From: OC GCP Questions
To: [redacted]
Subject: Clinical Trial Question
Date: Saturday, March 28, 2015 10:30:56 AM

Good morning –

Please send your question directly to the Center for Devices at DICE@fda.hhs.gov.

Kind regards,

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

From: [redacted]
Sent: Friday, March 27, 2015 3:49 PM
To: OC GCP Questions
Subject: Clinical Trial Question

To whom it may concern:

I am doing some research on clinical trials for medical devices where a person participated in a trial but the medical device was not approved. The medical device was implanted, so if it is removed or not replaced, the person could suffer severe harm.

What safeguards are in place for patients who participate in a clinical trial for a Class III medical device that was subsequently not approved by the FDA? Specifically, what does the FDA do in respect to duties owed to the patient, replacement, maintenance, costs of device after the study IF the patient still depends on the device.

I need to find any statutes, regulations, or guidance that speaks to ethical implications of clinical trials and what happens to participants when the FDA does not approve a device.

Thanks in advance for your assistance. Please feel free to email or call [illegible]. I look forward to hearing from you.

[redacted]