and needs additional time to prepare for the hearing:

(iii) Your representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing;

(iv) A witness who will testify to facts material to your case would be unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained;

(v) Transportation is not readily available for you to travel to the hearing; or

(vi) You are unrepresented, and you are unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which you may have.

■ 12. Amend § 416.1438 by revising paragraphs (b)(3), (b)(5), and (c) and adding paragraph (d) to read as follows:

§ 416.1438 Notice of a hearing before an administrative law judge.

* * * * *

(b) * * *

(3) How to request that we change the time of your hearing:

* * * * *

(5) Whether your appearance or that of any other party or witness is scheduled to be made by video teleconferencing, in person, or, when the circumstances described in § 416.1436(c)(2) exist, by telephone. If we have scheduled you to appear by video teleconferencing, the notice of hearing will tell you that the scheduled place for the hearing is a video teleconferencing site and explain what it means to appear at your hearing by video teleconferencing:

* * * * *

(c) Acknowledging the notice of hearing. The notice of hearing will ask you to return a form to let us know that you received the notice. If you or your representative do not acknowledge receipt of the notice of hearing, we will attempt to contact you for an explanation. If you tell us that you did not receive the notice of hearing, an amended notice will be sent to you by certified mail.

(d) Amended notice of hearing. If we need to send you an amended notice of hearing, we will mail or serve the notice at least 20 days before the date of the hearing. Similarly, if we schedule a supplemental hearing, after the initial hearing was continued by the assigned administrative law judge, we will mail or serve a notice of hearing at least 20 days before the date of the hearing.

■ 13. Amend § 416.1450, by revising paragraphs (a) and (e) to read as follows:

§ 416.1450 Presenting evidence at a hearing before an administrative law judge.

(a) The right to appear and present evidence. Any party to a hearing has a right to appear before the administrative law judge, either by video teleconferencing, in person, or, when the conditions in § 416.1436(c)(2) exist, by telephone, to present evidence and to state his or her position. A party may also make his or her appearance by means of a designated representative, who may make the appearance by video teleconferencing, in person, or, when the conditions in § 416.1436(c)(2) exist, by telephone.

* * * * *

(e) Witnesses at a hearing. Witnesses you call may appear at a hearing with you in the same manner in which you are scheduled to appear. If they are unable to appear with you in the same manner as you, they may appear as prescribed in § 416.1436(c)(4). Witnesses called by the administrative law judge will appear in the manner prescribed in § 416.1436(c)(4). They will testify under oath or affirmation unless the administrative law judge finds an important reason to excuse them from taking an oath or affirmation. The administrative law judge may ask the witness any questions material to the issues and will allow the parties or their designated representatives to do so.

* * * * *

■ 15. Amend § 416.1476, by revising paragraph (b) to read as follows:

§ 416.1476 Procedures before the Appeals Council on review.

* * * * *

(b) Oral argument. You may request to appear before the Appeals Council to present oral argument. The Appeals Council will grant your request if it decides that your case raises an important question of law or policy or that oral argument would help to reach a proper decision. If your request to appear is granted, the Appeals Council will tell you the time and place of the oral argument at least 10 business days before the scheduled date. You will appear before the Appeals Council by video teleconferencing or in person, or, when the circumstances described in § 416.1436(c)(2) exist, we may schedule you to appear by telephone. The Appeals Council will determine whether any other person relevant to the proceeding will appear by video teleconferencing, telephone, or in person as based on the circumstances described in § 416.1436(c)(4).

[FR Doc. 2018–24711 Filed 11–14–18; 8:45 am]
BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50, 312, and 812

[Docket No. FDA–2018–N–2727]

RIN 0910–AH52

Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This proposed rule, if finalized, would allow an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an Institutional Review Board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

DATES: Submit either electronic or written comments on this proposed rule by January 14, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery/courier (for written/paper submissions) will be considered on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your
comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

* If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions.”)

**Written/Paper Submissions**

Submit written/paper submissions in the following ways:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2018–N–2727 for “Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23889.pdf.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** With regard to the proposed rule: Janet Norden, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1127, or Carol Drew, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3505.

**SUPPLEMENTARY INFORMATION:**

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**I. Executive Summary**

**A. Purpose of the Proposed Rule**

The purpose of this proposed rule is to implement the statutory changes made to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by section 3024 of the Cures Act (Pub. L. 114–255) to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an IRB to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations.

B. Summary of the Major Provisions of the Proposed Rule

The major provisions of the proposed rule would add §50.22 to part 50 (21 CFR part 50) to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that waives or alters certain informed consent elements or that waives the requirement to obtain informed consent for certain minimal risk clinical investigations. In order for an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the proposed rule would require an IRB to find and document four criteria that are consistent with the “Federal Policy for the Protection of Human Subjects” (the Common Rule) (56 FR 28001, June 18, 1991). FDA believes proposed §50.22 would provide appropriate safeguards to protect the rights, safety, and welfare of the human subjects participating in such clinical investigations. We are also proposing conforming amendments to FDA’s regulations, including §50.20, 21 CFR 312.60, and 21 CFR 812.2.

**C. Legal Authority**

Sections 505(i)(4) and 520(g)(3) of the FD&C Act (21 U.S.C. 355(i)(4) and 360(g)(3)), as amended by section 3024 of the Cures Act, in conjunction with FDA’s general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as FDA’s principal legal authority for this proposed rule.

**D. Costs and Benefits**

We do not anticipate additional costs associated with this rulemaking. This proposed rule would help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered. We expect benefits in the form of healthcare advances from such minimal risk clinical investigations and from harmonization of FDA’s informed consent regulations with the Common
Rule’s provision for waiver of informed consent for certain minimal risk research. We cannot quantify all of these benefits because of the lack of relevant data available to FDA. The benefits that we are able to quantify are the cost savings to IRBs because the time burdens of reviewing certain minimal risk clinical investigations under differing requirements would be reduced. The estimated cost savings of the proposed rule are approximately $237,6 thousand, with a lower bound of approximately $59.4 thousand and an upper bound of $950.5 thousand. The estimated annualized costs savings of the proposed rule are approximately $27 thousand, with a lower bound of approximately $6,762 and an upper bound of approximately $108.2 thousand, discounted at 3 percent over 10 years. The estimated annualized costs savings of the proposed rule are approximately $26 thousand, with a lower bound of approximately $6,509 and an upper bound of $104.1 thousand, discounted at 7 percent over 10 years.

II. Background and Description of the Proposed Regulation

A. Background

On December 13, 2016, the Cures Act was signed into law, amending certain provisions of the FD&C Act. FDA is proposing to update its regulations to reflect some of those changes that are now in effect. Specifically, section 3024 of the Cures Act amended sections 520(g)(3) and 505(i)(4) of the FD&C Act to provide FDA with the authority to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This proposed rule, if finalized, would implement this statutory change.

Sections 505(i) and 520(g) of the FD&C Act require FDA to publish regulations governing the use in human subjects of drugs and devices in clinical investigations. In 1962, amendments to section 505(i) of the FD&C Act provided that FDA regulations must ensure that informed consent for investigational use of drugs (including biological products) in human beings is obtained except where it is not feasible or it is contrary to the best interests of such human beings. The Medical Device Amendments of 1976 subsequently added section 520(g) to the FD&C Act. Among other requirements, section 520(g)(3)(D) of the FD&C Act directed that FDA regulations governing investigational use of devices require that informed consent be obtained except where the investigator determines in writing that there exists a life-threatening situation involving the human subject of such testing that necessitates the use of such device and it is not feasible to get the consent of the subject and there is not sufficient time to obtain such consent from the subject’s representative. Section 520(g)(3)(D) of the FD&C Act further provided that a licensed physician not involved in the research must also concur in this determination, unless immediate use is necessary to save the subject’s life and there is not time to get concurrence.

In 1979, FDA proposed revisions to its regulations governing informed consent (44 FR 47713, August 14, 1979). The Agency recognized in the preamble to its proposed rule that the statutory language regarding exceptions from informed consent for investigational drugs differed from that regarding investigational devices. However, the Agency explained that its prior regulations implementing the statutory exception from informed consent for investigational drugs “carefully limited” the exception to certain situations that assume “the patient subject is seriously ill” and did not differ greatly from the new statutory exceptions from informed consent for devices (see 44 FR 47713 at 47718). When FDA issued final revisions to its informed consent regulations in 1981, it adopted a single set of requirements for informed consent for all FDA-regulated clinical investigations that reflected the device standard in section 520(g)(3)(D) of the FD&C Act (see 46 FR 8942, January 27, 1981). FDA explained its intent to adopt a single standard that reflected the most current congressional thinking on informed consent (see 44 FR 47713 at 44718; 46 FR 8942 to 8944).

Currently, FDA’s regulations governing the protection of human subjects (21 CFR parts 50 and 56) allow exception from the general requirements of informed consent only in life-threatening situations when certain conditions are met (50.23) or when the requirements for emergency research are met (§ 50.24). In all other cases, FDA regulations require that a human subject provide informed consent before participating in a clinical investigation. At this time, FDA’s regulations do not allow an exception from the general requirements of informed consent for minimal risk clinical investigations.

In contrast, the Common Rule has included waiver of informed consent provisions for minimal risk research since it was originally issued in 1991 (56 FR 28001). The Common Rule sets forth requirements for the protection of human subjects involved in research that is conducted or supported by the Department of Health and Human Services (HHS) (see 45 CFR 46, Subpart A) and 15 other Federal departments and agencies. The purpose of the Common Rule is to promote uniformity, understanding, and compliance with human subject protections as well as to create a uniform body of regulations across the Federal departments and agencies. The Common Rule standard has permitted an IRB to waive the requirements to obtain informed consent, or to allow changes to, or explanation of, some or all elements of informed consent if the IRB finds and documents that: (1) The research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation (45 CFR 46.116(d); 56 FR 28001 at 28017).

FDA amended its regulations in parts 50 and 56 to conform them to the Common Rule in 1991 (56 FR 28001 at 28025) but diverged from the Common Rule’s provision for waiver or alteration of informed consent for minimal risk research at 45 CFR 46.116(d). In explaining the reason for this departure, FDA cited sections 505(i) and 520(g)(3)(D) of the FD&C Act and stated that the FD&C Act “requires informed consent to be obtained from all subjects except in very limited circumstances” and that the Agency did “not have the authority under the act to...”

1 80 FR 53931 at 53935, September 8, 2015.

2 References to the Common Rule in this document are to the 1991 version of the Common Rule, unless otherwise noted. A final rule that revised the 1991 version of the Common Rule adopted an effective and general compliance date of January 19, 2018 (82 FR 7149, January 19, 2017). On January 22, 2018, an interim final rule was published that delayed the general compliance date until January 21, 2019, while allowing the use of three burden-reducing provisions for certain research during the delay period (83 FR 28497). The revised version of the Common Rule, including amendments made by the January 22, 2018 interim final rule and the June 19, 2018 final rule, is referred to in this document as the “revised Common Rule.”

3 FDA’s proposed rule also cited section 507 of the FD&C Act, which established requirements for the conduct of clinical investigations of antibiotic drugs and provided the same exceptions from the informed consent requirements as those provided under section 505(i). Section 125 of the Food and Drug Administration Modernization Act of 1997 repealed section 507 of the FD&C Act.
waive this requirement” (53 FR 45671 at 45679, November 10, 1988).

The Common Rule provision recognizes that there may be proposed research that cannot practically be conducted without a waiver or alteration of informed consent, but the research would contribute valuable medical or scientific knowledge and would present no more than minimal risk to subjects. FDA believes this is also true for some minimal risk FDA-regulated clinical investigations. On March 13, 2014, the Secretary’s Advisory Committee on Human Research Protections (SACHRP) considered whether the Common Rule standard for waiver of informed consent for minimal risk research would be appropriate and helpful for FDA-regulated clinical investigations.

SACHRP recommended to the Secretary of HHS that FDA adopt the provisions for waiver of informed consent that existed under the Common Rule at that time at 45 CFR 46.116(d). On October 26, 2016, SACHRP reiterated that recommendation to the Secretary. 4 FDA believes that the Common Rule provision has provided appropriate safeguards to protect the rights, safety, and welfare of human subjects participating in certain minimal risk research for over 25 years. Consistent with SACHRP’s recommendations, FDA also believes that this standard is appropriate for FDA-regulated clinical investigations posing no more than minimal risk to human subjects. The Cures Act statutory revision authorizes FDA to permit an exception from informed consent requirements when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject. This enables FDA to harmonize with the Common Rule’s well-established waiver provision for certain minimal risk research, thereby facilitating investigators’ ability to conduct minimal risk clinical investigations that could contribute substantially to the development of products to diagnose or treat diseases or other conditions, without compromising subjects’ rights, safety, or welfare. Because some clinical research is subject to both FDA and HHS regulations, harmonization of this waiver provision should also reduce burden on the research community.

The Common Rule was recently revised (82 FR 7149, January 19, 2017), introducing new terminology and regulatory provisions. Although it retains the same criteria for IRB waiver or alteration of informed consent as were included in the 1991 version of the Common Rule, it adds a fifth criterion, i.e., “if the research involves using identifiable private information or identifiable biospecimens, the research could not practically be carried out without using such information or biospecimens in an identifiable format” (new requirement at 45 CFR 46.116(f)(3)(iii)). We are proposing to adopt the four criteria from the 1991 version of the Common Rule. At this time, we are not proposing to adopt the new fifth criterion in the revised Common Rule, which has a general compliance date of January 21, 2019; however, we invite comments on this issue. Section 3023 of the Cures Act requires the Secretary of HHS, to the extent practicable and consistent with other statutory provisions, to harmonize the differences between the HHS human subject regulations and FDA’s human subject regulations. FDA will be working with others in HHS to carry out this statutory directive with respect to new terminology and regulatory provisions in the revised Common Rule, such as this new fifth criterion.

Subsequent to the Cures Act amendment to the FD&C Act, FDA issued a guidance document for immediate implementation, entitled “Institutional Review Board Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects” (82 FR 34535, July 25, 2017). This guidance informed sponsors, investigators, and IRBs that FDA does not intend to object to an IRB waiving or altering informed consent requirements, as described in the guidance, for certain minimal risk clinical investigations. In addition, the guidance informed sponsors, investigators, and IRBs that FDA does not intend to object to a sponsor initiating, or IRBs conducting, a minimal risk clinical investigation for which an IRB waives or alters the informed consent requirements as described in the guidance. FDA intends to withdraw the guidance after regulations to implement section 3024 of the Cures Act become effective. Obtaining informed consent from those who volunteer to participate in research is a fundamentally important principle of human subject protection. FDA is issuing this proposed rule to permit IRB waiver or alteration of informed consent in limited circumstances, consistent with the Cures Act. Given the variety and complexity of clinical investigations being conducted in today’s research environment, FDA is soliciting additional stakeholder input on the types of FDA-regulated minimal risk clinical investigations for which sponsors would anticipate requesting a waiver or alteration of informed consent from the IRB.

B. Description of the Proposed Regulation

FDA proposes to add § 50.22, “Exception from informed consent requirements for minimal risk clinical investigations” to part 50. The proposed exception would allow the IRB responsible for the review, approval, and continuing review of the clinical investigation to approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent in § 50.25(a) and (b) of FDA’s current regulations, or that waives the requirement to obtain informed consent, provided that the IRB finds and documents that:

• The clinical investigation involves no more than minimal risk to the subjects;
• The waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects;
• The clinical investigation could not practicably be carried out without the waiver or alteration of informed consent; and
• Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Consistent with the amendments made by section 3024 of the Cures Act, § 50.22(a) would limit the application of a waiver or alteration of informed consent under proposed § 50.22 to clinical investigations that involve no more than minimal risk. FDA regulations and the Common Rule have shared the same definition of “minimal risk” since 1991 (see 56 FR 28025, June 18, 1991; § 50.3(k); 45 CFR 46.102(i)). Proposed § 50.22 also provided for appropriate safeguards to protect the rights, safety, and welfare of human subjects. Proposed § 50.22(b) requires the reviewing IRB to find that the waiver or alteration will not adversely affect the rights and welfare of the subjects. To make this finding, IRBs may consider, for example, whether the waiver or alteration has the potential to negatively affect the subjects’ well-being or whether the subject population in


5 In the revised Common Rule, the definition of “minimal risk” is found at 45 CFR 46.102(i).
The rulemaking would not allow an IRB to approve an informed consent document that is a waiver of consent or alteration of the informed consent document that is not feasible to obtain informed consent, except when the IRB finds and documents the following:

1. The waiver or alteration is necessary to protect the rights, safety, and welfare of the human subjects or others, and the IRB is satisfied that the clinical investigation could not practicably be carried out without the waiver or alteration.
2. The waiver or alteration is not feasible to obtain informed consent.
3. The waiver or alteration is not harmful or contrary to the best interests of the subjects.

The rulemaking would allow an IRB to approve an informed consent document that is a waiver of consent or alteration of the informed consent document that is not feasible to obtain informed consent, except when the IRB finds and documents the following:

1. The waiver or alteration is necessary to protect the rights, safety, and welfare of the human subjects or others, and the IRB is satisfied that the clinical investigation could not practicably be carried out without the waiver or alteration.
2. The waiver or alteration is not feasible to obtain informed consent.
3. The waiver or alteration is not harmful or contrary to the best interests of the subjects.

The rulemaking would also allow an IRB to approve an informed consent document that is a waiver of consent or alteration of the informed consent document that is not feasible to obtain informed consent, except when the IRB finds and documents the following:

1. The waiver or alteration is necessary to protect the rights, safety, and welfare of the human subjects or others, and the IRB is satisfied that the clinical investigation could not practicably be carried out without the waiver or alteration.
2. The waiver or alteration is not feasible to obtain informed consent.
3. The waiver or alteration is not harmful or contrary to the best interests of the subjects.

The rulemaking would not allow an IRB to approve an informed consent document that is a waiver of consent or alteration of the informed consent document that is not feasible to obtain informed consent, except when the IRB finds and documents the following:

1. The waiver or alteration is necessary to protect the rights, safety, and welfare of the human subjects or others, and the IRB is satisfied that the clinical investigation could not practicably be carried out without the waiver or alteration.
2. The waiver or alteration is not feasible to obtain informed consent.
3. The waiver or alteration is not harmful or contrary to the best interests of the subjects.

The rulemaking would also allow an IRB to approve an informed consent document that is a waiver of consent or alteration of the informed consent document that is not feasible to obtain informed consent, except when the IRB finds and documents the following:

1. The waiver or alteration is necessary to protect the rights, safety, and welfare of the human subjects or others, and the IRB is satisfied that the clinical investigation could not practicably be carried out without the waiver or alteration.
2. The waiver or alteration is not feasible to obtain informed consent.
3. The waiver or alteration is not harmful or contrary to the best interests of the subjects.
of the rule to obtain informed consent for certain minimal risk research. The Common Rule provision is currently used by numerous other Federal departments and agencies. Some clinical research is subject to both FDA’s regulations and the Common Rule, so harmonization of this specific waiver provision would benefit those entities that conduct, sponsor, or review certain minimal risk clinical investigations by reducing confusion and burden created by the need to comply with differing requirements.

B. Cost Savings of the Proposed Rule

The proposed rule would harmonize FDA’s informed consent regulations with the 1991 version of the Common Rule’s provision for waiver of the requirement to obtain informed consent for certain minimal risk clinical investigations. As in a previous economic analysis of the 2017 revisions to the Common Rule (Ref. 1), we attempt to quantify the effects of the proposed rule where possible. We conducted a search for active IRBs regulated by both FDA and the Office for Human Research Protections (OHRP) in HHS in the ‘‘Office for Human Research Protections (OHRP) Database for Registered IORGs & IRBs, Approved FWAs, and Documents Received in the Last 60 Days’’ (Ref. 2). Using this data, we are able to determine whether an IRB is active or inactive, and whether it is regulated by FDA, OHRP, or both. We multiply the number of active IRBs by the percentage of IRBs regulated by both FDA and OHRP to yield an estimate of 2,442 active IRBs that are regulated by both FDA and OHRP (= 3,507 × 0.696). We expect that some of these IRBs would be affected by the proposed rule, and would experience a reduction in the time burden of determining whether to approve a waiver of the requirement to obtain informed consent for a minimal risk clinical investigation by reviewing it under a harmonized standard. ⁶ We estimate that 50 percent of affected IRBs would incur time savings from the proposed rule, with a lower bound of 25 percent of affected IRBs and an upper bound of 100 percent of affected IRBs.

We estimate that for affected IRBs, cost savings would be incurred in the form of time savings to IRB administrators, IRB chairs, IRB voting members, and IRB administrative staff from evaluating a minimal risk clinical investigation under FDA’s and the Common Rule’s harmonized regulations for waiving the requirement to obtain informed consent. Based on discussion with FDA subject matter experts (Ref. 3), we estimate that the reduced time burden of the proposed rule is 30 minutes (0.5 hours), with a lower bound of 15 minutes (0.25 hours) and an upper bound of 60 minutes (1 hour).

We draw from Bureau of Labor Statistics data to estimate hourly wage rates for IRB chairs, IRB voting members, and IRB administrative staff in 2016 dollars. Based on an economic analysis of impacts of revisions to the Common Rule (Ref. 1), we use wages for postsecondary education administrators to proxy for IRB administrator wages (Ref. 4), wages for office and administrative support workers to proxy for IRB administrative staff wages (Ref. 5), and wages for postsecondary health teachers to proxy for the wages of IRB chairs and IRB voting members (Ref. 6). We double each hourly wage to account for benefits and overhead, yielding wage rates of $134.50 for IRB administrators (= $67.25 × 2), $35.94 for IRB administrative staff (= $17.97 × 2), $109.40 for IRB chairs (= $54.70 × 2), and $109.40 for IRB voting members (= $54.70 × 2). We estimate that each of these forms of labor would experience time savings as a result of the proposed rule ranging from 15 to 60 minutes, with a central estimate of 30 minutes. We also estimate that time savings would be incurred by one IRB administrator, one IRB administrative staff, one IRB chair, and one IRB voting member. We multiply the number of active IRBs regulated by the percentage of IRBs affected by the proposed rule, the estimated reduced time burden of the proposed rule, and the sum of each IRB wage rate to yield a total estimated cost savings of approximately $237,631 (= 2,442 × 0.50 × 0.50 × [$134.50 + $109.40 + $109.40 + $35.94]), with lower bound estimated cost savings of approximately $59,408 (= 2,442 × 0.25 × 0.25 × [$134.50 + $109.40 + $109.40 + $35.94]) and upper bound estimated cost savings of approximately $950,524 (= 2,442 × 1 × 1 × [$134.50 + $109.40 + $109.40 + $35.94]). The net present value of the cost savings of the proposed rule is approximately $230.7 thousand, discounted at 5 percent, with a lower bound of approximately $57.7 thousand and an upper bound of approximately...
$922.8 thousand. The net present value of the cost savings of the proposed rule are approximately $222.1 thousand, discounted at 7 percent, with a lower bound of approximately $55.5 thousand and an upper bound of approximately $888.3 thousand. The annualized cost savings of the proposed rule are approximately $26 thousand discounted at 7 percent over 10 years, with a lower bound of approximately $6,509 and an upper bound of approximately $104.1 thousand. The estimated cost savings of the proposed rule to IRBs are summarized in table 1.

**TABLE 1—COST SAVINGS OF THE PROPOSED RULE TO IRBs**

<table>
<thead>
<tr>
<th>Metric</th>
<th>Low</th>
<th>Middle</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of active IRBs</td>
<td>3,507</td>
<td>3,507</td>
<td>3,507</td>
</tr>
<tr>
<td>Percentage of IRBs regulated by FDA and OHRP</td>
<td>69.6%</td>
<td>69.6%</td>
<td>69.6%</td>
</tr>
<tr>
<td>No. of active IRBs regulated by FDA and OHRP</td>
<td>2,442</td>
<td>2,442</td>
<td>2,442</td>
</tr>
<tr>
<td>Percentage of FDA/OHRP regulated IRBs affected by the proposed rule</td>
<td>25%</td>
<td>50%</td>
<td>100%</td>
</tr>
<tr>
<td>Reduced time burden of the proposed rule (hours)</td>
<td>0.25</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>Hourly wage, IRB administrator</td>
<td>$134.50</td>
<td>$134.50</td>
<td>$134.50</td>
</tr>
<tr>
<td>Hourly wage, IRB chair</td>
<td>$109.40</td>
<td>$109.40</td>
<td>$109.40</td>
</tr>
<tr>
<td>Hourly wage, IRB voting member</td>
<td>$109.40</td>
<td>$109.40</td>
<td>$109.40</td>
</tr>
<tr>
<td>Hourly wage, IRB administrative staff</td>
<td>$35.94</td>
<td>$35.94</td>
<td>$35.94</td>
</tr>
<tr>
<td>Total cost savings of the proposed rule</td>
<td>$59,408</td>
<td>$237,631</td>
<td>$950,524</td>
</tr>
<tr>
<td>Net present value of the proposed rule (3%)</td>
<td>$57,677</td>
<td>$230,710</td>
<td>$922,839</td>
</tr>
<tr>
<td>Net present value of the proposed rule (7%)</td>
<td>$55,521</td>
<td>$222,085</td>
<td>$888,340</td>
</tr>
<tr>
<td>Annualized cost savings of the proposed rule (3%, 10 years)</td>
<td>$6,762</td>
<td>$27,046</td>
<td>$108,185</td>
</tr>
<tr>
<td>Annualized cost savings of the proposed rule (7%, 10 years)</td>
<td>$6,509</td>
<td>$26,035</td>
<td>$104,141</td>
</tr>
</tbody>
</table>

**C. Costs of the Proposed Rule**

We do not anticipate additional costs associated with this rulemaking. This proposed rule would help enable the conduct of certain minimal risk clinical investigations for which the requirement to obtain informed consent is waived or for which certain elements of informed consent are waived or altered.

**D. Executive Order 13771**

Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that the proposed rule, if finalized, is deregulatory under Executive Order 13771 and does not require us to identify cost offsets. The net present value of the cost savings of the proposed rule are approximately $222.1 thousand, discounted at 7 percent, with a lower bound of approximately $55.5 thousand and an upper bound of approximately $888.3 thousand. The annualized cost savings of the proposed rule are approximately $15,546, discounted at 7 percent on an infinite time horizon, with a lower bound of approximately $3,886 and an upper bound of approximately $62,184. Discounted at 3 percent, the net present value of the cost savings of the proposed rule are approximately $230.7 thousand, with a lower bound of approximately $57.7 thousand and an upper bound of approximately $922.8 thousand. The annualized cost savings of the proposed rule are approximately $6,921, discounted at 3 percent on an infinite time horizon, with a lower bound of approximately $1,730 and an upper bound of approximately $27,685. The estimated net cost savings under Executive Order 13771 are summarized in table 2.

**VI. Analysis of Environmental Impact**

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**VII. Paperwork Reduction Act of 1995**

This proposed rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). IRB actions related to the waiver or alteration of informed consent requirements are currently approved under OMB control numbers 0910–0014, 0910–0078, 0910–0130, and 0910–0755. Therefore, FDA tentatively concludes the requirements in this document are not subject to additional review by OMB.

**VIII. Consultation and Coordination With Indian Tribal Governments**

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We
have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the Federal Register, but websites are subject to change over time.


2. Memorandum to File, FDA summary of data analysis; HHS, “Office for Human Research Protections (OHRP) Database for Registered IRGs & IRBs, Approved FWAs, and Documents Received in Last 60 Days”, prepared by Christian Brown, FDA, September 20, 2017.


List of Subjects

21 CFR Part 50

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 50, 312, and 812 be amended as follows:

PART 50—PROTECTION OF HUMAN SUBJECTS

§ 50.20 General requirements for informed consent.

Except as provided in §§50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. * * *

§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all of the elements of informed consent set forth in §50.25(a) and (b), or that waives the requirement to obtain informed consent, provided the IRB finds and documents the following:

(a) The clinical investigation involves no more than minimal risk to the subjects;

(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(c) The clinical investigation could not practically be carried out without the waiver or alteration; and

(d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

§ 312.60 General responsibilities of investigators.

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator’s care; and for the control of drugs under investigation. An investigator shall obtain the informed consent of each human subject to whom the drug is administered, in accordance with part 50 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

§ 812.2 Applicability.

(iii) Ensures that each investigator participating in an investigation of the
device obtains from each subject under the investigator’s care, informed consent in accordance with part 50 of this chapter.

* * * * *

Dated: November 7, 2018.

Scott Gottlieb,
Commissioner of Food and Drugs.

[FR Doc. 2018–24822 Filed 11–13–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 570

RIN 1235–AA22

Expanding Employment, Training, and Apprenticeship Opportunities for 16- and 17-Year-Olds in Health Care Occupations Under the Fair Labor Standards Act, Comment Extension Period

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends the period for submitting written comments on the Notice of Proposed Rulemaking (NPRM) entitled “Expanding Employment, Training, and Apprenticeship Opportunities for 16- and 17-Year-Olds in Health Care Occupations Under the Fair Labor Standards Act.” The comment period now ends on December 11, 2018. The Department of Labor (Department) is taking this action to provide interested parties additional time to submit comments in response to a request for extension, as some supporting documents for the proposal may not have been originally fully visible in the docket.

DATES: The comment period for the proposed rule published September 27, 2018, at 83 FR 48737, is extended. Comments should be received on or before December 11, 2018.

ADDRESSES: To facilitate the receipt and processing of written comments on this NPRM, the Department encourages interested persons to submit their comments electronically. You may submit comments, identified by Regulatory Information Number (RIN) 1235–AA22, by either of the following methods:


Mail: Address written submissions to Melissa Smith, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210.

Instructions: This NPRM is available through the Federal Register and the http://www.regulations.gov website. You may also access this document via the Wage and Hour Division’s (WHD) website at http://www.dol.gov/whd/. All comment submissions must include the agency name and Regulatory Information Number (RIN 1235–AA22) for this NPRM. Response to this NPRM is voluntary. The Department requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this NPRM. Submit only one copy of your comment by only one method (e.g., persons submitting comments electronically are encouraged not to submit paper copies). Please be advised that comments received will become a matter of public record and will be posted without change to http://www.regulations.gov, including any personal information provided. All comments must be received by 11:59 p.m. on the date indicated for consideration in this NPRM; comments received after the comment period closes will not be considered. Commenters should transmit comments early to ensure timely receipt prior to the close of the comment period. Electronic submission via http://www.regulations.gov enables prompt receipt of comments submitted as DOL continues to experience delays in the receipt of mail in our area. For access to the docket to read background documents or comments, go to the Federal eRulemaking Portal at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Melissa Smith, Director of the Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210, telephone: (202) 693–0406 (this is not a toll-free number). Copies of this NPRM may be obtained in alternative formats (Large Print, Braille, Audio Tape or Disc), upon request, by calling (202) 693–0675 (this is not a toll-free number). TTY/TDD callers may dial toll-free 1 (877) 889–5627 to obtain information or request materials in alternative formats.

Questions of interpretation and/or enforcement of the agency’s regulations may be directed to the nearest WHD district office. Locate the nearest office by calling the WHD’s toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD’s website at http://www.dol.gov/whd/americas.htm for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

On September 27, 2018, the Department published an NPRM and request for comments in the Federal Register (83 FR 48737), proposing to revise Hazardous Order Number 7 under the FLSA to allow for 16- or 17-year-olds to operate power-driven patient lifts. The NPRM also requested public comments on the NPRM on or before November 26, 2018. Not all supporting documents in the public docket may have been originally fully visible. That issue has now been addressed, however, and the documents are fully publicly viewable. In light of the above, and out of an abundance of caution, the Department has extended the period for submitting public comment to December 11, 2018.

Bryan L. Jarrett,
Acting Administrator, Wage and Hour Division.

[FR Doc. 2018–24945 Filed 11–14–18; 8:45 am]
BILLING CODE 4510–27–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2018–8]

Noncommercial Use of Pre-1972 Sound Recordings That Are Not Being Commercially Exploited: Extension of Comment Period

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of inquiry; extension of comment period.

SUMMARY: The Copyright Office is extending the deadline for the submission of written comments in response to its October 16, 2018 notice of inquiry regarding the Classics Protection and Access Act, title II of the recently enacted Orrin G. Hatch–Bob Goodlatte Music Modernization Act.

DATES: The initial comment period for the notice of inquiry, published on October 16, 2018, is extended by an additional ten days. Initial comments must be made in writing and must be received in the U.S. Copyright Office no later than 11:59 p.m. Eastern Time on November 26, 2018. Written reply comments must be received no later