From: Hommel, Carolyn - OC
Sent: Friday, April 29, 2005 5:08 PM
To: [Redacted]
Subject: IRB question

Importance: High

Dear [Redacted]:

You had left a phone message for me last week, and I apologize for the delay in getting back to you. In your message, you described the following scenario:

You noted that during a device study at your site, there had been a protocol violation in which a subinvestigator (who had not yet been officially designated to participate in a study), had implanted the investigational device in a patient. After the protocol violation had been reported to the sponsor and IRB, the IRB advised your site that the data from this individual could not be used. You had asked if FDA has any guidance on who is responsible for determining whether data collected under such circumstances may or may not be used.

The situation you described is not addressed in FDA's regulations or guidance, so there is no single right answer. There are certainly arguments on both sides that should be considered when trying to decide how to handle information related to this patient.

Perhaps the IRB is concerned that if the site is allowed to enroll the patient in the study, it may appear that the site is benefiting from the protocol deviation, and the IRB does not want to send an inappropriate message to the study site (and other sites or investigators as well). For example, if the site were to include the individual in the study and received payment from the sponsor or "credit" toward an enrollment bonuses (when in fact the site had not followed the study protocol), it might appear that the site is being "rewarded" for failing to follow the approved study protocol.

On the other hand, if the individual who received the device were to suffer an adverse event as a result of having received the test article, it would be important for the sponsor (and FDA) to have the information, to ensure that it's appropriately reported and followed to resolution, and included in any safety assessments related to the device.

In general, it's important to defer to the IRB's judgment, as they are responsible for ensuring that the study is conducted ethically. However, perhaps there is a middle ground, in which the individual's experiences, particularly if there is any adverse effect, could be included in safety assessments.

I hope this is helpful,

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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