Complete Version of the Email Correspondence Dated December 21, 2005, to Dr. Spence from Cathy Jackson Provided to the OHRP in the January 12, 2005 correspondence

(02-0898)

Dr. Kimberly Spence

Title: Precursor Preference in Surfactant Synthesis of Newborns

Spence, Kimberly

From: Spence, Kimberly
Sent: Monday, December 27, 2004 10:33 AM
To: 'jacksonc@msnotes.wustl.edu'
Subject: RE: 407 Panel

Dear Ms. Jackson,

Marilyn Maksin will forward you a copy of my grant application. My protocol is attached.

As far as the lettetter to the DHHS secretary there are some clarifications/corrections to be made:

1) The extra 2.5 ml of blood will not, in and of itself, prompt the need for a transfusion; The normal population are larger full term babies. The extra 2.5 ml of blood is not the same relative volume it is to premature infants weighing only 1 kg. 2) Also as per #1, the normals are full term infants but not normal healthy babies - they are in the ICU for some reason and are sick - they just have normal lungs by our definition. 3) We will attempt to coordinate the blood draws with clinically indicated blood draws. However, it might be necessary for research purposes to draw 1-2 specimens at other times with the consent of the parents.

Please see my attached revisions. Thanks.

kim

-----Original Message-----
From: jacksonc@msnotes.wustl.edu [mailto:jacksonc@msnotes.wustl.edu]
Sent: Tuesday, December 21, 2004 1:41 PM
To: Spence, Kimberly
Subject: Fw: 407 Panel

Dr. Spence,

I am writing in regards to your study titled "Precursor Preference in Surfactant Synthesis of Newborns". As you know this study went Back to the Committee on December 16, 2004 for re-review. Because the new healthy control group you propose to study falls under the regulatory requirements for research involving minors under category 46.407 this study will need to be sent to the DHHS secretary for final approval. Please review the attached letter in the email below which we plan to send to the DHHS Secretary and let me know if you see anything that is incorrect. Also, can you please send me an entire copy of your grant application and an entire copy of your research protocol so I may forward it on to them. When sending this information, please mark it to my attention.

Thank you very much and let me know if you have any questions.

Cathy Jackson
Senior Protocol Coordinator
Human Studies Committee
E-mail jacksonc@msnotes.wustl.edu
Phone Number (314) 633-7442
Fax Number (314) 367-3041

----- Forwarded by Cathy Jackson/HumanStudies/Medicine/Washington University on 12/21/2004 01:30 PM -----

Patricia Scannell/HumanStudies/Medicine/Washington University

To jacksonc@msnotes.wustl.ec
cc
Subject 407 Panel

12/20/2004 02:56 PM

(See attached file: 407 Panel.doc)

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