FDA COVID MyStudies App Enables Investigators to Obtain Electronic Informed Consent

06-22-20 • alert • katherine leibowitz

Recognizing the pandemic-driven challenges faced by investigators when trying to obtain informed consent, FDA recently announced that it is making available its previously developed FDA MyStudies app to investigators as a free platform for obtaining electronic informed consent from subjects for "eligible clinical trials" if in-person consent is not possible or practical because of COVID-19. As we previously reported, FDA prefers electronic informed consent (eIC) to the remote consent methods discussed in the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic. The app is referred to as "COVID MyStudies" in the Apple App and Google Play stores. You can access FDA's announcement here.

The COVID MyStudies app enables the investigator to send the electronic informed consent document directly to the subject or authorized representative. The subject receives an electronic copy after signing the document. (FDA regulations require the subject to be provided with a copy of the informed consent, and FDA prefers that it be the signed copy.) The investigator can also access the signed consent document electronically and can print or transfer it electronically.

While FDA has not made clear what trial types are eligible for use with the app, the app appears to be aimed at IND studies. FDA directs interested investigators to email CDER at CDERMedicalPolicy-RealWorldEvidence@fda.hhs.gov and to include their pre-IND or IND number if applicable. The Harvard Pilgrim Health Care Institute will provide technical assistance for the app. FDA will fund this assistance "as resources permit." We have heard that FDA has been inundated with requests and is prioritizing as quickly as possible.

FDA reminds users that the IRB must approve the informed consent process and documents. While presumably a combined informed consent form/HIPAA authorization can be submitted to the app, it is not clear whether a standalone HIPAA authorization can be executed via the app. The Mobile App Quick Overview for Research indicates that current capabilities include HIPAA-compliant data storage although users should consider whether other HIPAA obligations apply.

If you have any questions or would like more information about these developing issues, please contact the following:

KATHERINE LEIBOWITZ
1-610-896-5788
Katherine.Leibowitz@LeibowitzLawTeam.com