From: OC GCP Questions
To: [redacted]
Date: Friday, July 06, 2018 9:05:00 AM
Attachments: [redacted]

Good morning –

As you refer ICH E-6(R-2) which states -- 2.7 - The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.

Your question about whether you an unlicensed foreign physician may perform physical exams under the supervision of the clinical investigator is not an easy yes or no answer.

FDA has addressed your question in the guidance, "Supervisory Responsibilities of Investigators" (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf.) I have pasted the pertinent excerpt below:

Investigators who conduct clinical investigations of drugs, including biological products, under 21 CFR Part 312 commit to personally conduct or supervise the investigation. Investigators who conduct clinical investigations of medical devices, under 21 CFR Part 812 commit to supervise all testing of the device involving human subjects. It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by the investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated and the investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.

In assessing the adequacy of supervision by an investigator, FDA focuses on four major issues: (1) whether delegated individuals were qualified to perform such tasks, (2) whether study staff received adequate training on how to conduct the delegated tasks and were provided with an adequate understanding of the study, (3) whether there was adequate supervision and involvement in the ongoing conduct of the study, and (4) whether there was adequate supervision or oversight of any third parties involved in the conduct of a study to the extent such supervision or oversight was reasonably possible.

I. What is Appropriate Delegation of Study-related Tasks?

The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience to perform the delegated task. Appropriate delegation is primarily an issue for tasks that would be 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 part of the medical care provided to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Such licensing requirements will vary from state to state and local laws. Clinical investigators should take such qualifications/licensing requirements into account when considering to whom it would be appropriate to delegate specific tasks. During inspections, FDA has identified instances in which study tasks have been delegated to individuals lacking appropriate qualifications. Examples of inappropriate delegation include:

Screening evaluations, including obtaining medical histories and assessment of inclusion/exclusion criteria, conducted by individuals with inadequate medical training (e.g., a medical assistant)

Physical examinations performed by unqualified personnel

Evaluation of adverse events by individuals lacking appropriate medical training, knowledge of the clinical protocol, and knowledge of the investigational product

Assessments of primary study endpoints (e.g., tumor response, global assessment scales) by individuals lacking appropriate medical training and knowledge of the protocol

Informed consent obtained by individuals who lack the medical training, knowledge of the clinical protocol, or

familiarity of the investigational product needed to be able to discuss the risks and benefits of a clinical trial with prospective subjects.

The investigator is responsible for conducting studies in accordance with the protocol (see 21 CFR 312.60, Form FDA-1572, 21 CFR 812.43 and 812.100). Some protocols specify the qualifications of the individuals who are to perform certain protocol-required tasks, and these protocols must be followed even if state law permits differently qualified people to perform the task. For example, even if the state in which the study site is located permits nurse practitioners to perform physical examinations under the supervision of a physician, if the protocol specifies that physical examinations must be done by a physician, a physician must perform such exams.

The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks, and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

In addition, at times the sponsor may need to be consulted for appropriate delegation of tasks.

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: Tuesday, July 03, 2018 3:29 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject:

Requesting clarification regarding Clinical Research:
GCP R2 / THE PRINCIPLES OF ICH GCP # 2.7 page number 9

Does the FDA find it expectable for a foreign trained physician who is not licensed in the US, to perform physical exams, under the direction of the Principal Investigator who is a U.S. licensed MD?
I chose not to pursue my license in the U.S. due to the long process involved and the fact that I am a mother of [redacted] I have 9 years experience as a practicing physician in [redacted].

Please reply at your convenience
[redacted]

Sent from my iPhone