

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Charity Responsibility.
Date: Wednesday, February 11, 2015 11:01:28 AM

Good morning –

I can only answer questions related to FDA-regulated clinical studies. Additionally I cannot give you medical or legal advice. From the information in your email it appears that what you describe may not be under FDA's jurisdiction.

However if you are still unclear you can contact someone in the Center for Drugs (CDER) or the Center for Devices (CDRH)

Druginfo@fda.hhs.gov (Drugs)

DICE@fda.hhs.gov (Devices)

Additionally you might also want to check with some at OHRP. Please see their link below.

[Contact OHRP | HHS.gov](#)

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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, February 10, 2015 1:33 PM
To: OC GCP Questions
Subject: Charity Responsibility.

To whom this may concern,

My name is [redacted], and I am working to help start a charity for military veterans, particularly if there is a history of head trauma and or PTSD.

There has been interest within the charity to try try hyperbaric oxygen therapy as an attempted treatment for some of the symptoms these Vets.

My question is medical, legally and ethically what are our responsibilities for these veterans in regards to the therapy. Additionally, this may presumably be a large cohort of people who can serve as data for future research.

If data was collected for possible publishing on the Vets who choose to pursue the treatment, what would the charity be required to do? Is the responsibility different if no data is

collected?

Thank you for your time,

