the office will still be valid on and after January 21, 2019 for their effective period. Additionally, any changes made to the assurance process will take account of the fact that some institutions might oversee protocols that comply with the pre-2018 and 2018 Requirements.]

One commenter expressed concern with how auditors would handle IRBs reviewing protocols governed by both the pre-2018 Requirements and the 2018 Requirements, given that the 2018 Requirements do not require that every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women (pre-2018 Requirements at §__.107(b)).

[*Response:* We believe that the §__.107(a) requirements for diversity on IRBs serves the same purpose, and thus do not see a conflict between the diversity requirements for IRBs under the pre-2018 Requirements and the 2018 Requirements.]

While the NPRM did not solicit comments on the requirement for cooperative research to be reviewed by a single IRB (see §__.114), we received several comments discussing this provision. Several asked for an additional 2-year delay before the changes at §__.114(b) become effective. Others said that this provision should be amended such that use of a single IRB is voluntary in cooperative research. These comments argued that the 2018 Requirements' preamble (published in the January 19, 2017 final rule) underestimated the costs of the single IRB mandate and the confusion that implementing this policy would create for investigators. Several of these comments acknowledged that over time, as institutions become accustomed to developing reliance agreements and managing the single IRB process, the costs currently being experienced would decrease.

[*Response:* We appreciate the comments received on the single IRB of record requirement in cooperative research (§__.114(b)). We continue to believe that a compliance date of January 20,

2020 for this provision gives institutions sufficient time to prepare and implement this requirement. While these commenters anecdotally indicated that implementing this requirement has been more costly to institutions than the January 19, 2017 final rule preamble estimated, no comment provided data about the actual costs to implement this provision. In the absence of specific data, we retain our cost and benefit assumptions related to this provision.]

One comment suggested adding the exemption category for secondary use where consent is not required (§__.104(d)(4)) to the burden-reducing provisions. This commenter noted that because the inability to implement the revised exemptions during the delay period (i.e., July 19, 2018 through January 20, 2018) accounted for the majority of the costs estimated in the NPRM for this delay, it would be preferable for the final rule to permit the early implementation of this exemption category.

[*Response*: As explained in the April 20, 2018 NPRM, we did 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, we noted in the NPRM that 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. Specifically in regard to §__.104(d)(4), this exemption involves several regulations and statutes outside of the scope of the Common Rule. As a result, it is a much more complicated provision to implement, and thus was not included as one of the burden-reducing provisions of the 2018 Requirements that institutions could voluntarily implement during the delay period. After consideration of the

public comments received, we continue to believe that the approach proposed in the NPRM makes the most sense.]

One commenter argued that the 2018 Requirements should be withdrawn, and that Common Rule departments and agencies should issue several smaller NPRMs to revise specific aspects of the Common Rule.

[*Response:* We disagree with this comment. We believe that the 2018 Requirements will provide a meaningful improvement in human subjects protection, while reducing administrative burden on institutions.]

One commenter proposed that institutions or other Common Rule departments and agencies be required to file interim reports with HHS about their status with regard to full implementation and compliance with the 2018 Requirements. This commenter suggested that HHS could issue waivers for full implementation of the rule based on these interim reports. Additionally, such a reporting requirement would give HHS and other Common Rule departments and agencies the data necessary to determine if another adjustment to the 2018 Requirements might be needed.

[*Response:* We believe that this approach is impractical and unnecessary. We believe that this final rule will give institutions sufficient time to implement the 2018 Requirements, which also precludes the need for such a phased approach.]

One commenter indicated a desire to see a final rule containing the flexibility included in the original publication of the 2018 Requirements, on January 19, 2017, that institutions be permitted to implement provisions of the 2018 Requirements at any time before the effective date.

[*Response:* This commenter misunderstood the transition provision as written in the first publication of the 2018 Requirements; the transition provision published in the January 19, 2017 final rule revising the Common Rule did not include the ability for institutions to implement all provisions of the 2018 Requirements before the effective date and general compliance date.]

As with the comments on the interim final rule, a few comments expressed concern with the waiver provision at §__.101(i) allowing federal departments and agencies to waive some or all provisions of the Common Rule (which could allow research to be conducted on people without their informed consent). These comments additionally expressed concern with institutions being permitted to implement the exclusion of certain operational activities conducted by intelligence agencies during the delay period and suggested that this carve-out from the definition of research be removed from the 2018 Requirements.

[*Response:* We are not contemplating modifying the carve-outs from the definition of research. Regarding the carve-out from the definition of research pertaining to authorized operational activities in support of national security missions, the January 19, 2017 final rule preamble noted that "[t]hese authorized operational activities, as determined by each agency, do not include research activities as defined by the Common Rule, nor have they ever in the past been

considered regulated by the Common Rule. This category of activity is removed from the definition of research to make explicit that the requirements of the final rule do not apply to authorized operational activities in support of national security missions. This clarification is not intended to narrow the scope of the Common Rule."]

II. Delay of the General Compliance Date until January 21, 2019

Through this final rule, the general compliance date for the 2018 Requirements is delayed for a 6-month period until January 21, 2019. Section __.101(l)(2) is revised to make this delay explicit. The dates included in the transition provision, set forth at §__.101(l)(3), (4), and (5), are also modified to reflect this revised general compliance date.

As a result of this rule, regulated entities will be required to comply with the pre-2018 Requirements prior to January 21, 2019 (putting aside the burden-reducing provisions discussed in section III below). Regulated entities may not, prior to January 21, 2019, comply with all provisions of the 2018 Requirements, with the exception of the three burden-reducing provisions, in lieu of all provisions of the pre-2018 Requirements. Of course, regulated entities are permitted to adopt provisions that do not conflict with the pre-2018 Requirements, prior to January 21, 2019. For example, institutions may choose to incorporate additional elements of informed consent that happen to be found in the 2018 Requirements, or elsewhere, so long as such implementation does not conflict with the pre-2018 Requirements. In other words, institutions have the same flexibility they have always had (i.e., to exceed the minimum requirements set by the regulations).

The compliance date for the cooperative research provision of the 2018 Requirements (§_.114(b)) remains January 20, 2020.

III. Optional Flexibility: Implementation of Certain Burden-Reducing Provisions during the Delay Period

As detailed in revised §__.101(l)(4) and as set forth below in more detail, during the additional 6-month period that the general compliance date for the 2018 Requirements is delayed (July 19, 2018 through January 20, 2019), institutions may transition a research study to the 2018 Requirements in order to take advantage of three burden-reducing provisions of the 2018 Requirements. This final rule also restructures §__.101(l)(3) and (4) (now numbered (5)) to aid readability. A new section (now §__.101(1)(4)) describes how the requirements apply to research transitioning to take advantage of the burden-reducing provisions during different time periods. Below, we provide an overview of the revised transition provision to clarify its application to different types of studies, including studies taking early advantage of the three burden-reducing provisions of the 2018 Requirements.

A. Research Subject to the pre-2018 Requirements (§__.101(l)(3))

As a default, studies initiated (i.e., initially approved by an IRB, or for which IRB review was waived by the government pursuant to §__.101(i) or determined to be exempt) before January 21, 2019 (the new general compliance date for the 2018 Requirements) will continue to be

subject to the pre-2018 Requirements. This approach will maintain the ability of institutions to hold such studies to the same set of standards throughout their duration and will avoid a circumstance in which such research is subject to two sets of rules. However, as described below, institutions may elect to transition such studies to comply with the 2018 Requirements.

B. Research Subject to the 2018 Requirements (§__.101(l)(5))

Research initiated (i.e., initially approved by an IRB, or for which IRB review was waived by the government pursuant to §__.101(i), or determined to be exempt) on or after January 21, 2019 (the new general compliance date for the 2018 Requirements) must be conducted in compliance with the 2018 Requirements.

C. Research that Transitions to Comply with the 2018 Requirements on or after January 21, 2019 (§__.101(l)(4)(ii))

Section __.101(l)(4)(ii) applies to studies following the pre-2018 Requirements that transition to comply with the 2018 Requirements on or after January 21, 2019. In such circumstances, the study must be conducted in compliance with the 2018 Requirements beginning on the transition date (i.e., the date the transition determination is documented, on or after January 21, 2019) for its duration.

D. Research that Transitions to Comply with the 2018 Requirements during the 6-Month Delay Period (§__.101(l)(4)(i))

As described in §__.101(l)(4)(i)(A), the option of applying the three burden-reducing provisions of the 2018 Requirements during the 6-month delay period is only available with respect to studies that transition to comply with the 2018 Requirements between July 19, 2018 through January 20, 2019.

Beginning on the date that the transition determination is documented, through January 20, 2019, such studies must comply with the pre-2018 Requirements, except that the studies will comply with the three burden-reducing provisions instead of or in addition to the comparable pre-2018 Requirements (specified in §__.101(l)(4)(i)(A)(*1*)-(*3*)).

- Pursuant to §__.101(l)(4)(i)(A)(*1*), §__.102(l) of the 2018 Requirements (definition of research) will apply instead of §__.102(d) of the pre-2018 Requirements).
- Pursuant to §__.101(l)(4)(i)(A)(*2*), §__.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) will apply instead of §__.103(f) of the pre-2018 Requirements.
- Pursuant to §__.101(l)(4)(i)(A)(*3*), §__.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) will apply instead of §__.103(b) of the pre-2018 Requirements (as related to the requirement for continuing review) and in addition to §__.109 of the pre-2018 Requirements.

This approach is designed to 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 provisions during the delay period.

In addition, beginning on January 21, 2019, such studies must, for the balance of their duration, comply with the 2018 Requirements in their entirety.

We believe this rule strikes an appropriate balance of permitting voluntary early adoption of provisions that reduce burdens without creating significant complexities. 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 in which the remaining activities consist only of completing data analyses, the new requirements for informed consent generally would not be applicable.

While the three burden-reducing provisions are a regulatory package, an institution that takes advantage of this flexibility may, as a matter of institutional policy, adopt a more stringent standard (such as that of the pre-2018 Requirements) for any or all of the circumstances addressed by these three provisions. For example, if an institution chooses to adopt a policy that studies that qualify for expedited review under a certain category should continue to be subject to

annual continuing review, this rule does not prevent the institution from adopting and implementing that policy.

Given that studies taking advantage of this flexibility will be complying with provisions from both the pre-2018 Requirements and the 2018 Requirements during the delay period, we explain how some provisions interact and clarify our intended interpretations of particular regulatory provisions that will apply during the 6-month delay period. For studies electing to transition to comply with the 2018 Requirements during the 6-month delay period (July 19, 2018 through January 20, 2019), once the decision to transition the study is documented:

1. In applying the definition of research under the 2018 Requirements (§__.102(l)(3)), the reference to a "public health authority" will be given the meaning provided in the definition of "public health authority" in the 2018 Requirements (§__.102(k)). This interpretation arises because "public health authority" is defined in the 2018 Requirements, but not in the pre-2018 Requirements.
2. In applying §__.103(d) of the 2018 Requirements, the reference to research "exempted under §__.104" will be interpreted to refer to research exempted under §__.101(b) of the pre-2018 Requirements. This interpretation arises given that only the exemptions set forth in the pre-2018 Requirements will be in effect during the 6-month delay period.
3. The reference to "[r]esearch eligible for expedited review in accordance with §__.110" in §__.109(f)(1)(i) of the 2018 Requirements will be interpreted to refer to §__.110 of the pre-2018 Requirements.

4. The documentation requirements described in §__.115(a)(3) of the 2018 Requirements (documenting an IRB's rationale for conducting continuing review not otherwise required) are not applicable during this period.
5. Section__.103(d) of the 2018 Requirements will 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.

E. General Transition Issues

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.

Section __.101(l)(4)(ii) applies to studies following the pre-2018 Requirements that, at some point on or after January 21, 2019, transition to comply with the 2018 Requirements. If the determination to transition a study to the 2018 Requirements is documented on or after January 21, 2019, as of the date of documentation the study must be conducted in compliance with the 2018 Requirements for its duration.

We clarify that the transition provision at §__.101(l)(4) of the 2018 Requirements extends to research newly initiated during the delay period. Research newly initiated between July 19, 2018 and January 20, 2019 may be either conducted under the pre-2018 Requirements, in accordance with §__.101(l)(3); or, an institution may transition research newly initiated during the delay period to the 2018 Requirements, in accordance with §__.101(l)(4), in which event the research would be conducted under the pre-2018 Requirements, with substitution of the three burden-reducing provisions of the 2018 Requirements for the comparable provisions of the pre-2018 Requirements. In addition, on or after January 21, 2019, an institution may choose to transition research initiated during the delay period that was initially conducted under the pre-2018 Requirements, to compliance with the 2018 Requirements. In the NPRM, proposed §__.101(l)(4) referenced application by an institution "engaged in research" to "ongoing" research. In order to clarify the Common Rule departments' and agencies' intention that research newly initiated during the delay period may transition to the 2018 Requirements, this final rule no longer includes the qualifier of "ongoing" to describe research that transitions to the 2018 Requirements in accordance with §__.101(l)(4). The final rule at §__.101(l)(4) also includes the additional wording "planning or" before "engaged in research" to clarify that institutions are allowed to take advantage of the 2018 Requirements' carve-outs from the definition of research for studies newly initiated during the delay period (which would allow a study that qualifies for one of the carve-outs to be conducted without prior IRB review and approval or application of the other regulatory requirements).

This final rule revises the requirement, now set forth at §__.101(l)(4), regarding which entity may document an institution's decision to transition research. This change will offer institutions

greater flexibility regarding who documents the transition determination. Under the January 19, 2017 final rule, an institutional determination that research would transition to comply with the 2018 Requirements had to be documented by an IRB. Under this rule, such a determination may be documented either by an IRB or an institution (through officials who have the authority to make such determinations on behalf of the institution). Such documentation must include the date of the transition determination, and records documenting the transition decision must be retained in accordance with §__.115(b).

As a general matter, once an institution decides to transition a study to the 2018 Requirements and that determination is documented, the date of documentation will serve as the de facto compliance date for either the three-burden reducing provisions for transition determinations documented between July 19, 2018 and January 20, 2019, or the 2018 Requirements as applied to the study for transition determinations documented on or after January 21, 2019.

This final rule has an effective date of July 19, 2018, to enable regulated entities to take advantage of the three burden-reducing provisions during the delay period. However, as explained in this rule, the requirements a study must comply with beginning on July 19, 2018 are detailed in the transition provision codified at §__.101(l)(1)-(5). Finally, for consistency, headings were added to §__.101(l)(1) and (2).

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; Pub. L. 107-296, sec. 102, 306(c); Pub. 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 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, 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 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 rule was submitted to the Office of Management and Budget (OMB) for review and has been determined to be a "significant" regulatory action. This regulation has been designated as "regulatory" under Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs, issued on January 30, 2017). We estimate that this rule generates $2.02 million in annualized costs at a 7% discount rate, discounted relative to year 2016, over a perpetual time horizon. Details on the estimated costs of this final rule can be found in the economic analysis below.

1. Need for this Final Rule 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 rule was amended in a final rule published in the *Federal Register* on January 22, 2018 and adopted by HUD through a final rule published on January 26, 2018.

This final rule allows regulated entities to continue to comply with the pre-2018 requirements until January 21, 2019. As discussed above, this final rule also permits 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 elimination of the requirement for annual continuing review of certain categories of research, and (3) the elimination of the requirement that IRBs review grant applications or proposals related to the research. As described in section III above, this flexibility is permitted for studies for which an institution makes a choice to have those studies be subject to the 2018 Requirements.

2. Public Comments on the April 20, 2018 NPRM RIA and Response to Comments

The April 20, 2018 NPRM RIA solicited comment on the following assumptions:

- 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, the assumption 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.
- That some entities will experience cost savings as a result of this rule, and some entities would experience costs as a result of this rule.
- That 50 percent of regulated entities will take advantage of the option to implement three burden-reducing provisions of the 2018 Requirements early. Additionally, the NPRM sought 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.
- That this rulemaking will not have a significant economic impact on a substantial number of small entities.

We received several comments on the costs and benefits associated with the April 20, 2018 NPRM to delay the 2018 Requirements. None of these comments provided specific feedback on the cost and benefit assumptions included in the NPRM.

These comments indicated that the timing and implementation of the interim final rule created additional administrative burden on institutions that were prepared to implement the 2018 Requirements on January 19, 2018.

As discussed above, one comment noted that if we permitted the exemption at §__.104(d)(4) for secondary research where consent is not required to be implemented prior to the general compliance date, this delay would essentially be cost neutral. While we appreciate that there might be economic benefits to permitting the early implementation of one or more of the new or revised exemption categories, we did not include the exemptions as one of the provisions of the 2018 Requirements institutions can utilize during the delay period finalized in this rule because of the added complexity of implementing the exemptions in the absence of guidance.

Finally, we received several comments indicating that the January 19, 2017 final rule preamble underestimated the costs of implementing the cooperative research provision at §__.114. These comments argued that, at best, this provision would represent a shifting of administrative costs and burdens, but would not represent an overall cost savings. We continue to believe that the original compliance date of this provision in January 2020 gives institutions sufficient time to prepare and implement this requirement. While these commenters anecdotally indicated that implementing this requirement has been more costly to institutions than the January 19, 2017 final rule preamble estimated, no commenter provided data about the actual costs to implement this provision. In the absence of specific data, we continue with our cost and benefit assumptions related to this provision.

3. Analysis of Benefits (Cost-savings) and Costs (Foregone Benefits)[4]

The RIA for the 2018 Requirements described the benefits and costs of 16 broad categories of changes finalized. The RIA for this 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 the general implementation of the 2018 Requirements by six months. The time period for the analysis in this RIA is the 6-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 for the 2018 Requirements by 6 Months (from July 19, 2018 to January 21, 2019)

	Annualized Value by Discount Rate (Millions of 2016 Dollars)	
BENEFITS (COST-SAVINGS)	**3 Percent**	**7 Percent**
Quantified Benefits	6.4	5.9

[4] 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.

COSTS (FOREGONE BENEFITS)	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 6 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 6 Months[5]

	Annualized Value over 1 Year by Discount Rate (Millions of 2016 dollars)			
	Benefits (Cost-savings)		Costs (Foregone Benefits)	
2018 Requirement RIA Category	**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	-	-	-	-

[5] Zeroes in Table 2 (represented by "-") signify that the category has been unaffected by the 6-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 6-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 Compliance with the 2018 Requirements by 6 Months[5]

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%
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 or Proposal 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)[6]	-	-	-	-
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	-	-	0.07	0.06

[6] 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 Compliance with the 2018 Requirements by 6 Months[5]

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%
in Certain Subject Recruitment Activities				
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 6 months are what would have been the benefits of implementing the 2018 Requirements during the period of July 2018 through January 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 6 months are what would have been the costs of implementing the 2018 Requirements during the period of July 2018 through January 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.

Categories with different assumptions are described below.

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 6-month delay, regulated entities and OHRP will 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 final rule, and some entities will experience costs as a result of this rule, but we lack data 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 or other Funding Proposal 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 included in this final rule to implement three burden-reducing provisions of the 2018 Requirements prior to the

general compliance date. 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 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 would generally not be applicable. Therefore, we assume that there are situations in which an institution would want to take advantage of the three burden-reducing provisions, and situations in which 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 19, 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 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 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 or IRB staff at the IRB Administrative staff level[7] 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.

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.

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

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

categories.[8] 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 provisions of the 2018 Requirements have not yet been issued, 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.

4. Analysis of Final Rule Alternative

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

An alternative to the proposal finalized in this rule was to delay the effective date and general compliance date to January 21, 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 provisions of the 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)	
BENEFITS (COST-SAVINGS)	**3 Percent**	**7 Percent**
Quantified Benefits	7.4	6.9
COSTS (FOREGONE BENEFITS)	**3 Percent**	**7 Percent**
Quantified Costs	50.8	47.0

B. Paperwork Reduction Act (PRA)

This final 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) permits studies to transition to the 2018 Requirements between July 19, 2018 and January 21, 2019 (which would be the new general compliance date for 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 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 elimination of the requirement for 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 provisions of the 2018 Requirements during the time period of July 19, 2018 through January 21, 2019. We estimate that this provision includes 7,674 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.

We have determined that this final rule 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 final rule would not impose a regulatory burden for regulated small entities because it would delay the general compliance date for the 2018 Requirements, allowing the status quo to be retained for the period of delay. Additionally, regulated small entities are permitted to comply voluntarily with those aspects of the 2018 Requirements that do not conflict with the pre-2018 Requirements, prior to January 21, 2019.

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)

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." In 2018, that threshold is approximately $150 million. 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.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 this 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 this 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 further amended as follows:

Text of the Amended Common Rule

PART __—PROTECTION OF HUMAN SUBJECTS

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

§__.101 To what does this policy apply?

* * * * *

(l) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 6 CFR part 46 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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; Pub. L. 107-296, sec. 102, 306(c); Pub. L. 108-458, sec. 8306.

2. Amend §46.101 by adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

* * * * *

Claire M. Grady,

Deputy Secretary (Acting), 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 further amends 7 CFR part 1c as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 10 CFR part 745 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

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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 recordkeeping requirements, Research.

For the reasons stated in the preamble, National Aeronautics and Space Administration further amends 14 CFR part 1230 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 15 CFR part 27 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 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), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

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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 further amends 20 CFR part 431 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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,

Acting 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 further amends 22 CFR part 225 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

* * * * *

Irene Koek,

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 further amends 24 CFR part 60 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim final rule published in the *Federal Register* on January 22, 2018 (83 FR 2885), and adopted by HUD through an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 29 CFR part 21 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

* * * * *

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 further amends 32 CFR part 219 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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; 42 U.S.C. 300v-1(b).

2. Amend §219.101 by adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

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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 further amends 34 CFR part 97 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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; 42 U.S.C. 300v-1(b).

2. Amend §97.101 by adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements.* * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

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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 recordkeeping requirements, Research.

For the reasons stated in the preamble, Department of Veterans Affairs further amends 38 CFR part 16 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements*. * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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,

Acting 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 further amends 40 CFR part 26 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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; and 42 U.S.C. 300v-1(b).

2. Amend §26.101 by adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements*. * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 45 CFR part 46 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements*. * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 45 CFR part 690 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements*. * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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 further amends 49 CFR part 11 as published in the *Federal Register* on January 19, 2017 (82 FR 7149), and as amended in an interim 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 adding a heading for paragraph (l)(1), 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) * * *

(1) *Pre-2018 Requirements*. * * *

(2) *2018 Requirements.* 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 planning or engaged in research otherwise covered by paragraph (l)(3) of this section determines that such 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 through 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.

* * * * *

Elaine L. Chao,

Secretary of Transportation.

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