

MINUTES

Institutional Review Board August 12, 2010

Present: Lisa Ferrari, Petra Perkins, Garret Milam (chair), Grace Kirchner

Chair Milam called the meeting to order at noon. Kirchner agreed to serve as secretary for the day.

Orders of Business:

1. **Deliberation on Protocol 0910-17.** Key issues and questions included the following:

- The use of videotape to record some interviews was the issue that generated the most concern. Videotaping seems to increase risk that anonymity might be compromised and incriminating or compromising statements could become public. Furthermore, the investigators had not yet determined in what way they would use the videotaped interviews. The PI agreed that it would be better to eliminate the videotaping component of the research study from the current protocol with the understanding that the researchers could return at a later date seeking IRB approval for that component.
- Concern was expressed that the interviews might uncover social or psychological problems. The PI indicated that subjects would be referred to available resources and that such referrals were standard procedure.
- Because government funding is involved, there was concern that the government might have some control or ownership over the data. The IRB requested that the researchers determine whether or not this is the case.
- Subjects will likely speak a variety of languages, including some that are not commonly spoken. The PI explained that there are assistants who will be available for translation.
- The PI clarified how subjects would be recruited and how informed consent would be obtained. The PI explained why the informed consent was oral as opposed to written. Members agreed with the rationale and observed that written informed consent provides an undesirable linkage to subjects' identities. The consent form, however, needs to include more details about the audio taping and data storage, including potential uses of the data. Members expressed concern that data was going to be stored on laptop computers, which could make it vulnerable to being stolen or compromised. It was suggested that a more secure means of data storage be developed, including the possibility of using computers located in the United States.

Action: The committee voted unanimously to authorize Chair Milam to give final approval pending the changes noted.

2. Deliberation on Protocol 0809-17.

Action: This resubmission was approved as written.

3. Deliberation on Protocol 0910-016. Key issues and questions included the following:

- Members did not recall previously seeing a drawing that shows the placement of electrodes. One set of electrodes is low on the abdomen, which for some subjects might cause discomfort. Members concluded that whoever is placing the electrodes needs to ask permission to place them.
- The consent form needs to indicate more clearly that the study is not intended to assess the overall health of the subjects' hearts and those persons who know they have heart problems should not be participating.

Action: The committee voted unanimously to authorize Chair Milam to give final approval to the protocol pending these changes.

Respectfully submitted,

Grace Kirchner