

Institutional Review Board

April 16th, 2009

I. Call to Order:

Meeting was called to order at 9:00 am

Members present: (Scientific/Non-scientific)

In Person: Dr. Janet McNellis, Dr. Shari Hoppin, Dr. Eddie Clark, Dr. Stephen Landers and Mr. Chase Taylor (Non-Scientist)

Via V-Tel: Dr. Glenda Avery, Dr. Richard Caldarola, Dr. Isabelle Warren, Dr. Dennis Self, Dr. Carol Moore and Ms. Sheila Bennet

Via Phone: Dr. Robert Abbey

Absent with notice: Dr. Terry Anderson, Dr. Dianne Barron and Dr. Brad Willis

Absent with no notice:

II. Approval of Minutes:

Dr. Janet McNellis made a motion to approve the minutes with the recommended changes. Dr. Shari Hoppin seconded. The motion carried with all approved.

III Chair Comments on IRB Productivity:

Since March 19th, the IRB received the total of 17 proposals. 2 proposals are pending, 13 are Exempt and 2 require Full Review. 3 applications are collaboration between students and faculty. 9 were submitted by students and 5 were submitted by faculty.

IV Review of Research Proposal:

A) Dr. Green Michael & Dr. Taylor (Caffeine Study)

Upon hearing the proposal's overview and discussing potential risks, the board members decided not to approve the study as is and made the following recommendations.

In the Recruitment Materials:

- Change the minimum age of participation to 19 or older.

In the Informed Consent Document:

- Insert a statement that if any physical or mental health issues are identified, participants will be given a referral to appropriate treatment options.
- In the "Voluntary Participation and Withdrawal section, change the statement, "However, any information already used to the point when you withdraw consent may not be removed." to "If you decide to end your participation, you may also choose to have all data collected on you removed from the study and destroyed."
- Change the IRB contact statement to "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"
- Explain what will be done with the health history forms (who will have access to them, where they will be stored, when they will be destroyed).

In the Health History Document:

- Instead of asking for BMI, measure their height and weight and calculate BMI based on this.
- Include a question asking if they are pregnant.
- Include a question asking if they are on a collegiate athletic team.
- Include "epilepsy" in the medical diagnosis section.
- Include a question specifically asking if they are using any blood thinners, including aspirin.

In an Addendum statement (this may be an emailed statement):

- State that you will ask participants to show you proof of health insurance.
- State that the minimum age of participants will be 19.
- State that pregnant individuals will be excluded from the study.
- State that collegiate athletes will be excluded from the study.
- State that you will follow all TROY University-level, College-level, and Departmental-level guidelines for safe collection, storage and disposal of blood and blood-collection instruments.
- Give the name of a medical consultant to whom you can refer participants in case physical injury occurs as a result of study participation.
- State that you understand that if any unforeseen adverse reactions occur, or if any serious injuries occur to any participant, you will suspend your study immediately and will notify the IRB.

Dr. Janet McNellis stated that the protocol will not be approved until the recommended changes are made. She added that this protocol does not need to go through a Full Board review again: The Board has given Dr. McNellis the authority to issue approval if the changes are made and no other changes are made to the protocol. Dr. Clark motioned and Dr. Landers seconded. Two members however abstained from voting on the protocol due to concerns about the data collection strategy, subjects' protection and legality issues.

C) Dr. Michael Green, Dr. Brandon Sluder & Mr. Tyler Martin

Upon discussing some elements of the proposal with the investigators and reviewing the overall study, the IRB board members decided not to approve the study as is. They made the following recommendations:

In the Recruitment Materials:

- Change the minimum age of participation to 19 or older.

In the Informed Consent Document:

- Insert a statement that if any physical or mental health issues are identified, participants will be given a referral to appropriate treatment options.
- In the "Voluntary Participation and Withdrawal section, change the statement, "However, any information already used to the point when you withdraw consent may not be removed." to "If you decide to end your participation, you may also choose to have all data collected on you removed from the study and destroyed."
- Change the IRB contact statement to "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"
- Explain what will be done with the health history forms (who will have access to them, where they will be stored, when they will be destroyed).
- State whether data will be shared with coaches or anyone outside the research team.

In the Health History Document:

- Change asking for the "date of birth" to asking for "Age".
- Include "epilepsy" in the medical diagnosis section

In an Addendum statement (this may be an emailed statement):

- State that you will ask participants to show you proof of health insurance.
- State that there will be an AED at all testing locations.

Dr. Janet McNellis stated that the protocol cannot be approved as is. Dr. Hoppin made a motion not to approve the study until the recommended changes are made and that Dr. McNellis will review the changes. Dr. Clark seconded. The motion carried with all approved.

V IRB Training:

Dr. Janet McNellis announced that the IRB training site is complete and ready to be used. She encouraged board members to review the training and take the quiz in order to give some feedback.

VI Miscellaneous:

In agreement with the board members, Dr. McNellis stated that the May IRB meeting will be scheduled as needed.

VII Adjourn:

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Meeting adjourned at 10:44am.