From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Question on Human Subject Research
Date: Monday, August 20, 2018 8:34:00 AM
Attachments: [redacted]

Good morning –

The situation that you describe might need an IND (Investigational New Drug) application. You will need to contact the Center for Drugs (CDER) as they determine if an IND is needed. Please see their contact information below.

Phone: 855-543-3784
Phone: 301-796-3400

E-mail: druginfo@fda.hhs.gov

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

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.

From: [redacted]
Sent: Friday, August 17, 2018 2:34 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question on Human Subject Research

Hello, there.

We are a start-up company that will soon be offering personalized patient therapy to help a cancer patient's oncologist make more informed decisions on their best course of cancer treatment. To do this, [redacted] We report data back to the oncologist so he/she can discuss results with the patient and determine the best option for the patient moving forward. This falls under CLIA oversight.

[redacted]

Would this type of research be considered "human subject" research, and if so, would it require we have IRB approval of consent and/or protocol before sourcing out contract research opportunities with pharmaceutical companies?

Thank you in advance!

Warm regards,
[redacted]