

5. E-mail correspondence dated April 19, 2005 from Tasha Osafo (Assistant Director of IRB) to Dr. Rosenfield.

X-Sieve: CMU Sieve 2.2
X-Sender: (redacted)
Date: Tue, 19 Apr 2005 14:54:37 -0500
To: Tasha Osafo <tosaf@bsd.uchicago.edu>
From: (redacted)
Subject: Re: Protocol 13472A, Amendment #2
X-OriginalArrivalTime: 19 Apr 2005 19:58:52.0779 (UTC)
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Tasha,

It was a mistake--a carry-over from one of the other dozens of paste-ins from somewhere.

This protocol specifies the study of prepubertal and early pubertal girls (only).

The offending phrase has been deleted or changed in each of these docs. I hope this will suffice.

rlr

Dear Dr. Rosenfield,

I received the amendment in response to dr. sheridan's comments for 13472A. i have one question about the omission of the pregnancy testing.

Formerly your consent forms stated pregnancy testing was to occur in children. now it has been removed because "study subjects are in early puberty and not sexually mature". However, your grant states that admission procedures in the CRC include a "urine pregnancy test" on "pubertal or post-menarcheal females".

Can you please clarify why there is a discrepancy between the grant and the information in this amendment.

If you have decided to revise your protocol to exclude the pubertal or post-menarcheal females, you will need to submit a revised protocol indicating this change.

Thank you,

Tasha Osafo
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