From: OC GCP Questions
To: [redacted]
Subject: Ref- Registered Nurse
Date: Monday, May 14, 2018 8:12:00 AM
Attachments: [redacted]

Good morning –

FDA's "Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf), includes the following information –

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Licensing requirements may vary by jurisdiction (e.g., states, countries). Investigators should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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: Saturday, May 12, 2018 1:26 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Ref- Registered Nurse

Hello Sir,

I have a aquestion.

In [redacted] registered Nurse is required to administer IV antibiotics to the patients.

My question is, is it the same thing applicable to research study patients for a inpatient clincial trials which require antibiotics to be administered intravenously.

This is very important question, as I saw some of the places, non RN personnel such as forign MD's are pefroming this functions on regular basis.

Thanks
[redacted]