

Institutional Review Board Minutes
December 8,2003

Members present: Allen, Cohen, Coogan, Finney, Foster, Goodman, Preiss

The meeting was opened at 11:02 AM in Collins Memorial Library.

1) Review of Protocol #0304-005

The following issues were raised by members of the Board:

- A revised consent form was provided by the investigator to bring patient consent for the use of information obtained from medical chart records in compliance with HIPAA requirements for protection of patient privacy.
- It was suggested the survey could include N/A as a response option for some of the items.

The protocol was approved by unanimous vote (7-0-0).

2) Review of Protocol #0304-006

The following issues were raised by members of the Board:

- The protocol states that the principle investigator is “a UPS affiliated Research Scientist” when, in fact, he has no formally granted affiliation of this type with the University. Suggested remedies for this inaccuracy could be to remove this line and any similarly misleading statements from the protocol, related documents, and consent forms or make the coinvestigator, who is a UPS faculty member, the principle investigator of record.
- The investigators are directed to remove Robin Foster’s name from the informed consent form as an individual subjects may contact with questions regarding rights as a research subject and substitute the Office of the Associate Dean (253) 879-3207.

The protocol was approved by unanimous vote (7-0-0), pending the above revisions.

3) Review of Protocol #0304-007

The following issues were raised by members of the Board:

- A letter of agreement for the site to participate in this study from Rose House is required.

- The “second institution” must be identified and a letter of agreement to participate in this study also provided.
- The investigator needs to clarify inclusion/exclusion criteria related to the mental status of the participants? Will all participants be able to read and comprehend the informed consent form? Do any potential subjects from the sampling sites possess metacognitive disorders?
- The Board strongly recommends piloting the survey with a “member” of the population of interest.
- The consent form requires major revision to be an acceptable document for obtaining informed consent. The following must be addressed in the consent form:
 - Provide a correct estimate of the time required to complete the survey based on pilot testing and actual timing.
 - Describe all procedural elements in addition to the survey.
 - Use appropriate headings based on consent form template or samples.
 - Include a section on Risks & Benefits.
 - Include a section on Costs/Payments
 - Include a description of the subject’s right to refuse or discontinue participation without consequences.
 - Provide an investigators phone number for any questions participants may have.
 - Include a separate section and signature line for consent to videotape.
- The suggestion that data will be analyzed and stored in the student researcher’s home is inappropriate. Data must be kept on campus in a secured location.
- A full description of post survey procedures is required. Specifically, what participant behaviors will be observed and under what conditions, what will be asked in the semi-structured tape-recorded interviews, what will be the guiding questions or themes of the open-ended survey questionnaire specify the nature of “member produced documents, and what will be the guiding questions and/or themes for the “focus groups” and who will participate in them?
- This is not an IRB issue, however, the use of 80 subjects seems overly ambitious for a student research project working under a limited time frame. The board strongly suggests the student and faculty advisor consider reducing this sample size significantly. There appears no need to be wedded to the 40/40 sample.

The Board does not approve the protocol in its present form and will send it back to the investigator, faculty advisor, and departmental IRB designate for reconsideration and revision.

4) Meeting was adjourned at 11:57 PM.

Respectfully submitted,
Roger Allen, IRB Secretary