From: Hommel, Carolyn - OC
Sent: Wednesday, November 08, 2006 1:24 PM
To: [purged]
Subject: RE: 1995 FDA/NIH Report on the Public Forum on Informed Consent
f or Emergency Research

Dear [purged],

I haven't heard yet from DMB, and it may take awhile for them to scan the document and put it on disc for you in pdf. (<That would be nice in some respects, because then you can easily search the document for key words, etc.) Do you want me to copy it in the meantime so that you get a copy sooner rather than later?

Carolyn

-----Original Message-----
From: [purged]
Sent: Wednesday, November 08, 2006 1:22 PM
To: Hommel, Carolyn - OC
Subject: RE: 1995 FDA/NIH Report on the Public Forum on Informed Consent f or Emergency Research

Dear Carolyn, this is excellent news thanks so much for looking into this
for me! I'm glad that that document is at least obtainable in some
format--a hard copy would be totally fine, so whatever is easiest to
arrange with DMB.

Best, [purged]

> Dear [purged]:
>
> I found a hard copy of the document. From what I can tell, it was placed
> in
> the public docket that was created when the rules related to emergency
> research studies were first proposed in 1995 [Docket #95N-0158]. However,
> there doesn't seem to be an electronic version of that document posted on
> Dockets Management Branch's (DMB) website, so I'm checking further to see
> if
> they'd be able to scan it for you. Worst case scenario is that I just
> have
> to copy it and send you the hard copy (it's over an inch thick).
>
> Anyway, I'll let you know what DMB tells me.
>
> Carolyn
>
> _____
>
> From: Hommel, Carolyn - OC
> Sent: Wednesday, November 08, 2006 8:41 AM
> To: [purged]
> Subject: RE: 1995 FDA/NIH Report on the Public Forum on Informed Consent
> for
> Emergency Research
>
>
> Dear [purged],
>
> I'll see what I can find out for you.
>
> Carolyn
>
> _____
>
> From: [purged]
> Sent: Tuesday, November 07, 2006 4:30 PM
> To: Hommel, Carolyn - OC
> Subject: 1995 FDA/NIH Report on the Public Forum on Informed Consent for
> Emergency Research
>
>
>
> Dear Carolyn, I'm a graduate researcher in biomedical ethics at [purged] and I'm trying to locate a copy of a FDA/NIH report that was
> released in 1995 entitled "Report on the Public Forum of Informed Consent
> in
> Clinical Research Conducted in Emergency Circumstances" that seems to be a
> precursor to the formatting of the FDA recommendations for IRB in
> emergency
> research (21 CFR 50.24). I've contacted the library of medicine at the NIH
> and they have no record of such a document but it has been cited in a
> number

> of articles and even in a powerpoint presentation (given by Sara F.
> Goldkind
> & Michael Carome on Oct 11, 2006) entitled, "Exception from Informed
> Consent
> for Emergency Research" which includes a section on the History of 21 CRF
> 50.24, which I found available on the FDA website. Obviously, I've done a
> thorough internet search, FDA, NIH, Worldcat and so forth, and have been
> unable to find a copy of it. What I did find was the FDA's "Guidance"
> document for IRBs on Exception from Informed Consent Requirements for
> Emergency Research from which I obtained your contact information.
>
>
>
> The only information I have about the report is that it was an FDA and NIH
> co-sponsored public forum on emergency research in which various opinions
> from the forum were documented. I wonder if you could please assist me in
> obtaining a copy (.pdf document if possible) of this original report?
>
>
>
> My interest in this document is for historical research purposes only.
>
> Thanks kindly.
>
> Regards, [purged]
>
>
>
>