MINUTES
Institutional Review Board
February 23, 2010

Present: Garrett Milam (Chair), Lisa Ferrari, Mary Rose Lamb, Grace Kirchner, Julia Looper, David Lupher, Petra Perkins, and David Moore

Meeting was called to order at 8:05 a.m.

Announcements: Garrett reviewed the agenda for the meeting, which included: (1) deliberation on Protocols 0910-008 and 0910-009, (2) discussion and review of the Research Misconduct Policy, and (3) discussion of ideas for how to improve communication and transparency between the IRB and other entities, such as researchers and department designates. Garrett also provided a follow-up on the protocol reviewed and deliberated via Email correspondence following the committee's last meeting, noting that this had been revised per the IRB suggestions and approved.

Orders of Business:

1. **Deliberation on Protocol 0910-008.** Key issues and questions included the following:

    - The researcher needs to clarify the process of data collection with the children themselves, including detailing where and how the data will be collected. In particular, the IRB requests clarification regarding: (a) how the researchers will approach children, (b) how, where, and when observations will be made, (c) how the study will be incorporated within the existing classroom setting, and (d) whether the children recruited for the study are in a special classroom or mainstreamed.
    - Some concerns were raised about how the researchers currently propose to obtain consent, namely by sending the consent form home to parents in the child's backpack and then asking parents to sign and return the form via the child. The IRB recommends that the researcher first send a flyer and/or letter to the parents (via the child) informing them of the study. For parents who express willingness to allow their child to participate, the researcher can then send/mail the consent form, contact the parents over the phone, and give parents the opportunity to ask any questions that they have. Finally, once the informed consent is signed, the researcher can administer the planned screening and interview with parents.
    - The researcher needs a letter of approval from the sponsoring school, before data can be collected.
    - The protocol could use some additional editing, to correct typos and minor problems in wording.

    Action: M/S/P The protocol was unanimously approved (8-0), pending the requested revisions.

2. **Deliberation on Protocol 0910-009**. Key issues and questions included the following:

    - The researcher should reduce or revise the technical wording in the consent form in order to be more readily understandable to study participants.
    - A few discrepancies in wording need to be resolved between the protocol and the consent form (e.g., the consent form says that trials will be separated by 48 hours vs. "at least 24 hours" in the protocol).
    - It is recommended that the PI either provide a supporting citation for or "tone down" the assertion that exercise does not induce cardiovascular event in the absence of pre-existing conditions (e.g., "It has not been shown that…" or "There is no established evidence that…").
    - The PI should clarify what criteria will be used by researchers to determine that a participant is not safe to continue the test as well as what information will be provided to participants regarding signs that they themselves may not be safe to continue.
    - Please clarify who else besides the PI will be conducting the research.
    - Please clarify the exclusion criteria. For example, it was unclear whether a single "yes" answer on the screening questionnaire were reason for exclusion, or whether certain "yes" answers (e.g., on orthopedic questions) would not disqualify a given subject from participating.
    - In regards to risk management, it is recommended that the researcher summarily exclude participants with a history of relevant pre-existing conditions.
    - Please clarify how long the data will be retained regarding genetic analysis on the obtained samples.
    - In order to safeguard the confidentiality of the Medical History Questionnaire, it is recommended that participants' identifying information be separated from these data and that, instead, a participant ID number be used.
    - A few minor editing changes are needed (e.g., missing preposition before "swish" in the consent form; "Exercise" is misspelled on the cover sheet).

    Action: M/S/P The protocol was unanimously approved (8-0), pending the requested revision above and review of the revised protocol via Email correspondence by IRB members.

3. **Discussion and Review of Research Misconduct Policy.**

Lisa began this discussion by providing some background information on this issue. She noted that institutional policies regarding research misconduct are required by the U.S. government; such policies relate to how incidents involving misconduct in research are handled (from mistreatment of participants to academic dishonesty). The University's research misconduct policy was drafted by John Finney in 1977 but has not been revised since that time. There is a charge from Dean Bartanen to review the policy and revise it

as needed. In taking up this charge, the PSC has reviewed the policy and is seeking IRB advice regarding any necessary revisions, particularly in light of a recent National Science Foundation (NSF) policy which stipulates that the home institutions of all NSF grant applications must have a research misconduct training program in place at the time of the grant application, in order for researchers at those institutions to be elibible to receive NSF grant funding. The IRB's charge is thus to review the University's existing policy, along with the NSF policy, and consult with the PSC regarding any recommended changes.

One option on the table would be to require researchers and IRB departmental designates to complete the National Institute of Health (NIH) ethics training, in order to more adequately ensure that researchers are aware of procedures for appropriate ethics conduct. One advantage of this is that the training is free and it grants a certificate upon completion to demonstrate successful completion of this requirement.

Given the lateness of the hour, it was decided that IRB members should carefully review the University's research misconduct policy as well as the NSF guidelines before our next meeting, in order to continue this discussion.

4. **Improving communication and transparency between the IRB and other entities.**

The committee briefly discussed the need to increase "user-friendliness" and accessibility of IRB-related information as communicated via the IRB web pages. Garrett and Lisa volunteered to review the website and provide some suggestions for the whole committee to consider. Some initially suggested changes included: (1) adding boilerplate language for sample consent forms regarding limits of confidentiality in the case of child abuse disclosure, (2) communicating to researchers the importance of having referral options for vulnerable populations when necessary, (3) perhaps including a "Top 10 list" of common errors to avoid in IRB protocols, and (4) providing clearer guidelines regarding data storage and security issues.

The committee also briefly discussed the importance of developing and articulating clear guidelines for the process that follows IRB review of a given protocol. This would include adopting a policy about the available options for researchers in the case where a protocol is denied. The opportunity to submit a modified protocol was discussed, as well as whether the IRB would want to adopt a policy on any form of appeal process. It was suggested that the IRB should examine other academic institutions' policies on these issues, in order to serve as a guide for any new guidelines that we might adopt. Lisa volunteered to research other institutions' policies and report back to the committee.

The meeting was adjourned at 9:05 a.m.

Respectfully submitted,

David Moore