From: OC GCP Questions
To: [redacted]
Subject: Mobile Chemotherapy
Date: Thursday, January 30, 2014 11:28:06 AM

Good morning –
Often whether a person can participate in a particular study is determined and driven by the sponsor of the study and the protocol. There is nothing in the FDA regulations that prohibit a person that is receiving mobile chemotherapy services from participating in a clinical trial. The restrictions would be dictated by the protocol in the exclusion/inclusion section. The terms of enrollment should be included in the study protocol, specifically in the inclusion and exclusion criteria section.

Under the IND regulations 312.23 (a)(6) states--

(6)Protocols. (i) A protocol for each planned study. (Protocols for studies not submitted initially in the IND should be submitted in accordance with 312.30(a).) In general, protocols for Phase 1 studies may be less detailed and more flexible than protocols for Phase 2 and 3 studies. Phase 1 protocols should be directed primarily at providing an outline of the investigation--an estimate of the number of patients to be involved, ***a description of safety exclusions,*** *and a description of the dosing plan including duration, dose, or method to be used in determining dose--and should specify in detail only those elements of the study that are critical to safety, such as necessary monitoring of vital signs and blood chemistries. Modifications of the experimental design of Phase 1 studies that do not affect critical safety assessments are required to be reported to FDA only in the annual report.*

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

From: [Redacted]
Sent: Thursday, January 30, 2014 5:41 AM
To: OC GCP Questions
Subject: Mobile Chemotherapy

Hello,

Some institutitions are now providing mobile chemotherapy services to patients for convenience and to help reduce travel time. Can you please advise if patients can be enrolled into a clinical trial who will be treated in a chemo bus?

Best Regards,
[Redacted]