IRB Committee Minutes
October 7, 2004

Members present: Roger Allen, Patrick Coogan, Lisa Ferrari, John Finney, Robin Foster and Kathi Lovelace.

I. Business

1. IRB members approved the September 2 minutes. It was agreed that future minutes could be approved via email exchanges so that they could be posted quickly.
2. Chair Allen announced that visitors are planning to sit in on future IRB meetings when student protocols are under review. IRB members agreed that visitors would not have a vote on the approval of such protocols, and decided to consider (but did not do so at this time) the extent to which visitors can deliberate in the process. One member asked for clarification of the visitors' purpose for attending the IRB deliberations.

II. Proposals Reviewed: The IRB committee reviewed one protocol (#0405-001).

Protocol #0304-022. Approved 5-0-1
This project proposed to use thermographic images to create a vasomotor map that might be used to facilitate accurate diagnosis of the cause of lower extremity pain. Participants in this study will be physical therapy professionals, and the research will be conducted at an off campus location. The risk identified in the study is potential injury due to injection of an anesthetic agent, but that risk was determined to be very small, based in part on past experience with the procedure.

General comments and suggestions made by IRB members appear below:

In their deliberation of the proposal, IRB members made the following comments and requests for minor modifications to the proposal.

1. IRB members requested a typographical correction in section (A) of the "Project Description"
2. One member asked the researcher to clarify the duration of action of the anesthetic because slightly different information about the expected effects of the anesthesia and precautions appeared in the "Risks to Subjects" section of the protocol, the "Consent Form—Project Description", and the "Consent Form—Risks and Benefits" sections.
3. IRB members suggested that the participants be evaluated before leaving the experiment for the type of injury recognized as the greatest risk to participants in the study.
4. One IRB member suggested that the researchers submit a letter to physical therapists clarifying the patterns of pain due to vascular causes that are commonly misdiagnosed as nonorganic (e.g., conversion disorder).
5. IRB members acknowledged that the proposed research expands on previous work by the same investigators, and that it adopts identical procedures and techniques, and it poses similar risk. The previous study was approved by the IRB and no instances of injury occurred in the previous study.

III. Other Business

1. Informational Follow-Up for IRB Approved Research Projects
   - Chair Allen handed out a draft of the Informational Follow-Up form for IRB approved projects that would serve as a final report (see attachment to the minutes).

- Concerns were raised about whether researchers would remember to submit the form. Finney suggested that it could accompany the IRB approval letter, that receipt of the "annual follow up report" would be "due on the anniversary of the approval date", and that a reminder would be sent out one year after approval (if not yet submitted). It was suggested that the reminder might also note that projects not completed within one year of approval (i.e., data collection must be complete) must formally request continuation from the IRB.
- Finney noted that the UPS Human Subjects Document recognizes an "annual approval period" (p. 24) and that researchers are to notify the IRB within 90 days of termination of a project (p. 25). Finney added that at present final reports are hit-or-miss at the University IRB level.
- The proposed form would target incidents, changes in protocol, whether risks were properly assessed, etc. These issues appropriately bear on IRB concerns. Finney asked whether the last question on the form "…what changes were made and why?" might be self-incriminating, given that changes to a protocol are to be formally requested and approved. Finney also wondered whether liability might shift—from the institution to the researcher, for example—if changes noted on a follow-up form were made without IRB approval.
- Ferrari suggested adding a statement to the document assuring participants that their responses would not incriminate them in any way. Several phrasings were suggested (e.g., "In the course of research sometimes it becomes necessary to make slight modifications to a project.")
- IRB members proposed revisions to the second page of the Follow up form. They were: (1) below the boxes "no" and "yes" add: If yes, (a) please describe the situation~~?~~. (addition of (a) and replacement of ? with .), (2) to add: and (b) ~~If yes,~~ please describe efforts undertaken…..(add (b) and strike "if yes"), (3) move "Additional questions specifically pertaining to this protocol" to the end of the document.
- Allen clarified that the section on "additional questions specifically pertaining to this protocol" refers to questions raised by the IRB in its deliberation of a specific protocol.
- Allen promised to revise this document to be included in these minutes.

2. Web Site Concerns
   - IRB members decided to prioritize documents relevant to student projects in the review of the web page. Some items mentioned by IRB members included sample consent and assent forms.
   - IRB members agreed to schedule the web-site review during a meeting with few protocols.

The next scheduled meeting of the IRB is Thursday November 4, 2004 from 8:00-9:30 am in Wyatt 326.

Respectfully submitted 10/28/04
Robin Foster

Informational Follow-up
IRB Approved Research Project

The fundamental charge of the Institutional Review Board (IRB) is to protect human research subjects. Approval by the IRB is for a period of one-year and researchers are to notify the IRB within 90 days of termination of an approved project. An annual report to the IRB is required of all approved protocols. To help simplify this process, please respond to the following questions pertaining to the status of your approved research project. The purpose of this follow-up form is not to have researchers provide self-incriminating documentation in the event of an unanticipated occurrence during the study, it is merely to inform the IRB of the status of the project and report on any modifications made to the originally proposed protocol.

IRB Protocol #: _____ Date of Approval: _____

Project Title: _____

_____

_____

Principle Investigator(s): _____

CMB: _____ email: _____ Phone: _____

1. Project status (please check one):

☐ Complete _____ ☐ Ongoing _____
completion date estimated completion date

☐ Discontinued
On a separate page, please state why the study was discontinued.

2. During the course of conducting a research project sometimes it becomes necessary and/or prudent to alter experimental protocols. Did any circumstances require significant modification in the investigative protocol for which you will be seeking IRB approval?

☐ no ☐ yes

If yes, what changes were made and why? (Please use an additional page to explain changes.)

3. During the course of conducting the research project did any event occur that may have placed a human subject(s) at risk or caused any human subject to be harmed?

☐ no ☐ yes

If yes,

a. Please describe the situation (use a separate page if necessary).

b. Please describe efforts undertaken to minimize harm to the subject or modify the protocol to reduce the probability of similar harm occurring to future subjects (use a separate page if necessary).

Please return completed form to:
Institutional Review Board
CMB 1020