From: OC GCP Questions
To: [redacted]
Subject: Telemedicine in Research
Date: Tuesday, September 04, 2018 10:42:00 AM

Good morning --

Please see a few FDA webpage links below.

Digital Health

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf

You can also perform a web search "FDA and telemedicine" and you will find other resources.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [redacted]
Sent: Thursday, August 30, 2018 11:39 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Telemedicine in Research

Dear GCP Questions,

Are there any FDA recommended resources on incorporating telemedicine with clinical research?

[redacted]