



4164-01-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; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the proposed rule that appeared in the *Federal Register* of November 15, 2018. In the *Federal Register* of December 20, 2018, the Agency extended the comment period until February 13, 2019. The Agency is taking this action to reopen the comment period to allow interested persons additional time to submit comments due to technical issues with the Federal eRulemaking Portal (<https://www.regulations.gov>) on February 13, 2019.

DATES: FDA is reopening the comment period on the proposed rule published November 15, 2018 (83 FR 57378). Submit either electronic or written comments by March 7, 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 March 7, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 7, 2019. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 as follows:

- 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/2015-23389.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: Janet Norden, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1127.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 15, 2018 (83 FR 57378), FDA published a proposed rule with a 60-day comment period to implement the statutory changes made to the Federal Food, Drug, and Cosmetic Act by section 3024 of the 21st Century 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 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 minimal risk clinical investigations. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for IRB waiver or alteration of informed consent for certain minimal risk clinical investigations.

The Agency received a request for a 60-day extension of the comment period for the proposed rule. This request conveyed concern that the 60-day comment period did not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA considered the request and in the *Federal Register* of December 20, 2018 (83 FR 65322), the Agency extended the comment period for the proposed rule for 30 days, until February 13, 2019. The Agency believed that a 30-day extension allowed adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

On February 13, 2019, the date that the comment period closed for the proposed rule, the Federal eRulemaking Portal (<https://www.regulations.gov>) was unavailable to receive public comments from 5:35 pm until 7:40 am on February 14, 2019. The Agency is aware that interested persons attempted to submit comments during the period of time that <https://www.regulations.gov> was unavailable. Therefore, FDA is reopening the comment period for the proposed rule for 10 days, until March 7, 2019 to allow additional time for interested persons to submit comments.

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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