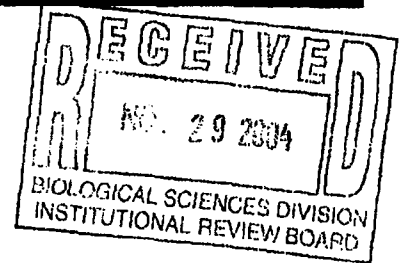


**Walsh, Deborah**

**From:** Robert Rosenfield, M.D. [robros@peds.bsd.uchicago.edu]  
**Sent:** Monday, November 29, 2004 1:57 PM  
**To:** tosafo@delphi.bsd.uchicago.edu  
**Cc:** Walsh, Deborah  
**Subject:** 13472A revision



13472A\_AssentFor 13472A\_AssentFor 13472A\_CF\_AdGnD 13472A\_CF\_PTS\_1 13472A\_CF\_VOL\_1  
m\_PTS\_11-23-0\_... m\_Vol\_11-23-0\_... \_11-29-04.doc (... 1-29-04\_.doc (8... 1-29-04\_.doc (8...

Dear Dr. Moss,

Re the IRB Pending-Conditional review of Protocol 13472A, we have responded as suggested and are attaching hard copies of the assent and consent forms. They have all been revised as suggested. Hard copies of the originals and versions with highlighted changes are being hand-delivered under separate cover.

Two items deserve comment.

1. Re #I. We look forward to the 407 review of this protocol. We urge you to submit these as soon as possible.
2. Re#II. The material (amendment #6) was submitted to the FDA belatedly by Fed Ex on Nov 15, 2004. The documents had inadvertently gotten buried in a pile on my RN's desk rather than being sent out when I had anticipated. We will inform you when the 30-day wait period has passed.
3. Re #III. The assent and consent forms have all been revised as suggested.

I trust that this will finalize the documentation needed for conditional approval (of patients) and 407 review (for control children).

Sincerely,

Bob Rosenfield

X-Sieve: CMU Sieve 2.2

X-Sender: rrosenfi@peds-es01.bsd.uchicago.edu (Unverified)

Date: Mon, 20 Dec 2004 16:44:49 -0600

To: tosafo@delphi.bsd.uchicago.edu

From: "Robert Rosenfield, M.D." <robros@peds.bsd.uchicago.edu>

Subject: 13472A

Cc: "Deborah Walsh, MS, RN" <dwalsh@peds.bsd.uchicago.edu>

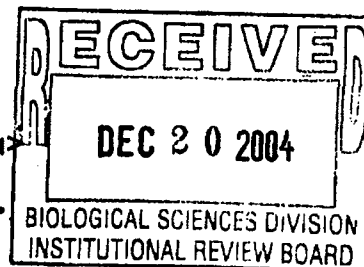
"Nancy Devine, RN" <ndevine@peds.bsd.uchicago.edu>,

"Elizabeth Baumann, MD" <ebaumann@peds.bsd.uchicago.edu>

X-OriginalArrivalTime: 20 Dec 2004 22:48:42.0021 (UTC) FILETIME=[0DB77550:01C4E6E6]

X-Spam-Not-Checked: Messages over 100K not checked

X-Scanned-By: MIMEDefang 2.35



Tasha,

A loose end.

I have received the critique from the CRC with their provisional acceptance. They had minor suggestions that affected the wording of the protocol and the DSMP.

My response letter and accordingly revised protocol and DSMP are attached.

Also a revised Narrative is enclosed that reflects all the little changes since the last version was submitted.

All the changes are in blue on the electronic version.

The FDA 30-day waiting period has passed without a response from them (the amendment was sent by 2-day Federal Express on Nov 11, 2004). Therefore, we can proceed with the 407 submission using the documents that you now have in hand.

Bob Rosenfield



CRC Adv Comm#13472A.doc



13472A\_research\_plan\_new\_full\_3



13472A\_DSMP\_APPLIC\_12-04.doc



13472A\_CF\_PTS\_11-29-04\_1.doc



DETAILED\_NARR\_13472A1#77E6E.doc