From: OC GCP Questions
To: [redacted]
Subject: Lost original consent but have a copy
Date: Thursday, January 16, 2014 1:06:12 PM
Attachments: image001.png

Good afternoon –

All efforts should be made to recover lost documentation and the attempts should be documented in writing with a detailed "note to file" in case an FDA inspection should occur at your site. Since the subject cannot be re-consented due to death, detailed documentation of this situation is important.

You might also want to inform the sponsor of the study and the reviewing IRB of this situation.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [Redacted]
Sent: Thursday, January 16, 2014 12:32 PM
To: OC GCP Questions
Subject: Lost original consent but have a copy

Good afternoon,

I have a case in which the patient was consented, a copy was given to the patient and another copy was kept in the research binder. After reviewing the patient's paper medical record it was noted that the original (wet ink) consent was lost. We have a copy of the original (wet ink). How should we document this ? Patient is off the study and deceased.

Please advice.

Thanks,

[Redacted]

About Hackensack University Medical Center HackensackUMC, a nonprofit teaching and research hospital located in Bergen County, NJ, is the largest provider of inpatient and outpatient services in the state. It is the flagship hospital of the Hackensack University Health Network, one of the largest health networks in the state comprised of 1,140 beds, nearly 10,000 employees and 2,200 credentialed physicians. HackensackUMC was listed as the number one hospital in New Jersey and one of the top three New York metro area hospitals in the U.S. News & World Report's Best Hospital rankings for 2013-14. It also received 10 national rankings in: Cancer; Cardiology & Heart Surgery; Ear, Nose & Throat; Gastroenterology & GI Surgery; Geriatrics; Neurology & Neurosurgery; Orthopedics; Pulmonology; Urology; and the Joseph M. Sanzari Children's Hospital ranked as one of the Top 50 Best Children's Hospitals for Neurology and Neurosurgery in the 2013-14 Best Children's Hospitals list. HackensackUMC is among Healthgrades® America's Best 100 Hospitals in 10 different areas – more than any other hospital in the nation, is one of Healthgrades America's 50 Best Hospitals™ for seven years in a row, and received the Healthgrades Distinguished Hospital Award for Clinical Excellence™ 11 years in a row. The medical center has also been named a Leapfrog Top Hospital, and received 19 Gold Seals of Approval™ by the Joint Commission – more than any other hospital in the country. It was the first hospital in New Jersey and second in the nation to become a Magnet® recognized hospital for nursing excellence. HackensackUMC is the Hometown Hospital of the New York Giants and the New York Red Bulls, and remains committed to its community through fundraising and community events. To learn more, visit: www.HackensackUMC.org.