

**Institutional Review Board Minutes  
December 17, 1997**

**Present:** Joe Detorri, John Finney, Ernie Graham, Paul Hansen, Suzanne Holland, Melissa Weinman, Tom Wells, Ann Ekes Wilson, .

Minutes of November 13, 1997 meeting were read and approved.

**Proposals considered:**

9798-014

The question was raised as to why this proposal was submitted for a full review. It was pointed out that one of the treatment techniques, while not known to be harmful, was not a standard treatment technique.

Approved: Vote, 7 Yes, 0 No

9798-015

No concerns were identified.

Approved: Vote, 7 Yes, 0 No

9798-016

It was explained that this proposal was submitted for a full review since the population that was to be studied has a high incidence of drug and alcohol use.

Recommendations: 1, Strike the last line under risks and benefits as it has the potential to offend the subjects. 2, Support in the experimental design why one gender is selected to the exclusion of the other.

Approved with inclusion of recommendations: Vote, 7 Yes, 0 No

9798-017

It was explained that this proposal concerned incarcerated juveniles.

Questions were raised about the complexity and relatively high reading level of the informed consent. Committee members raised concerns that the juveniles who were to read this form may not be able to understand the language used.

Questions were also raised as to the lack of labeling of the difference for the two forms.

It was suggested that there was a possibility that by having supervisors identify subjects who would be good participants there was a potential of risk to the subjects. It was suggested that by changing the means by which this identification took place that this risk could be minimized.

Approve: 1 Yes, 6 No

Reject: 0 Yes, 7 No

Approved with above modifications: 7 Yes, 0 No

9798-018

A question was raised if the subjects were able to understand what "self efficacy" meant in the informed consent. Given the targeted population it was suggested that a clearer statement could be used.

Since it was possible that the subjects may feel that the overt observation of their behaviors may be discomfoting, it was asked that the authors identify the discomfort of being observed as a potential risk in the subject's informed consent.

Approved with modification: 7 Yes, 0 No

9798-019

In general the proposal was unclear as to the purpose, methods, and risks.

Approve with modifications: 0 Yes, 6 No

No action: 6 Yes, 0 No

9798-020

Two items requiring completion or further explanation were identified: 1) Signatures of all investigators are missing on the application. and 2) Who would be handling the urine specimens and how would those fluids would be safely handled?

Approved with modifications: 6 Yes, 0 No

Three additional questions concerning proposals, consent forms and exclusion of one gender from studies were raised and broadly discussed.

1. Many of the proposals have been written in the past tense. It has been explained that this is done to minimize the number of re-writes once data have been collected. It was suggested that the use of the past tense suggested that the work had already been completed, although it had not. It was suggested, that if an researcher decided to use the past tense to describe data collection procedures then it would be best to include a short statement of the reasons as to why this was done.
2. It was pointed out that many of the informed consents seem to be too technically written or to contain professional or academic jargon. These attributes of the informed consent may reduce the ability of the subject to comprehend the risks and benefits of the experiment to which they are consenting. It was suggested that the revised IRB guidelines may address this concern. The discussion was tabled until the discussion of the revised IRB guidelines.
3. The question was raised if it was the responsibility of the IRB committee to establish that the researcher had justified why they chose to exclude one particular gender. It was pointed out that both the military and NIH both require such justification. Tom Wells and Joe Detorri volunteered to follow-up on this question for the committee.

Potential meeting times for spring semester were discussed.

Regular meetings during spring semester will be held on the fourth Wednesday of each month from 8:00 am to 9:00 am in C-105 of South Hall.

The meeting dates are as follows: January 28, February 25, March 25, April 22. If additional meetings are necessary, they will be scheduled for Friday afternoons at 3:00 pm. The IRB will meet at least once during the term at this time. The date will be announced later.

The next IRB Committee will be on Wednesday, January 28, 1998 at 8:00 am.

Ann Ekes Wilson adjourned the meeting

Respectfully submitted,

Paul Hansen