

EXHIBIT C



This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.

-----Original Message-----

From: Brook Jackson <brookjackson04@gmail.com>
Sent: Friday, September 25, 2020 10:33 AM
To: CBER OCOD Consumer Account <cberocod@fda.hhs.gov>
Subject: ATTN: Laura Re: Pfizer C4591001 Patient Safety Report

Hello Laura,

Thank you for your time this morning. It is without hesitation that I am reporting my immediate concern for subject safety in the above-mentioned trial. In total, the 3 sites have enrolled over 1,000 subjects. I am the Regional Director for 2 of those 3 sites and have been in my current position for almost 2 weeks.

I have been witness to subjects that were discharged prior to the protocol required 30 minute post dose assessment.

Subjects are dosed without PI oversight or a MD, NP or RN available in the event of a reaction.

Subjects are placed in a hallway after their injection of IP and are not being monitored by clinical staff. This is done because the practice is scheduling more subject visits than the clinic can accommodate and exam rooms are needed.

Safety assessments via e-diaries are not being completed.

SAE follow-up is not being performed in a timely manner.

Temperature excursions have not been reported, IP not quarantined and the Sponsor has not been made aware.

Protocol deviations are not being captured or reported to the Sponsor.

Laboratory specimens are mislabeled.

Site SOPs are not being followed.

Other company policies and procedure are not being followed.

HIPAA information is not being protected.

Clinical site staff are targeted for pointing out these findings.

The site is in full "clean-up" mode and bringing staff from other locations for immediate QC.

I would like to request to speak with your department regarding my concerns.

Thank you for your immediate attention.

Brook Jackson
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