# April 7, 2020 - Letter to the HHS Secretary

April 7, 2020

The Honorable Alex M. Azar II
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

**RE: Providing New Information to Previously Enrolled Research Subjects and Clarifying Requirements in Digital Health Technologies Research: End-User License Agreements (EULAs) and Terms of Service (ToS) and Their Relation to Study Consent and to IRB and Investigator Roles**

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Dear Mr. Azar:

On behalf of the Secretary's Advisory Committee on Human Research Protections (SACHRP), I respectfully submit for your consideration recommendations relevant to the Department of Health and

Human Services (HHS) human subjects protection regulations at 45 CFR part 46. These recommendations were presented to SACHRP by SACHRP's Subcommittee on Harmonization and Subpart A Subcommittee, and were approved at the meeting held March 11-12, 2020.

1. Providing New Information to Previously Enrolled Research Subjects (Attachment A)

2. Clarifying Requirements in Digital Health Technologies Research: End-User License Agreements (EULAs) and Terms of Service (ToS) and Their Relation to Study Consent and to IRB and Investigator Roles (Attachment B)

On behalf of SACHRP, I would like to thank you for your consideration of theses recommendations. The committee, the Subpart A. Subcommittee and the Subcommittee on Harmonization have been actively working in pursuit of their charges, and remain dedicated to continuing this work to enhance human subjects protections for the benefit of all Americans.

Sincerely,

/s/

Stephen Rosenfeld, M.D.
Chair, Secretary's Advisory Committee
on Human Research Protections
(SACHRP)

cc: Jerry Menikoff, Executive Secretary, SACHRP
Julia Gorey, Executive Director, SACHRP

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