Helen Hayes Hospital Institutional Review Board

MEETING MINUTES

June 14, 2011

Noyes Conference Center

The meeting was called to order on June 14, 2011 at 2:00 PM and a quorum was present.

ATTENDANCE

Voting Members Present:

Philip Fey	Non-Affiliated, Non-Scientific
Jason Greenberg	Scientific
Andrew Hornstein	Scientific
Marjorie King	Chair
Francine Weber	Scientific
Steven Lichtman	Scientific
Patty LeGeyt	Scientific
John Pellicone	Scientific
Jonathan Karmel	Legal Specialist, Non-Scientific

Non-Voting Attendees, Staff and Guests Present:

Sharon VanHouten-Watkins	IRB Coordinator

ITEMS

1 **CALL FOR CONFLICTS OF INTEREST - Marjorie King M.D.**

Not applicable - no studies reviewed.

2 **ATTENDEE ROLL CALL**

Dr. Lindsay was absent.

3 **REVIEW OF MINUTES:**

Dr. King asked the members if there were any comments or corrections to the minutes from the May 17th meeting and there were none. There were no conflict of interest.

The April meeting was canceled.

The March 8, 2011 Minutes were reviewed and approved electronically.

4 **OLD BUSINESS:**

Update on educational issues is tabled.

5 **NEW BUSINESS:**

New Business – Possible Conflict of Interest (COI) Issue

Mr. Val Gray (CEO, HHH) asked the IRB to help the institution with an issue that arose related to possible conflict of interest. Recently, Dr. Robert Lindsay (Director, Clinical Research, HHH) was contacted by a reporter who asked him whether there is a conflict of interest related to his NIH research regarding the actions of parathyroid hormone (PTH) on bone metabolism and his honoraria and consulting fees from Eli Lilly and Company (Lilly), who market Forteo, which is a recombinant analog of part of the human PTH molecule. Dr. Lindsay reported this to Mr. Gray, who brought it to the attention of executive staff, including the legal division, at the New York State Department of Health (DOH). After discussion, they felt that the HHH Institutional Review Board (IRB) was in the best position to determine whether a conflict of interest exists and requested the Board to do so. The letter with that charge, including the specific questions and background appendices, were distributed to IRB members in advance of the June 14th meeting. All read the document and participated in the discussion. Dr. Lindsay (also a member of the IRB) attended the meeting only briefly to answer questions and did not participate in the discussion and vote.

Before discussion about the specific questions from the DOH, Mr. Jonathan Karmel (legal counsel for HHH and an IRB member) provided background information about the regulations related to COI for research with Federal Public Health Service funding, compared to the guidance for an IRB to develop a policy about COI. Federal regulations (42 CFR §§ 50.603 to 50.605) require institutions that receive federal Public Health Service funding to have policies requiring investigators to declare significant financial interests (SFI) that create a COI to the institution prior to applying for funding. The DOH policy about this is APPM 250.1, with an accompanying form for the investigators to submit to HRI. The IRB also has a separate COI policy, which is based on federal guidance for human subject protection (69 Fed. Reg. 26393). The IRB is not required to follow the federal guidance for human subject protection, but the IRB nevertheless decided to follow it when developing the HHH IRB policy about COI. The DOH asked the IRB to refer to the APPM 250.1 policy and form, and answer the questions listed below about possible COI in Dr. Lindsay's situation.

Specific Questions from the DOH to the HHH IRB:

Question #1: Did Dr. Lindsay have a "significant financial interest" within the meaning of APPM Item 250.1 during any year within the relevant period (September 2005 through May 2010)?

Answer: Yes, unanimous vote

Discussion:

The IRB acknowledged that Dr. Lindsay received an aggregate of >$10,000 per year in non-exempt categories from Lily, making the answer to this question "yes".

Question #2: Is there any reason to believe that Dr. Lindsay had a significant financial interest that was likely to have been affected by his NIH-funded research?

Answer: No, unanimous vote

Discussion: After discussion, the IRB agreed that there is no information to suggest that Dr. Lindsay's SFI in Lilly would be impacted by the results of his NIH-funded research.

Question #3: Assuming Dr. Lindsay had a "significant financial interest" during any year within the relevant period, did he have an interest in an entity whose financial interests would reasonably appear to be affected by the NIH-funded research?

Answer: No (unanimous), there is no evidence that Lilly's interests would benefit or suffer from the results of the NIH-funded research. In addition, it should be noted that there is no area on the APPM Item 250.1 form to declare this COI if it existed.

Discussion: There was significant discussion about this question and Dr. Lindsay was invited into the meeting to answer specific questions. The following factors were considered and helped formulate the answer:

1. Speakers at presentations sponsored by pharmaceutical companies are generally chosen because they are knowledgeable and have good presentation skills, not related to their research funding.
    1. Dr. Lindsay and colleagues at HHH have been studying the action of PTH on bone metabolism since 1984. He is recognized as a world expert in this field.
2. Dr. Lindsay's involvement in research regarding PTH and bone metabolism pre-dates any SFI with Lilly
    1. Dr. Lindsay's NIH funding related to PTH has been continuous (with the exception of 1 year) since that time.
    2. Lilly did not begin to study their formulation of PTH (Forteo) until the late 1990's and it was not FDA approved until 2004.
    3. Prior to commercial availability of PTH as Forteo, Dr. Lindsay and colleagues used a compounding pharmacy to provide PTH for use by study subjects. Forteo is a more convenient form of PTH for subjects to use (individual doses are packaged in syringes). As with many NIH funded studies, the pharmaceutical company provides free study drug to help lower the cost of the study, which benefits taxpayers.
    4. Dr. Lindsay's relationship with Lilly did not begin until 2000, when he was asked by the FDA to design an observational study to determine whether use of Forteo is associated with an increased risk of bone tumors.
3. Dr. Lindsay's fees are in no way related to study outcome, nor are they based on results which would lead to increased use of Forteo
    1. Consulting and speaking fees from Lilly are fee-for-service, with no incentives.
    2. The NIH does not allow investigators to discuss any unpublished data during their medical presentations. The results of Dr. Lindsay's NIH funded studies can not be discussed by him or others before publication.
    3. Dr. Lindsay's research uses cyclical administration of PTH to look at bone metabolism. Cyclical, rather than daily continuous, administration uses less drug and Lilly has told Dr. Lindsay that they do not plan to apply for FDA approval for cyclical administration, which would have a negative impact on revenue.
    4. Although it is conceivable that Lilly could use the results of Dr. Lindsay's previous published research that shows efficacy of cyclical use of PTH in subjects previously treated with bisphosphonates, there is no evidence that they have done so nor that they plan to do so.

Question #4: In the event Dr. Lindsay is found to have had a substantial conflict of interest, is there any need to inform any individuals who were subjects in Dr. Lindsay's completed NIH-funded research, or in study 1ROIAR056651-01A2, which is ongoing, of this finding?

Answer: This does not need to be answered, because the IRB did not find that Dr. Lindsay had a substantial COI. However, it should be noted that there is an independent data safety monitoring board (DSMB) for all of these studies. One of the purposes of a DSMB is to add protection for human subjects from any bias caused by COI.

6 **NEXT MEETING DATE:**

Wednesday, July 6, 2011 at 1:00 PM

7 **ADJOURN AT:**

The meeting adjourned on June 14, 2011 at 4:15 PM.