From: [redacted]
To: [redacted]
Subject: RE: Query about Medical Expert
Date: Friday, February 09, 2018 12:42:41 PM
Attachments: [redacted]

Hello,

As far as I am aware, FDA's regulations do not specifically define the role of a "Medical Expert" in a clinical investigation. The sponsor is responsible for selecting an investigator who is qualified by training and experience (see 21 CFR 312.53 and 812.43). FDA considers this to include the investigator meeting any licensing requirements of the jurisdiction where the trial takes place. The regulations further require investigators to supervise the testing (for investigations of drugs, including biological products, under 21 CFR Part 312, investigators commit themselves to personally conduct or supervise the investigation; for investigations of medical devices, under 21 CFR Part 812, investigators commit themselves to supervise all testing of the device involving human subjects).

The investigator, in turn, may delegate certain study-related tasks of a clinical investigation to an individual who is appropriately qualified to perform the delegated task. Please see the guidance on "Investigator Responsibilities" (https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) for additional information.
The guidance is intended to clarify for investigators and sponsors FDA's expectations concerning the investigator's responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety, and welfare of study subjects.

The following section refers to medical care and may be relevant to your question:

Reasonable Medical Care Necessitated by Participation in a Clinical Trial
During a subject's participation in a trial, the investigator (or designated subinvestigator) should ensure that reasonable medical care is provided to a subject for any adverse events, including clinically significant laboratory values, related to the trial participation. If the investigator does not possess the expertise necessary to provide the type of medical care needed by a subject, the investigator should make sure that the subject is able to obtain the necessary care from a qualified practitioner. For example, if the study involves placement of a carotid stent by an interventional neuroradiologist and the subject suffers a cerebral stroke, the neuroradiologist should assess the clinical status of the subject and arrange for further care of the subject by a neurologist. Subjects should receive appropriate medical evaluation and treatment until resolution of any emergent condition related to the study intervention that develops during or after the course of their participation in a study, even if the follow-up period extends beyond the end of the study at the investigative site.

It is important to note that any individual who is directly involved in the treatment or evaluation of research subjects would be subject to the financial disclosure reporting requirements under 21 CFR Part 54. Additional guidance on Clinical Investigator Financial Disclosure is available here: https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf. The reviewing IRB should also be consulted to ensure that there isn't a conflict of interest regarding this individual's involvement in the study.

I hope that this information is useful.

Sincerely,

Bridget A. Foltz, M.S., MT(ASCP)
Health Scientist Policy Analyst

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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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From: [redacted]
Sent: Sunday, February 04, 2018 11:31 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Query about Medical Expert

Dear USA FDA team,

Is it acceptable for the Director of the Clinical Trial Centre of one big hospital participating in a Phase III trial to be the Medical Expert for the same trial. The Medical expert is not one of the investigators participating in the trial, only the Director of the CTC at the hospital where the trial is ongoing.

I could not locate guidance related to the role of the Medical Expert except that the ME can be from Sponsor or CRO.
Thank you

Regards
[redacted]