From: Hommel, Carolyn - OC
Sent: Monday, September 22, 2003 2:05 PM
To: [Redacted]
Subject: RE: Research in Emergency Critical Care settings

You're very welcome.

There is some information in the public docket, because, as you know, sponsors are required, under 21 CFR 312.54(a), to provide FDA with a copy of the information that was "publicly disclosed" about the studies. You would need to contact Dockets Management Branch for a copy of the information submitted to Docket Number 95S-0158. [There may be a fee involved.] The complete address is:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857
Phone: 301/827-6860
fax: 301/827-6870
e-mail: fdadockets@oc.fda.gov

Carolyn

-----Original Message-----
From: [Redacted]
Sent: Monday, September 22, 2003 1:45 PM
To: 'Hommel, Carolyn - OC'
Cc: Lepay, David; Woollen, Stan - OC; Lee, Bonnie; [Redacted]
Subject: RE: Research in Emergency Critical Care settings

Carolyn -
thanks for the response

And thanks for the comments on the abstract - as you likely noted, I only included a cursory list (and not ALL) of the required elements - given the space limitation, I wanted to refer to your formal regulation and the relevant guidance for the specific requirements. But that being said, I will certainly use your comments to reword some of the text and to be certain that the regulation itself must be accessed.

Is there any possibility of getting more specific information about the types of studies that were allowed to proceed? Or is this information confidential?

thanks

[Redacted]

-----Original Message-----
From: Hommel, Carolyn - OC [mailto:Carolyn.Hommel@OC.FDA.GOV]
Sent: Monday, September 22, 2003 1:25 PM
To: [Redacted]
Cc: Lepay, David; [Redacted]; Woollen, Stan - OC;
Lee, Bonnie

Subject: RE: Research in Emergency Critical Care settings

Dear Ms. [Redacted],

Dr. Lepay and Stan Woollen asked me to respond to your question regarding how often FDA has allowed studies to go forward under 21 CFR 50.24. Unfortunately, I don't have a precise, current figure for the number of studies that FDA has allowed to proceed. We are periodically asked this question, but because the applications for these studies are submitted directly to the Center with jurisdiction over the product involved and there is no central repository for information about the submissions, we do not have a readily available, "current" count.

In April 2000, the latest date for which I have metrics available, FDA had received 19 submissions that included a request for an exception from informed consent under 21 CFR 50.24. Of those, FDA allowed 12 "to proceed." This number, however, still does not provide a complete picture of the studies that were or are active because some of the studies were subsequently withdrawn or terminated by the sponsor because of other considerations associated with the studies.

You might want to simply state that FDA has allowed only a small number of these studies to proceed, of which a smaller number were actively pursued by the sponsor.

Your audience may also be interested to know that FDA developed draft guidance on this issue; the document, "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research," can be found online at the following URL:

http://www.fda.gov/ora/compliance_ref/bimo/err_guide.htm

FDA has a working group that is actively working to update the draft guidance in light of comments that were submitted to the public docket established for the draft guidance.

I also looked at the synopsis of Dr. O'Rourke's presentation, and made a few comments related to the requirements of the regulation.

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
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
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.

-----Original Message-----
From: [Redacted]
To: 'dlepay@oc.fda.gov' <DLepay@OC.FDA.GOV>
CC: [Redacted]
Sent: Fri Sep 19 16:36:21 2003
Subject: Research in Emergency Critical Care settings

Hello David,

Per my voicemail message yesterday, please see attached abstract for above-mentioned title, submitted by [Redacted].

Please see paragraph 3, reference to FDA ..."provides narrow exception from the informed consent requirement for emergency research.. (4, 5) She has been asked to provide additional data to support this statement, particularly important to know how often is this FDA exception applied? In preparation for her response to conference committee, she will need to have this information early part of next week. Please let me know if you need any additional information at this time. Thank you for your help.

Regards,

[Redacted]