

INSTITUTIONAL REVIEW BOARD MINUTES

May 21, 2015

I. Call to Order:

A. Meeting called to order at 9:06 am.

Members Present:

Total 10

Voting Members 9

Non-scientists 2

B. Members Absent 5

Quorum met, Attendance was as follows:

Members	In Person	Via Phone	Via Vtel	Absent	Absent with notice	Voting Member
Xiaoli Su (Chair)	X					YES
Karen Ross (NS)	X					YES
Jonathan Taylor		X				YES
Gurumani Manish					X	YES
Joel Campbell			X			YES
Cozetta Shannon					X	YES
JeeHae (Helen) Lee			X			YES
William Heisler		X				YES
Sandra Pollock		X				YES
Susan Sarapin					X	YES
Michael Green				X		YES
Tom Reiner			X			YES
Chase Taylor (NI)(NS)				X		YES
Kathleen Sauer (NI)(NS)	X					YES
Dianne Barron (ExOfficio)(HPA)					X	NO
NS: Non-scientist member / NI: Non-institutional member						
Guest : Mary Anne Templeton, Associate Dean						

II. Approval of IRB Minutes

Approval of IRB Minutes from the April 16, 2015 meeting:

Motion to approve the minutes: Dr. Campbell; Second: Dr. Heisler

The motion passes unanimously

III. IRB Productivity: Chair Comments and IRB Discussion

- A. Exempt Applications: 0
- B. Withdrawn: 1
- C. Expedited Approvals: 3
 - 1. 201504003-Mack & Harris: Motivating and Instilling Sophisticated Students (MISS) into an Elite Society Leadership Program. Faculty/Troy. Dr. Su & Ms. Sauer. Expedited.
 - 2. 201503006-Faircloth,...Fu: Brick and Mortar Vs. Online Education. Collaborative/Troy. Dr. Su & Dr. Pollock. Expedited.
 - 3. 201503005-Conner: Leadership ratings and preferences: Comparing four domains of leadership strengths among school building leadership teams. Faculty/Dothan. Dr. Su & Dr. Taylor. Expedited.
- D. Outside Research Applications Pending: 0
- E. Outside Research Approvals: 1
- F. Continued Review Approvals and Modifications: 0
- G. Pending Full Review: 4
 - 1. 201504005-Gamble: A Rewards Based Discipline Program for Seventh Grade Students to Reduce Tardiness, Truancy, In School and Out of School Suspensions. Student/Phenix City. Full.
 - 2. 201504008-Perry: Effectiveness of a Walking Program on Reducing Body Mass Index (BMI), Body Weight, and Waist Circumference (WC) in Obese Adults 19-55 Years of Age. Student/Troy. Full.
 - 3. 201505001-Smith: Pediatric Sleep Assessment and Educational Intervention for Parents. Student/Troy. Full.
 - 4. 201505005-Crittenden: The Impact of Health Coaching on Lifestyle Modification in the Management of Hypertension in a Primary Care Setting. Student/Troy. Full.
- H. Full Review Approvals: 3
 - 1. 201503003-Turner: Pre-incision verses post incision intravenous acetaminophen in laparoscopic cholecystectomy patients: Impact on rescue opioids postoperatively. Student/Troy. Full.
 - 2. 201503008-Dunlap: Implementation of an Evidence-based Tool with Parkinson's disease Patients to Improve Motor Function. Student/Dothan. Full.
 - 3. 201504002-Brunner: Evidence-based Weight Loss. Student/Troy. Full.
- I. Pending Expedited Review: 3
 - 1. 201505004-Koo: The Development of Scenario Based Time Management Programs for Student-Athletes. Faculty/Troy. Dr. Su & Dr. Sarapin. Expedited.
 - 2. 201504010-Miller: The Effect of Relaxation Techniques on Test Anxiety in the First Semester Nursing Student. Student/Troy. Dr. Su & Dr. Ross. Expedited.
 - 3. 201504007-Reiner: Personality Traits Associated with Level of Cognitive Development, Preferred Thinking Style, and Belief in the Paranormal. Dr. Su & Dr. Heisler. Expedited.
- J. Pending Review: 4
 - 1. 201504009-Furr: Implications of Drug Shortage Among Alabama Certified Registered Nurse Anesthetists. Student/Troy. Dr. Su & Dr. Taylor. Expedited.

2. 201504011-Lipford: Needs Assessment of an Electronic Health Record at an Inpatient Psychiatric Hospital. Student/Troy. Dr. Su & Dr. Lee. Expedited.
 3. 201505002-Lippold: Improving Pneumonia Vaccine Compliance in Older Adults. Student/Montgomery. Initial.
 4. 201503004-Van Doorn: Balance of Workplace Benefits and Family Responsibility. Faculty/Phenix City. Full.
- K. Needs Revisions or Information: 11
1. 201409006-Lawton: The Classroom Teacher's Role in Digital Assessment. Faculty/Global. Dr. Su & Dr. Ross. Expedited.
 2. 201410003-Hamby & Wheatley: Instructional Methods Survey and Student Satisfaction. Faculty/Troy. Dr. Su & Dr. Ross. Expedited.
 3. 201501002-McDonald: The Hiring Game. Faculty/Troy. Initial.
 4. 201502018-Kelly: Factors that Relate to Decision Making: Observing Stress, Age, Personality and Peer Pressure. Student/Phenix City. Expedited.
 5. 201409004-Walls & Long: An Examination of the Relationship between Product Selection and the Extent to which Individuals Identify With Their Favorite College Football Team. Student/Phenix City. Dr. Su & Dr. Lee. Expedited.
 6. 201504004-Nichols: Tattoos in Today's Law Enforcement. Student/Troy. Expedited.
 7. 201504012-Dawson & Arrington: Troy University COE Mentoring Project. Faculty/Montgomery. Dr. Su & Dr. Manish. Expedited.
 8. 201504001-Mixon-Carter: Caring in Simulation. Student/Troy. Dr. Su & Dr. Shannon. Expedited.
 9. 201504006-Schaefer: Hinduism Within the Wiregrass Area. Student/Dothan. Initial.
 10. 201503007-Platt & Ash: The Effect of Postural Stability and Postural Stability Training at leg lift of the pitching motion on Pitching Efficiency and Upper Extremity Pathology. Faculty/Troy. Full.
 11. 201505003-McDougal: Development of a Protocol for the Management of Chronic Pain by a Nurse Practitioner in a Primary Care Setting. Student/Montgomery. Initial.

IV. Review of Current Proposals for Full Review:

- A. 201504008-Perry: Effectiveness of a Walking Program on Reducing Body Mass Index (BMI), Body Weight, and Waist Circumference (WC) in Obese Adults 19-55 Years of Age. Student/Troy. Full.
 1. Full review of protocol begins at 9:16 am. Merry Perry was present via phone.
 - a. Merry Perry provides an overview of the study.
 - b. Merry Perry answers questions from IRB members from 9:19 to 9:25 am.
 - c. Merry Perry exits meeting at 9:25 am.
 - d. Discussion continues from 9:26 to 9:44 am.
 2. Summary of Discussion and Recommendations:
 - a. Description of Participants and Recruitment
 - i. Needs to keep the number of participants consistent throughout the application. In one place, the PI indicates the number as 20-30; in other places, the PI says 30.

- ii. Needs to state that, after the participants sign up for the research, the PI will ask the physician to sign off as to the participants' fitness to take the walk.
- iii. Needs to include the P.I.'s information, e.g., name, title, institutional affiliation on the recruitment flyer.
- iv. Needs to clearly state that the purpose of the project is "to examine the effect of among obese adults."
- b. Methodology
 - i. Needs to clearly state the time commitment expected from the participants, including initial meeting, greeting session, pre-assessment, group walk, etc.
 - ii. Needs to justify why the PI will collect the demographic information and how to use the information.
- c. Risks of Participation
 - i. Needs to state that there are risks of physical injury and how to handle physical injury if it occurs. In addition, the PI needs to let the participants know that, if they feel discomfort or pain, they need to stop immediately.
 - ii. Needs to clearly state how and where the data will be stored, who will have access to the data, how long the data will be stored.
- d. To informed consent
 - i. Needs to revise "Only Merry Perry will have access to your information." to "Only I will have access to your information."
 - ii. Needs to revise "Your relationship with the researchers will not be affected by your choice to participate or not." to "Your relationship with your physician will not be affected by your choice to participate or not or your withdrawal from the research."
 - iii. Needs to clarify the time commitment (Saturday session: 15 question time + 45 group walk + 30 minutes for questions, submitting log, and taking the measurements).
 - iv. Needs to clearly state that the participants are expected to walk 150 minutes each week as a part of the intervention.
 - v. Needs to revise "You may notice reduced weight as a benefit from walking." to "Some of you may notice reduced weight as a benefit from walking."
 - vi. Needs to clearly state that there is no compensation for the participation.
 - vii. Needs to clearly state where the data and the informed consent will be stored.
 - viii. Needs to revise to reflect the revisions in the Risks of Participation section of the application (the risks of physical injury, how to handle when physical injury occurs, and a statement to waive liability).
 - ix. The readability level cannot be higher than 8.
- 3. Vote: Motion Not Approve as Written: Dr. Ross, Second; Dr. Campbell. Motion passes unanimously at 9:45.

4. Vote: Motion for Chair to review revised Application: Mrs. Sauer, Second Dr. Campbell. Motion passes unanimously at 9:45.
- B. 201505001-Smith: Pediatric Sleep Assessment and Educational Intervention for Parents. Student/Troy. Full.
1. Full review of protocol begins at 9:47 am. Sonia Smith was present for review via phone and Dr. Bernita Hamilton was present via Vtel.
 - a. Sonia Smith provides an overview of the study.
 - b. Sonia Smith answers questions from IRB members from 9:51 to 9:55 am.
 - c. Sonia Smith and Dr. Bernita Hamilton exit meeting at 9:55 am.
 - d. Discussion continues from 9:55 to 10:26 am.
 2. Summary of Discussion and Recommendations:
 - a. Description of Participants and Recruitment
 - i. In this proposed research, the children shall be treated as participants.
 - ii. Needs to keep the number of participants consistent throughout the application.
 - iii. Needs to provide recruitment materials.
 - b. Methodology
 - i. Needs to clearly state the time commitment expected from the participants.
 - ii. Needs to explain how the completed survey will be collected and how to protect the confidentiality of the survey data. It is recommended that the PI does not let the children to take back the survey. Using self-addressed (e.g., the addresses of both the sender and receiver are the PI's address), stamped envelope for the parents to mail back the survey to the P.I. is a better way to keep the survey data confidential.
 - c. Risks of participation
 - i. Needs to rewrite this section to reflect the changes in the following areas:
 - a) To address potential coercion issues. The PI needs to clearly state that the P.I. will inform the children and their parents that their refusal to participate or withdrawal from the research will not affect the relationship between the children and their teachers, their standing in the classes, and benefits that they otherwise are entitled.
 - b) To address the potential upset or discomfort that children may experience due to the intervention and the measures to minimize this risk.
 - c) To address the issue that parents may feel anxious about child's sleeping problem, e.g., the PI needs to let the parents know, if they feel anxious, they may stop participating in the research immediately. Whom to contact if help is needed.
 - ii. Needs to clearly state where and how the data will be stored, who will have access to the data, and how long the data will be stored.
 - d. Informed Consent Process
 - i. Needs to rewrite the informed consent process section since children are treated as participants in the proposed research.

- e. To Informed Consent
 - i. Needs to rewrite the informed consent for parent's participation to reflect the revisions in the application.
 - ii. The IRB waives the informed consent for children's participation. The P.I. will only need to provide the informed consent for parents' participation. Children's verbal assent and Parental consent for children's participation are not required.
 - iii. In the informed consent, the P.I. needs to make it clear that: The P.I. will provide the education or educational materials on sleep intervention for parents. However, it is optional whether or not the parents will use these intervention at home on their children. In other words, it is the parents' choice/decision as to whether or not to use the intervention on their children.
 - iv. In the informed consent, the P.I. needs to clearly state that there is no interaction between the children and the P.I.
 - v. The P.I. cannot refer children with potential sleep problems to the school nurses, staff, or other school authority. The P.I. may inform the parents, if they see potential sleep problems in children, and make the recommendation that they seek medical diagnosis and help from pediatrician.
- 3. Vote: Motion Not Approve as Written: Mrs. Sauer, Second; Dr. Campbell. Motion passes unanimously at 10:27.
- 4. Vote: Motion for Chair to review revised Application: Dr. Campbell, Second Dr. Pollock. Motion passes unanimously at 10:28.
- C. 201505005-Crittenden: The Impact of Health Coaching on Lifestyle Modification in the Management of Hypertension in a Primary Care Setting. Student/Troy. Full.
 - 1. Full review of protocol begins at 10:28 am. Darlene Crittenden was present for review via phone and Dr. Bernita Hamilton was present via Vtel.
 - a. Darlene Crittenden provides an overview of the study.
 - b. Darlene Crittenden answers questions from IRB members from 10:30 to 10:36 am.
 - c. Darlene Crittenden and Dr. Bernita Hamilton exit meeting at 10:36 am. Discussion continues from 10:36 to 10:51 am.
 - 2. Summary of Discussion and Recommendations:
 - a. Methodology
 - i. Needs to clearly state the time commitment expected from participants (e.g., time for in-depth explanation of study. How long will be the meeting? How long will be the education session?)
 - ii. Needs to clearly state that the PI will be the health coach.
 - iii. Needs to ask for the physician's clarification in his support letter. In the letter, the physician only indicates that a copy of blood pressure measurement at the first visit (pre-assessment) will be provided. The PI indicates that both pre-assessment and post-assessment will be provided by the physician. In addition, is the facility where the research will take place the physician's own practice or does the

physician only work there and there is a director of the facility? If it is the latter, a letter of support from the facility director is needed.

b. Risks of Participation

- i. Needs to address the risks of physical injury. In case unexpected physical injury occurs, whom the participants are expected to contact and who will be responsible for the expenses?

c. To Informed Consent

- i. Needs to clearly state the time commitment expected from the participants.
 - ii. Needs to delete "Your physician has agreed to manage any medical concerns found during this study." This is not shown in the letter of support from the physician. The P.I. may simply state that, if the participants have any medical concern during this study, please contact their physician (at their own expenses).
 - iii. Needs to inform the participants about the economic risks involved in the research and clearly state who will be responsible for the expenses.
 - iv. Needs to let the participants know that, if they feel discomfort or distress, they need to stop participating in the research immediately.
 - v. Needs to revise "If you smoke, your health coach will assist you to stop smoking." to "If you smoke, your health coach will assist you in your attempt to stop smoking."
3. Vote: Motion Not Approve as Written: Dr. Heisler, Second; Dr. Pollock. Motion passes unanimously at 10:51.
 4. Vote: Motion for Chair to review revised Application: Dr. Campbell, Second Dr. Ross. Motion passes unanimously at 10:52.

- V. Discussion of Corrections and Updates to Research proposals under Full Review:
- A. 201503003-Turner: Pre-incision versus post incision intravenous acetaminophen in laparoscopic cholecystectomy patients: Impact on rescue opioids postoperatively. Student/Troy. Approved.
 - B. 201503008-Dunlap: Implementation of an Evidence-based Tool with Parkinson's disease Patients to Improve Motor Function. Student/Dothan. Approved.
 - C. 201504002-Brunner: Evidence-based Weight Loss. Student/Troy. Approved.

VI. New Business and Information Items:

The revised review form is ready and will be voted on at the June IRB meeting

VII. Adjourn

Motion to Adjourn: Dr. Ross, Second: Dr. Campbell.
Motion passed unanimously.
Meeting adjourned 10:54 am.