270-F1]

SCIENCE AND TECHNOLOGY POLICY OFFICE

Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials

AGENCY: White House Office of Science and Technology Policy.

ACTION: Request for information (RFI) on clinical research infrastructure and emergency clinical trials; extension of comment period.

SUMMARY: On October 26, 2022, the Office of Science and Technology Policy (OSTP) published in the ***Federal Register*** a document entitled "Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials." This RFI invited comments on improving the U.S. clinical trials infrastructure and in particular, our ability to carry out emergency clinical trials. In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. In response to requests by prospective commenters that they would benefit from additional time to adequately consider and respond to the RFI, OSTP has determined that an extension of the comment period until January 27, 2023 is appropriate.

DATES: The end of the comment period for the document entitled "Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials," published on October 26, 2022 (87 FR 64821), is extended from December 27, 2022 to January 27, 2023.

ADDRESSES: Comments submitted in response to 87 FR 64821 should be submitted electronically to *emergencyclinicaltrials@ostp.eop.gov* and should include ''Emergency Clinical Trials RFI'' in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions: Response to this RFI (87 FR 64821) is voluntary. Each responding entity (individual or organization) is requested to submit only one response. Please feel free to respond to one or as many prompts as you choose. Please be concise with your submissions, which must not exceed 8 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders, including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from research institutions, clinical trialists, health care providers interested in clinical research, contract research organizations (CROs) and other clinical trial service providers, pharmaceutical and biotechnology companies, and community health care organizations. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI (87 FR 64821). Please be aware that comments submitted in response to this RFI (87 FR 64821) may be posted on OSTP's website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Grail Sipes at 202–456–4444 or *emergencyclinicaltrials@ ostp.eop.gov.*

SUPPLEMENTARY INFORMATION:

In accordance with the 2022 National Biodefense Strategy and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with NSC, is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. On October 26, 2022, OSTP published in the ***Federal Register*** a document inviting comments on improving the U.S. clinical trials infrastructure and in particular, our ability to carry out emergency clinical trials (87 FR 64821). The RFI was issued to seek input from a broad array of stakeholders on topics including the potential establishment of a U.S.-level governance structure; outreach to a wide range of institutions, clinical trial networks, and other potential trial sites that can participate in emergency research, both domestically and internationally; and ways to expand clinical research into underserved communities, as well as increase diversity among both trial participants and clinical trial investigators. The document stated that the comment period would close on December 27, 2022. OSTP has received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the RFI and prepare comments to address the topics listed therein. Therefore, OSTP is extending the end of the comment period for the RFI from December 27, 2022 to January 27, 2023.

Submitted by the White House Office of Science and Technology Policy on November 15, 2022.

Stacy Murphy,

Operations Manager.

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