

From: [Redacted]
To: [Redacted]
Cc: [OC_GCP_QUESTIONS](#)
Subject: Request For Medical Tool Device Clinical Trial
Date: Friday, May 30, 2014 3:03:38 PM

Dear [Redacted],

Thank you for your inquiry. We recommend that you send us a Pre-Submission. The specific information which is needed is as follows:

1. a detailed device description (for each device, if more than one is in the study)
2. the protocol for the study
3. a description of how the device will be used, if not included in the protocol
4. a description of the population, if not included in the protocol
5. the sponsor's name and contact person(s), including titles, address, phone number, fax number, and email address

The "Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff" which is available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf> can provide additional information.

The cover letter should state "Pre-Submission " in the reference line. Three copies should be submitted to the Document Mail Center.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
IDE Document Mail Center – WO66- G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

One of the copies should be electronic. More information about eCopies can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm>.

This submission will be assigned a "Pre-Submission number". This does not obligate the sponsor to submit an IDE, nor is there a fee for Pre-Subs. We use this as a tracking mechanism, and a method of giving feedback to sponsors. The sponsor will be sent an acknowledgement letter indicating the number assigned; please use this number for all future communications.

General IDE information can be found on FDA's website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>.

Information about the application can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046706.htm>.

If you have any questions, please contact me.

Regards,

Lynn

Lynn Henley, M.S., M.B.A.
Investigational Device Exemption (IDE) Program
Office of Device Evaluation
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From: OC GCP Questions
Sent: Thursday, May 29, 2014 5:18 PM
To: [Redacted]
Subject: Request For Medical Tool Device Clinical Trial

Hi CDRH, can you assist this person with a possible IDE? Thanks! Doreen

From: [Redacted]

Sent: Thursday, May 29, 2014 4:19 PM
To: OC GCP Questions
Subject: FW: Request For Medical Tool Device Clinical Trial

This is a second request.

Dear FDA Representative:

My name is [redacted], an inventor and legally blind. I have built a prototype called Bedsores Blocker which is a medical tool device that sits on a hospital bed and place it behind a patient's back of body (longitudinal lateral position). This device will prevent and diminish bedsores. I am requesting for a clinical trial to test it in a live environment to demonstrate the value and benefit for the healthcare providers and patients. To whom do I need to communicate with to get an approval and the process of pursuing the clinical trial?

Thank you for your support,

[Redacted]