FDA U.S. FOOD & DRUG ADMINISTRATION

October 3, 2022

Dear Tribal Leader:

The U.S. Food and Drug Administration (FDA) is initiating consultation with federally recognized American Indian and Alaska Native tribes on two proposed rules: *Institutional Review Boards; Cooperative Research*[1] and *Protection of Human Subjects and Institutional Review Boards*[2]. These proposed rules published in the Federal Register on September 28, 2022 and are intended to further our harmonization with the Federal Policy for the Protection of Human Subjects (the "Common Rule").

The first proposed rule, *Institutional Review Boards; Cooperative Research*, would replace current FDA requirements for cooperative research and require any institution located in the United States participating in FDA-regulated clinical trials involving multiple institutions to rely on approval by a single Institutional Review Board (IRB) for that portion of the research that is conducted in the United States, with some exceptions. For example, we propose to include an exception mirroring the Common Rule's exception for cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). FDA is proposing these revisions to streamline the IRB review process and decrease administrative burdens and inefficiencies for investigators and IRBs without compromising human subject protections.

The *Protection of Human Subjects and Institutional Review Boards* proposed rule would amend certain sections of FDA's regulations for the Protection of Human Subjects (21 CFR Part 50) and Institutional Review Boards (21 CFR Part 56) to harmonize with the revised Common Rule. For example, we are proposing to revise the content, organization, and presentation of information included in the informed consent form and process to facilitate a prospective participant's decision about whether to participate in the research. This includes a new, basic element of informed consent that would, if finalized as proposed, require a description of how information or biospecimens may be used for future research or distributed to another investigator for future research.

FDA invites you and/or your designated consultation representative(s) to participate in this consultation through an all tribes' call on **Monday, November 7, 2022** from **1:00 pm – 2:30 pm, ET**. We will be hosting the 90 minute call to provide an overview of the proposed rules, answer questions, and receive tribal feedback. A transcript of the consultation will be added to the dockets for both rules and a recording of the consultation discussion will be available after the call.

[1] https://www.federalregister.gov/documents/2022/09/28/2022-21089/institutional-review-boards-cooperative-research

[2] https://www.federalregister.gov/documents/2022/09/28/2022-21088/protection-of-human-subjects-and-institutional-review-boards

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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Tribal Consultation Call Information:
Monday, November 7 2022, 1:00 pm – 2:30pm, ET
To participate in the call, you must register via the link here.[3]

In addition to the consultation call, the Secretary's Advisory Committee for Human Research Protections (SACHRP) will be discussing these proposed rules at an upcoming public meeting on October 19th and 20th, 2022. FDA encourages tribal participation in this virtual advisory committee meeting. Time is allotted at every meeting for public comment. Additional details for the SACHRP meeting will be posted soon at https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.

Also, FDA welcomes your written comments on the proposed rules. Comments on the Institutional Review Boards: Cooperative Research proposed rule should be submitted to *Docket No. FDA-2019-N-2175*[4], and comments on the Protection of Human Subjects and Institutional Review Boards proposed rule should be submitted *to Docket No. FDA-2021-N-0286*[5]. All comments submitted by November 28, 2022 will be considered before any final rules on these proposals are published. **Comments must be submitted to FDA using any of the following methods**:

- **Electronic submissions**: Follow the instructions for submitting comments on the Federal eRulemaking Portal at http://www.regulations.gov.
- **Written submissions** via Mail/Hand delivery/Courier: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Received comments will be placed in the docket and publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions regarding the proposed rules, please contact FDA's Office of Clinical Policy (OCLiP) via email at gcpquestions@fda.hhs.gov. FDA's Intergovernmental Affairs (IGA) team is available to assist tribal officials for all FDA inquiries and can be reached via email at IGA@fda.hhs.gov. For more information regarding FDA's activities with federally recognized tribal governments, including FDA's Dear Tribal Leader Letters, please visit www.fda.gov/tribal or contact the IGA staff.

FDA encourages you to stay informed about further developments related to human subjects protections and Good Clinical Practice in clinical trials through the Office of Clinical Policy (OCLIP) website located at https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-clinical-policy, or by signing up for related announcements at https://public.govdelivery.com/accounts/USFDA/subscriber/new. You may also contact the Office telephone at 301-796-8340, via email at gcpquestions@fda.hhs.gov or via mail at 10903 New Hampshire Ave., Silver Spring, MD 20993.

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[3] https://fda.zoomgov.com/webinar/register/WN_FGzSq6x3Q82QRNZ5lpCVPg
[4] *https://www.regulations.gov/docket/FDA-2019-N-2175*
[5] https://www.regulations.gov/docket/FDA-2021-N-0286

I hope you can join us for the tribal consultation call on Monday, November 7, 2022. We look forward to continuing to strengthen the relationship between FDA and tribal governments as the Agency fulfills its mission to protect and promote public health.

Sincerely,

Hilary Marston, MD, MPH
Chief Medical Officer, FDA