From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Clinical Trial Medication Outside Our Facility
Date: Monday, December 04, 2017 11:51:00 AM
Attachments: [redacted]

Good morning –

Addressing the issue in general, FDA's regulations do not speak to institutions. Our regulations speak to sponsors (and parties they contract with), clinical investigators, and institutional review boards (IRBs). FDA regulations do not specifically address the situation you describe. Although the scenario you describe does occur often. Hospitals/Institutions would need to follow their own internal or written procedures for dispensing investigational product.

You may wish to review the guidance document below.

Search for FDA Guidance Documents > Use of Investigational Products When Subjects Enter a Second Institution - Information Sheet

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

From: [redacted]
Sent: Friday, December 01, 2017 10:42 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question Regarding Clinical Trial Medication Outside Our Facility

Good Morning

We are hoping you can assist us with this issue.

[redacted] is a 271 bed hospital located in [redacted] We have a local IRB concerned with small projects and "home-grown" studies done by nurses, physicians and physical therapists. Our larger, corporately-sponsored projects are outsourced to Western IRB.

Our question concerns patients from our community who are on a clinical trial elsewhere (not sponsored by our facility). Usually the patients are admitted to our community hospital, where they reside, for any variety of issues, either related or not to the study. We have a policy for patients who

come in on investigational drugs from studies done outside our institution, which is difficult to implement at times.

Often, patients arrive with study medication which is labeled with a number. There is no dispensing, administering, or information about adverse reactions, or even the purpose of the medicine.

In a nutshell, we require information about the drug and the study, and at minimum, a copy of the patient's informed consent. The medication, if the patient has a supply, must be submitted to our Pharmacy for verification and labelling.

If we have no information, we cannot, according to our policy, simply allow the patient to take the medication.

While the obvious answer is to contact the study sponsor/physician, this is often a very long process, particularly if the patient is admitted during non-business hours, weekends and holidays. Understandably, patients and families become irate when they are not permitted to continue study medication, which many times, in their mind, is helping them.

Please advise what is best practice from the standpoint of the FDA for hospitals in our situation.

Many thanks.