From: OC GCP Questions
To: [redacted]
Cc:
Subject: Question about exculpatory language
Date: Thursday, October 8, 2020 10:10:20 AM
Attachments: [redacted]

Good morning –
Thank you for your question. The issue of End User License Agreements (EULAs) and IRB review is a new evolving concern for which FDA currently has no guidance on. However, the Secretary's Advisory Committee for Human Research Protections (SACHRP) recently considered this issue and developed a series of recommendations which you might find useful. Their recommendations can be found at **https://www.hhs.gov/ohrp/sachrp-committee/recommendations/april-7-2020-attachment-b/index.html**. SACHRP recommendations are not considered to be federal agency guidance, but in areas where there may be limited or no guidance on a particular topic, our human subject protections stakeholders usually find SACHRP information to be helpful.
Although EULAs are not part of the informed consent document that IRB are required to review, as stated by SACHRP, *if consent to a EULA is required for a study, subjects should be informed of this in the consent process and any significant risks presented by use of the app (and by consent to its EULA) in the research must be identified to subjects*. As described by the SACHRP recommendations, how an IRB approaches the issue of EULAs may be based on whether the relevant device/app was acquired by the prospective subject prior to entering the research (e.g., a Fitbit purchased for personal use) or was provided to the subject as part of the research. Likewise, it might be relevant to consider whether the app manufacturer is involved with the design, funding and/or conduct of the study. However, in all the scenarios described in the SACHRP recommendation, the overall theme is that subjects should be informed of the risk associated with the use of the app (and its associated EULA).
I agree the language you underscored in your question appears to be exculpatory, however, since the EULA is not technically part of the consent document, it is not be subject to 21 CFR 50.20. However, the risks inherent with the use of the app and the terms of the EULA would be, in many situations, considered research risks and should be included in the consent discussion with prospective subjects.
I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov
Kevin A. Prohaska, D.O., M.P.H., Captain (USPHS)
Medical Policy Advisor/Senior Bioethics Consultant
Office of Good Clinical Practice
Food and Drug Administration

From: [redacted]
Sent: Tuesday, October 06, 2020 2:31 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: FW: Question about exculpatory language
Dear FDA:
Please see the below query regarding whether certain language runs afoul of the FDA's prohibition on exculpatory language in consent processes.

Thank you,

[redacted]

From: [redacted]
Sent: Tuesday, October 06, 2020 1:28 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Question about exculpatory language

Hello [redacted],

Thank you for contacting OHRP. Since the study you are asking about is an industry-sponsored trial, it likely does not fall under OHRP's regulatory authority (which covers non-exempt human subject research conducted or supported by HHS). Rather, it likely is subject to FDA's regulations, which you reference in your email.

For that reason, I suggest you contact FDA's Office of Good Clinical Practice, which oversees their human subjects protections regulations and policies. You can find information on how to contact them on their website, here: https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/good-clinical-practice-contacts.

Best regards,

[redacted]

* * * *

[redacted]

From: [redacted]
Sent: Monday, October 5, 2020 3:52 PM
To: [redacted]
Cc: [redacted]
Subject: Question about exculpatory language

Dear [redacted]:

We seek ORHP guidance regarding whether certain language in a subject-facing document runs afoul of the prohibition at 45 CFR 46.119(a)(6) against exculpatory language in the consent process. Similar language appears at 21 CFR 50.20

Specifically, an industry-sponsored trial is using a contract research organization (CRO) to manage the study data platform for the project. The data includes protected health information subject to HIPAA. As part of the consent process, subjects are told they will be presented with an End-User License Agreement (EULA) for the data platform. That is, the EULA is incorporated by reference into the consent, and subjects are required to sign the EULA as a condition of participation in the trial. The relevant portion of the EULA states (emphasis added):

> Limitation of Liability. EXCEPT FOR A BREACH OF THE WARRANTY ABOVE [for non-infringement of third-party intellectual property rights], IN NO EVENT WILL COMPANY [IQVIA] OR ITS AFFILIATES, OR

> ANY OF ITS OR THEIR RESPECTIVE LICENSORS OR SERVICE PROVIDERS, HAVE ANY LIABILITY ARISING FROM OR RELATED TO YOUR USE OF OR INABILITY TO USE THE PLATFORM. Notwithstanding anything to the contrary contained herein, nothing in this Agreement shall limit any rights End User may have in law or equity, including but not limited to any claims that cannot be waived by law.

UAMS views this language as a broad waiver of liability that can only be read as exculpatory. The sponsor disagrees, saying the EULA is not a study-specific document and does not require IRB review under any regulatory authority.

Please advise whether the highlighted language, in the context described above, would be considered exculpatory as prohibited by the regulation. A more detailed description and analysis, prepared by Associate General Counsel Nathan Chaney, cc'ed here, is attached.

Thank you,

[redacted]

[redacted]