From: Hommel, Carolyn - OC
Sent: Tuesday, September 05, 2006 1:15 PM
To: **[Redacted]**
Cc: **[Redacted]**
Subject: FW: 1572 required?

Hi, **[Redacted]**,

A 1572 is used only for drug studies. However, device studies require that sponsors obtain a "signed agreement" (similar to the 1572) from the clinical investigators. Please refer to 21 CFR 812.43(c) regarding the information that must be included in the signed agreement.

I am also copying a colleague in FDA's Center for Devices and Radiological Health in case CDRH has additional advice for you related to your study.

You can access the device regulations from our GCP website: http://www.fda.gov/oc/gcp .

As for our GCP questions e-mail account, try GCPQuestions@oc.fda.gov . Sorry the other address didn't work as expected.

Carolyn

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 14-B17
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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, September 05, 2006 1:03 PM
To: Hommel, Carolyn - OC
Subject: FW: 1572 required?

The email address listed below, did not work. Can you help with this or point me in the right direction?

[Redacted]

From: **[Redacted]**
Sent: Tuesday, September 05, 2006 9:11 AM
To: 'GCPQuestions@fda.hhs.gov'
Subject: 1572 required?

Is a FDA Form 1572 required for this study:

[Redacted]

[Redacted]