

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Request For Medical Tool Device Clinical Trial  
**Date:** Tuesday, April 15, 2014 7:17:41 AM

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Good morning –

You will need to contact the Center for Devices (CDRH) directly at [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)

Kind regards

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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.

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**From:** [Reacted]  
**Sent:** Monday, April 14, 2014 10:18 PM  
**To:** OC GCP Questions  
**Subject:** Request For Medical Tool Device Clinical Trial

Dear FDA Representative,

I have a patent pending medical tool device [REDACTED] I would like to test it in a clinical trial.

[REDACTED]. This will alleviate pressure from a patient's back of body, allow air flow around skin, and keep skin dry and allow healing on its own for those already have bedsores.

What would be the steps in order for me to commence the clinical trial?  
What is the processing fee to participate in a clinical trial?

I look forward to hearing from you within a week. I can be reached at [REDACTED]. However, email is the best communication method.

Thank you.

[REDACTED]