

INSTITUTIONAL REVIEW BOARD MINUTES

APRIL 19, 2012

I. Call to Order:

Meeting was called to order at 9:05am

Members Present:

Total	10
Voting Members	9
Non-scientists	2

Quorum was met, Attendance was as follows:

Members	In Person	Via Phone	Via Vtel	Absent	Absent with notice	Voting Member
Tim Buckner (chair)(NS)	X					YES
William Foxx					X	YES
Shari Hoppin (NS)	X					YES
Glenda Avery			X			YES
Gina Mariano	X					YES
Emma Peden				X		YES
Eddie Clark			X			YES
Christopher Pritchett			X			YES
Frank Hammonds					X	NO
Richard Caldarola				X		YES
Dionne Rosser-Mims			X			YES
Robert Abbey		X				YES
Susan R. DuBose (NI)			X			YES
Chase Taylor (NS)(NI)				X		YES
Janet McNellis (HPA)	X					No
NS: Non-scientist member / NI: Non-institutional member						

Dr. Buckner left the meeting early at 10 :03

Dr. DuBose enters the meeting late at 9:11

II. Approval of Last Meetings' Minutes

a. Febuary 16, 2012

b. March 8, 2012

c. March 20, 2012

Motion to approve all minutes: Dr. Abbey

Second: Dr. Clark

The Motion Passed Unanimously

III. Chair Comments on IRB Productivity

Report on Applications:	<u>Annual</u>
<u>Total</u>	<u>60</u>

Expedited	45
Exempt	2
Full Review	4
Pending	7
Cancelled	1
<u>Other University Approval</u>	<u>1</u>
Student	9
Faculty	15
Student/Faculty	36

IV. Full Review of Research Proposals

a. Kerri Outlaw: A Family Based Intervention for Management of Childhood Obesity

Discussion Begins and Applicant and Advisor enter at 9:12

Explanation of Project 9:13 to 9:20

Questions 9:20 to 9:34

- How long will session be? About an hour, possibly on Tuesday nights.
- Will the children have pedometers? Yes, they have been donated.
- What are the criteria for referral? The applicant will let the physician refer the child at their discretion.
- You ask about the parents, so are the parents part of the activity? No, it should be children. There is a wording issue.
- Do you have copyright privileges for your chart, ect? The applicant will check and provide proof.
- You cannot have a child sign a waiver. Can you remove the waiver from your project? Yes.
- Could you please include the time factor in your informed consent and that a participant can withdraw at anytime (participation is voluntary) and that there might be harm? And also could you update the IRB Information? Yes
- Will there be Spanish speaking participants? No, mainly because of transportation limitation. (Provider recommendation)
- Do you see problems/risks with conducting activities at the participant's home? No, the applicant's specialty is in home care and home health. She perceives families are much more receptive if they are comfortable with the researcher. She does not see any safety issues and does not think she would be referred children with home safety issues.
- Will the participants be in Troy? They will be in Pike County, but based on referrers the applicant and advisor believe the participants will mostly be from Troy.
- Have you considered how cultures affect habits? Yes, it's actually in her literary review.
- The cost is \$460, but there isn't any funding so where is the money coming from? Donations. Applying for a grant (Sigma Theta Tau Nursing Honors Society).

Applicant and Advisor exit at 9:39

Summary:

- Add "hour long" time factor to methodology and consent form.

- In the consent form specify participation is voluntary and that the participant can withdraw at any time.
- The consent form should mention the participant will have to wear a pedometer.
- The consent form should include potential for injury.
- Do not use waiver in study.
- Include Institutional Review Board information in study.
- Update wording that sounds like you are asking for parent participation.
- Change grade level of reading documents being read to participants/children to first or second grade reading level.

Vote: Motion to not approve as written and allow the IRB chair to review changes and approve: Dr. Clark, Second: Dr. Mariano, Passes unanimously

Applicant and Advisor enter again at 9:42

Applicant and Advisor exit 9:43

b. Rachel Jones: Effects of Caffeine Consumption on Strength Performance in the Lower Body

Discussion Begins and Applicant enters at 9:44

Explanation of Project 9:44 to 9:46

Questions 9:46 to 10:06

- The language might construe the risks. The leg press has risks. Can you include this in your project? Yes.
- Would you stop participants consuming caffeine? Yes, 24 hours prior to study. The participant may resume caffeine consumption after study. NOTE: this is included in the methodology, but needs to be included in the informed consent and stated clearly)
- Mention that discomfort may result from 24 hours without caffeine. Okay.
- How did you decide the level of caffeine? Applicant mimicked other study.
- Are there certain ages of the participants? No, but there are multiple ages at the gym.
- What are the exclusion criteria? If a participant is high risk they cannot participate. Moderate to low risk can participate. Pregnant women cannot participate. NOTE: exclusion criteria need to be clearer.
- Could someone be allergic to the powder or the Gatorade? Possibly, she will find out what allergens are in these and ask in advance.
- Who will be present during the process? Applicant and participant, but AED will be present and the study is 50 feet from hospital. The study is conducted in a hospital gym and she is CPR trained.
- How long is the session? 30 to 40 minutes
- The explanation about how you determine the weight is confusing. Can you provide a better explanation? And also the definitions of maximal and submaximal? Yes.
- As for the risk of confidentiality, who has access to this information? How will it be used? How will the participant be separated from the data? She will explain the risk of confidentiality.
- Are all the questions on your questionnaires necessary? Would you use any of them to exclude participants? No. Possibly. She will revise the questionnaires.

-How do you see the role of the fitness expert? How will the fitness expert interact with the participant? The fitness expert is the applicant. She has the degree and training. NOTE: maybe include in methodology.

-You might want to include a list of side affects. Okay.

Applicant Steps Out and Further Discussion 10:06

-Does she need permission from the hospital? Board decided yes.

-Should a physician sign off or permission from participant's provider? Board decided this was excessive.

-She needs a consistent questionnaire. Board agrees.

-Her email address is wrong on the consent form and should be correct. Board agrees.

Summary

-Obtain a second doctor's opinion

-Include in consent form and methodology that participant should not consume caffeine 24 hours prior to participation.

-Include in consent form and methodology potential for injury from leg press (address the risks).

-Clarify exclusion factors.

-Identify allergens specific to your study (i.g. in the Gatorade) and incorporate them into the questionnaires.

-Clarify max and submax.

-Include in methodology that you will ask participants if they are okay to leave.

-Obtain written permission from research site to conduct study.

-Consent form should indicate estimated duration of each session.

-It needs to be stated in you methodology that if high risk individuals are identified, you will refer them to a physician.

Vote: Motion to not approve as written and allow IRB chair to review changes and approve: Dr. Hoppin, Second: Dr. Avery, Passed unanimously

Applicant enters at 10:20

Applicant exits at 10:21

V. Discussion of Prior Meetings Full Review Research Proposal

Dr. Vicki Lindsay: Alabama Law Enforcement Officer's Alcohol Consumption Study
Comments

-The application should have a consistent verb tense and gender reference (i.e. all 1st, 2nd or 3rd person and all masculine or feminine).

-The survey monkey link needs to be more local. The current one is in Australia.

VI. Comments from HPA

-Next meeting is May 17th

XII. Adjourn

Motion to Adjourn: Dr. Clark

Second: Dr. Pritchett

Meeting ends at 10:29