December 12, 2023

In this letter, the American College of Emergency Physicians (ACEP) and the Society for Academic Emergency Medicine (SAEM) are responding to the Request for Information: Developing Consent Language for Research Using Digital Health Technologies (NOT-OD-24-002). ACEP and SAEM recognize there is the tremendous potential for advancing science and the promotion of health by harnessing the expanding use of digital health technology, including wearable devices. However, both organizations believe that such potential must be critically balanced with promotion of ethical research principles to maintain the welfare of affected participants. The National Institutes of Health (NIH) proposal to develop a structured model for informed consent language to be used in research studies involving digital health technologies is useful to promote subject safety and privacy. As proposed, the model for informed consent language adheres to the basic elements of informed consent including explanations of research purpose, procedures, subject risks, and potential benefits of research participation. Additional considerations for strengthening the model from our organizations are described within this response.

While disclosure regarding the current state of United States Food and Drug Administration (FDA) approval of devices for the purposes being studied is required, the current proposal does not differentiate safety protections between experimental devices compared to finalized commercial products. Research subjects may experience different levels of risk between these two device types, since commercial products benefit from wider user bases which can detect safety risks that might be unrecognized for devices still in the experimental phase. As the model applies to both research-grade and commercial products, this distinction should be specified clearly.

A section regarding costs appropriately addresses the potential financial risk to subjects as their electronic data submission in the study may be deducted from their own bandwidth allowance from their internet plans. However, the proposed language fails to address any compensation, financially or otherwise, that could be provided to subjects either for their participation or to offset any direct costs. The treatment protocols including financial responsibility for any injuries directly related to the study procedures are similarly not currently included within the consent language.

We agree that data privacy concerns are paramount when studies involve digital technologies, particularly at the scale which may be present in studies utilizing these products. The model as written includes language regarding data use and storage during the study, how the information could be used afterwards, and the procedures and duration of storage. We applaud this inclusion and encourage investigators to provide as many details regarding these processes as possible. The procedural considerations
include prompts to explain security protections provided by researchers while noting that device companies may not protect data in the same way. Where the study is performed using data obtained through a commercial entity, these procedures should be described in more detail to study participants as risks may be greater than the standard which commercial end-user agreements assume.

Data sharing and ownership considerations described by this document include the use of subject data within the context of larger repositories. Given that health data ownership and sharing can have significant implications for subject privacy concerns, we believe this area of disclosure should be expanded and strengthened with a focus on limiting the use of patient data by groups not explicitly allowed by consenting subjects. We are pleased to see the concerns highlighted by the NIH in the withdrawal section of this proposed consent language, but we suggest addressing specifically whether deleting the study application or otherwise misusing or failing to use the technology may automatically lead to withdrawal, and whether subjects should expect any feedback or data to be provided following either the completion or withdrawal from the study involving their data.

The NIH proposal states that the respective Institutional Review Board (IRB) should consider whether it is important to disclose any relationship between study investigators and companies which produce the digital health technology used in the study, but we recommend that this be a required disclosure in the model consent language. Any possible commercial relationship which affects research interpretation must be transparent to all participants and regulators in research process.

Following the approval of these model guidelines, we encourage the NIH to distribute them to partners both in academia and industry for widespread use.