

From: a-dreger@northwestern.edu  
Subject: Re: OHRP's Determinations RE: Dexamethasone in Pregnant Women Allegations  
Date: September 3, 2010 8:52:38 AM GMT-04:00  
To: Lisa.Buchanan@hhs.gov, Kristina.Borrer@hhs.gov  
Cc: efeder@american.edu, director@aiclegal.org

Dear Dr. Borrer:

Thank you for your message of yesterday. In order for members of the professional ethics and patient advocacy communities to understand your findings, we need more information from you.

1. You indicate "Dr. New conducted 3 studies while employed at WCMC involving provision of dexamethasone to pregnant women at risk of carrying a female fetus with CAH." Would you please clarify the precise nature of these studies, namely the specific methodology for each? Please also advise if you are aware of the actual study methodology varying from the methodology described in the application to the IRB.
2. What was the number of subjects enrolled for each of these three studies? (If any subjects dropped out of the study, we would like to know how many dropped out and for what reasons.)
3. We would also like to know the dates of each study, including the start and end dates of each study.
4. Would you please provide the informed consent form for each of these studies so that we can see why you have concluded that the women were adequately informed?
5. You indicate that Dr. New wrote one prescription for prenatal dexamethasone for CAH at MSSM. How many did she write for prenatal dexamethasone for CAH at WCMC?

My colleagues and I would appreciate a prompt written reply so that we can better understand your findings as we share them with others. Thank you.

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