

Institutional Review Board Minutes

October 15th 2009

I. Call to Order:

Meeting was called to order at 9:04 am.

Members present: (Scientific/Non-scientific)

In Person: Dr. Eddie Clark, Dr. Dianne Barron, Dr. Shari Hoppin, and Dr. Carol Moore.

Via V-Tel: Dr. Glenda Avery, Dr. Terry Anderson, Dr. Richard Cardarola, Ms. Sheila Bennett, Dr. Daneell Edwards, and Dr. Isabelle Warren

Via Phone: Dr. Tim Buckner and Dr. Robert Abbey

Absent with notice: Dr. Brad Willis, Dr. Dennis Self, and Mr. Chase Taylor (Non-Scientist)

II. Approval of Minutes

The IRB board members decided not to approve the minutes until some changes are made.

III Report on productivity

Since September 17th 2009, the IRB received the total of six applications. One was Exempt, one was Full Review and four were Pending. Two applications were submitted by students and four were submitted by faculty.

IV Review of Research Proposal:

A) Investigator A

Once the student gave an overview of the study and answered some questions; the IRB board members decided to approve the study with the recommended changes. Ms. Bennett made a motion to approve the study with the recommended changes. Dr. Hoppin seconded. The motion carried with all was approved.

B) Investigator B

The investigator started by giving an overview of her proposal than answered IRB board members questions.

The board members decided not to approve the study as is and made the following recommendations:

- Students working with the PI have to take the IRB training.
- Remove the University of Georgia from the informed consent.
- Add the statement, “This research has been reviewed and approved by the Troy University Institutional Review Board. For questions about the rights of research participants, contact the IRB at 334-808-6294 or irb@troy.edu” to the informed consent.

Dr. Hoppin made a motion to approve the study with recommended changes. Dr. Moore seconded. The motion carried with all was approved. Dr. Clark will review the changes.

C) Investigator C

The investigator gave an overview of his proposal and answered the IRB members’ questions.

Upon reviewing the principal investigator’s comments and the application, the IRB Board members motioned unanimously that the proposal needs additional review and can not be approved at the moment.

The following changes were requested:

1. Have a medical doctor review the study
2. Taking birth control pills needs to be considered as a criterion for exclusion from the study. Provide a response to this concern
3. Include the validation of the Health history Questionnaire as an instrument suitable for interpretation by non medical personnel and describe the ACSM procedures for the interpretation of “low risk” subjects
4. Include monitoring of the blood pressure changes throughout study as a safety precaution
5. Identify source of Echinacea and verification of dosage amount. Identify source of placebo
6. provide evidence of Echinacea dosage safety based upon U.S. studies
7. Refrain from exercise for 48hrs or 24hrs before testing? Contradiction between appendix and method section-clarify
8. Need evidence of training of researchers in CPR, and phlebotomy training
9. Provide Emergency Action Plan and ensure available AED in laboratory
10. Certification of lab/ adherence and knowledge of OSHA blood handling procedures- need some form of documentation of ability to properly adhere to procedures and dispose of blood contaminated items
11. Produce evidence of researcher’s liability insurance

Mrs. Bennett made a motion to table the study. Dr. Anderson seconded. Changes will be reviewed by the full board in next meeting.

V Miscellaneous

Some of the proposals discussed raised the issue as to whether the institutional review board should interfere in the design of the proposals reviewed.

IRB board members concurred that the thesis chair and supervisors should have more concrete roles in the protection of the human participants, while designing protocols with researchers.

IRB members are in the process of developing guidelines for faculty responsibility in the proposal process. A subcommittee has been created with the goal of reviewing the IRB policies, procedures, and guidelines.

VI Adjourn:

Meeting adjourned at 10:55 am.