From: OC GCP Questions
To: [redacted]
Subject: Question
Date: Thursday, November 08, 2018 8:07:00 AM
Attachments: [redacted]

Good morning –

One of FDA's mission is to protect the rights, safety and welfare of research subjects. Please see FDA's guidance on this topic. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf. While I cannot specifically state what the CI (PI) is doing would be wrong or illegal, it might compromise the safety of the screened research subject. However, it might also fall into the category of the "practice of medicine", which FDA does not regulate. If the change in treatment would worsen the subjects condition in order to gain entrance into the study, that would be concerning and not in compliance with good clinical practice.

Your IRB should be provided with the screening process for their review. The FDA Information Sheet "Screening Tests Prior to Study Enrollment" (available at www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm116332.htm) states, "Clinical screening procedures for research eligibility are considered part of the subject selection and recruitment process and, therefore, require IRB oversight."

In general, the information maintained on individuals screened for a study should be sufficient to demonstrate that the study screening was appropriately conducted per the investigational plan. Of course, for individuals who pass screening, records demonstrating that the screening criteria are met would be part of the case histories required to be maintained for the study. Please refer to 21 CFR 312.62 for drug and biologic studies and 21 CFR 812.140(a) for device studies for the regulatory requirements.

The screening records should demonstrate the failed screening for this subject in addition to what was done to have the subject pass screening to be eligible for the study. These are vital study records to support your position.

Additionally, FDA's regulations related to IRBs require that, "An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations." (See 21 CFR 56.109(a))

FDA considers the screening process part of the study, and therefore would expect information regarding the screening process and screening failures to be maintained as part of the study information, it might be less cumbersome and not so confusing to clearly separate the screening process from the actual conduct of the study.

Please consult your IRB to determine what should be done, if anything, with the situation that you describe in your email.

You may also report your situation to FDA's Center for Drugs (CDER) Office of Scientific Investigations (OSI). Please see the information below. You can remain anonymous.

FDA regulated drug studies:
Call 301-796-3150
Fax 301-847-8748
Email: CDER-OSI-GCPReferrals@fda.hhs.gov
(Office of Scientific Investigations, Office of Compliance, CDER)

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: Wednesday, November 07, 2018 9:07 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question

I want to know if this is considered wrong/illegal. If a patient screen fails for a study because they aren't having enough symptoms. Is the doctor/PI allowed to lower there meds and take them off one to make them sick enough to have symptoms to be in the trial?

For instance, If you have a patient/subject that screen fails because they aren't having enough loose stools or abdominal pain. The doctor/PI takes the patient/subject off [redacted] and puts them [redacted] and remove [redacted]. This is done hoping it will make the patient/subject have either abdominal pain or more loose stools so they can then rescreen for the clinical trial. The patient/subject was told that after a week if they didn't notice more loose stools or abdominal pain, they were to call and they would reduce the [redacted] Is this allowed? I have some great concerns that the doctor/PI is more worried about getting the patient/subject into a clinical trial then they are about there health. The patient/subject hasn't tried [redacted] but if they do and fail this drug they would have to wash out for 12 weeks before they could then try to get into the clinical trial. Please advise if this is something I should report as wrong doing and if so who do I report it to?

Thank you,
[redacted]