From: OC GCP Questions
To: [redacted]
Subject: Handling of Unsolicited Contacts from Patients
Date: Thursday, August 07, 2014 8:45:50 AM

Good afternoon –

Yes you may discuss future research from unsolicited emails and phone calls from patients as long as the following guidelines are followed. While an investigator may discuss the availability of studies and the possibility of entry into a study with a prospective subject without first obtaining consent, informed consent must be obtained prior to initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research. An investigator could not provide prospective subjects with any **information specific** to a study prior to approval/go-ahead from both the reviewing IRB and FDA but an investigator could provide general information about research at the institution to prospective subjects provided that no information specific to studies that have not received approval/go-ahead is provided. You may wish to ask the patients if you can contact them for additional consideration in other clinical studies. This should be documented in the patient's medical record. Creating a standard operating procedure would be advisable to make sure all staff understand the process and are consistent.

I believe you will need the patient's consent before you forward their information to other research sites. There might be privacy issues under HIPPA. Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as HIPAA and its related statutes are under the jurisdiction of the Office for Civil Rights (OCR) and not FDA. For questions regarding issues pertaining to HIPAA, you may wish to contact OCR directly at OCRPrivacy@hhs.gov. I suggest you send your question to OCR to get their response. Here also is a link to OCR's general website for HIPAA http://www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html . You may also wish to discuss your question with other in-house legal staff, including any Privacy Officer, within your sponsor organization.

You may wish to review FDA's guidance document on recruitment of study subjects and screening tests prior to enrollments. Please see the links below.

http:///www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

I hope this information is helpful.

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

From: [redcted]
Sent: Wednesday, August 06, 2014 1:14 PM
To: OC GCP Questions

Subject: Handling of Unsolicited Contacts from Patients

Hello – If we receive unsolicited emails or phone calls from patients interested in participating in a clinical trial, are we allowed to forward their contact information to our research sites? Furthermore, can we store their contact information in consideration of future trials and providing such information to future research sites?
[redacted]