

INSTITUTIONAL REVIEW BOARD MINUTES

July 16, 2015

I. Call to Order:

A. Meeting called to order at 9:25 am.

Members Present:

Total 9

Voting Members 8

Non-scientists 1

B. Members Absent 6

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
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 June 18, 2015 meeting:

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

III. IRB Productivity: Chair Comments and IRB Discussion

A. Exempt Applications: 0

- B. Withdrawn: 1
- C. Expedited Approvals: 1
 - 1. 201504011-Lipford: Needs Assessment of an Electronic Health Record at an Inpatient Psychiatric Hospital. Student/Troy. Dr. Su & Dr. Lee. Expedited.
- D. Outside Research Applications Pending: 0
- E. Outside Research Approvals: 0
- F. Continued Review Approvals and Modifications: 0
- G. Pending Full Review: 2
 - 1. 201504009-Furr: Implications of Drug Shortage Among Alabama Certified Registered Nurse Anesthetists. Student/Troy. Full.
 - 2. 201505002-Lippold: Improving Pneumonia Vaccine Compliance in Older Adults. Student/Montgomery. Full.
- H. Full Review Approvals: 0
- I. Pending Expedited Review: 0
- J. Pending Review: 3
 - 1. 201504012-Dawson & Arrington: Troy University COE Mentoring Project. Faculty/Montgomery. Dr. Su & Dr. Manish. Expedited.
 - 2. 201505003-McDougal: Development of a Protocol for the Management of Chronic Pain by a Nurse Practitioner in a Primary Care Setting. Student/Montgomery. Initial.
 - 3. 201506002-Sarapin & Vo: Coming to Terms with Online Click-to-Sign Contracts. Collaborative/Troy. Initial.
- K. Needs Revisions or Information: 19
 - 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. 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.
 - 5. 201504004-Nichols: Tattoos in Today's Law Enforcement. Student/Troy. Expedited.
 - 6. 201504001-Mixon-Carter: Caring in Simulation. Student/Troy. Dr. Su & Dr. Shannon. Expedited.
 - 7. 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.
 - 8. 201503004-Van Doorn: Balance of Workplace Benefits and Family Responsibility. Faculty/Phenix City. Full.
 - 9. 201504007-Reiner: Personality Traits Associated with Level of Cognitive Development, Preferred Thinking Style, and Belief in the Paranormal. Dr. Su & Dr. Heisler. Expedited.
 - 10. 201505001-Smith: Pediatric Sleep Assessment and Educational Intervention for Parents. Student/Troy. Full.

11. 201502018-Kelly: Factors that Relate to Decision Making: Observing Stress, Age, Personality and Peer Pressure. Student/Phenix City. Dr. Su & Dr. Pollock. Expedited.
12. 201504010-Miller: The Effect of Relaxation Techniques on Test Anxiety in the First Semester Nursing Student. Student/Troy. Dr. Su & Dr. Ross. Expedited.
13. 201505006-Allen: Paper Reminder Strategy: Increasing Adult Vaccination Against Pertussis. Student/Troy. Initial.
14. 201505007-Ellis & Green: Evaluation of Social Work Case Management Role in HIV. Collaborative/Dothan. Initial.
15. 201505004-Koo: The Development of Scenario Based Time Management Programs for Student-Athletes. Faculty/Troy. Dr. Su & Dr. Sarapin. Expedited.
16. 201504006-Schaefer: Hinduism Within the Wiregrass Area. Student/Dothan. Initial.
17. 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.
18. 201506001-Mariano, Arrington, Dawson & Doss: Faculty Research Mentoring Needs: How Can We Help? Faculty/Troy. Initial.
19. 201505005-Crittenden: The Impact of Health Coaching on Lifestyle Modification in the Management of Hypertension in a Primary Care Setting. Student/Troy. Full.

IV. Review of Current Proposals for Full Review:

- A. 201505003-McDougal: Development of a Protocol for the Management of Chronic Pain be a Nurse Practitioner in a Primary Care Setting. Student/Montgomery. Full.
 1. Full review of protocol begins at 9:31 am. Ginger McDougal and Dr. Robin Farrell were present for review.
 - a. Ginger McDougal provides an overview of the study.
 - b. Ginger McDougal answers questions from IRB members from 9:36 to 9:40 am.
 - c. Ginger McDougal and Dr. Robin Farrell exit meeting at 9:40 am.
 - d. Discussion continues from 9:41 to 9:58 am.
 2. Summary of Discussion and Recommendations
 - a. Date of proposed research
 - i. Needs to change to a later date. The beginning time cannot predate the IRB approval.
 - b. Description of Participants and Recruitment
 - i. Needs to specify the number of participants. The P.I. only mentioned 50 patients. How many nurse practitioners will be included in this research?
 - c. Methodology
 - i. Needs to clarify whether or not the data will be analyzed at aggregate level, and whether or not the P.I. will assign coded numbers to participants to link the surveys for analysis.
 - d. Risks of Participation
 - i. Needs to clearly state how the data will be stored (e.g., in a password-protected computer in P.I.'s office or locked file cabinet/drawer in

- P.I.'s office), how long data will be stored (Federal Regulations require the data to be stored for at least three years), and who will have access to the data.
- ii. Needs to clearly state how the patient account number will be used and be protected.
- e. To informed consent:
 - i. Needs to provide P.I.'s and faculty advisor's identification information including name, title, and institutional affiliation.
 - ii. Needs to add more details of the research to the informed consent to be consistent with the research procedures specified in methodology section of the application. For example, pre-intervention meeting is not mentioned in the informed consent.
 - iii. Needs to change "There is minimal to no risk involved in your participation in this study." to "There are minimal risks involved in your participation in this study."
 - iv. Needs to revise to reflect the revisions to the Risks of Participation section of the application.
 - v. Needs to add a statement "I have read and understood the above information. By signing this form, I agree to participate in the above-mentioned research." before the participant's signature.
 - vi. Needs to add lines for P.I.'s signature and date.
 3. Vote: Motion Not Approve as Written: Dr. Pollock; Second: Dr. Manish. Motion passes unanimously at 9:58.
 4. Vote: Motion for Chair to review revised Application: Dr. Campbell; Second: Dr. Taylor. Motion passes unanimously at 9:59.
- B. 201505006-Allen: Paper Reminder Strategy: Increasing Adult Vaccination Against Pertussis. Student/Troy. Full.
1. Full review of protocol begins at 10:01 am. Amanda Allen was present via phone and Dr. Shellye Vardaman was present in person.
 - a. Amanda Allen provides an overview of the study.
 - b. Amanda Allen answers questions from IRB members from 10:05 to 10:10 am.
 - c. Amanda Allen and Dr. Shellye Vardaman exit meeting at 10:10 am. Dr. Shellye Vardaman reenters at 10:26 am to answer additional questions. Dr. Shellye Vardaman exits at 10:28 am
 - d. Discussion continues from 10:11 to 10:31 am.
 2. Summary of Discussion and Recommendations:
 - a. Methodology
 - i. Needs to be consistent throughout the application as to the participants' age. Sometimes the P.I. indicated as "older than 19 years" and some other times, the P.I. indicated as "19 years of age or older."
 - b. Risks of Participation
 - i. Needs to clearly state where and how the data will be stored, how long the data will be stored, and who will have access to the data.
 - c. Informed Consent Process

- i. Needs to clearly state that the P.I. will verbally inform the participants where and how the data will be stored, how long the data will be stored, who will have access to the data, and the measures that the P.I. will use to protect the confidentiality of the information collected from the participants.
 - 3. Vote: Motion Not Approve as Written: Dr. Manish; Second: Dr. Pollock. Motion passes unanimously at 10:32.
 - 4. Vote: Motion for Chair to review revised Application: Dr. Campbell; Second: Dr. Sarapin. Motion passes unanimously at 10:33.
- C. 201506003-Everhardt, Cellon & Hopkins: The Impact of Gardening on Food Insecurity and Social Isolation Among Older Adults. Collaborative/Montgomery. Full.
 - 1. Full review of protocol begins at 10:33 am. Dr. Sharon Everhardt and Johnathon Cellon were present for review.
 - a. Dr. Sharon Everhardt provides an overview of the study.
 - b. Dr. Sharon Everhardt answers questions from IRB members from 10:37 to 10:41 am.
 - c. Dr. Sharon Everhardt and Johnathon Cellon exit meeting at 10:41 am.
 - d. Discussion continues from 10:41 to 11:08 am.
 - 2. Summary of Discussion and Recommendations:
 - a. Description of Participants and Recruitment
 - i. Needs to spell out the compensation for those who do not pass the dementia test.
 - ii. Needs to clearly state that the senior center where the P.I. will recruit participants is a senior activity center, not a senior living place/facility.
 - b. Methodology
 - i. Needs to clarify whether or not the P.I. will collect participants' names and date of birth (these two items are shown on the clock-drawing test).
 - ii. Needs to move the second paragraph of the "Purpose of the Study" section to the methodology section. In addition, in this paragraph "Troy will purchase approximately 30 vegetable plants..." Needs to revise to reflect that the P.I.s, with the grant, will purchase the vegetable plants.
 - iii. Needs to show the permission to use the questionnaire (on friendship). The P.I.s cannot assume that the author Dr. Hawthorne is dead. In addition, the death of the author/creator does not mean a permission to use the questionnaire.
 - c. Risks of participation
 - i. Needs to state how long the data will be stored. (Federal regulations require the data to be stored for at least three years.) The P.I.s cannot destroy the data upon completion.
 - ii. Needs to clearly state that refusal to participate in the research and withdrawal from the research will not affect the seniors' access to the milk crates gardening project. In other word, if they choose not to participate in the research or withdraw from the research, they still

- have access to the milk crates gardening project (and to the food and vegetables available in this project).
- iii. Needs to state the emotional risks involved such as feeling sad, depressed, or anxious. The emotional risks are discussed in informed consent. Needs to discuss it here as well and also clearly state that the P.I.s will let the participants know that, if the participants feel sad, depressed, or anxious, they may stop participating in the research immediately without affecting their relationship with researchers and their access to the milk crate gardening project.
 - d. Informed Consent Process
 - i. Needs to clearly state when and where the P.I.s will give information to the participants about the research project and obtain the informed consent.
 - ii. Data storage time should be at least 3 years. The data cannot be “destroyed upon the project completion.”
 - e. To Informed Consent
 - i. In the statement “The P.I. may stop your participation... or because you did not follow instruction...” needs to make it clear that stopping the participation won’t affect their access to the milk crate gardening project.
 - ii. Needs to revise the informed consent to reflect the revisions to the “Risks of Participation” section of the application.
 - iii. Needs to add P.I.s’ signature lines and date lines.
 - iv. Needs to simplify the informed consent to make it shorter.
3. Vote: Motion Not Approve as Written: Dr. Heisler; Second: Dr. Sarapin. Motion passes unanimously at 11:08 am.
 4. Vote: Motion for Chair to review revised Application: Dr. Taylor; Second: Dr. Manish. Motion passes unanimously at 11:09 am.
- D. 201506004-Bangurah: Hypertension control: Effects of cognitive and behavioral intervention. Student/Troy. Full.
1. Full review of protocol begins at 11:10 am. Saphie Bangurah was present via phone and Dr. Shellye Vardaman was in person.
 - a. Saphie Bangurah provides an overview of the study.
 - b. Saphie Bangurah answers questions from IRB members from 11:13 to 11:14 am.
 - c. Saphie Bangurah and Dr. Shellye Vardaman exit meeting at 11:14 am.
 - d. Discussion continues from 11:14 to 11:27 am.
 2. Summary of Discussion and Recommendations:
 - a. Description of Participants and Recruitment
 - i. Needs to add P.I.’s and faculty advisor’s identifying information including name, title, and institutional affiliation to the recruitment script.
 - b. Methodology
 - i. Needs to clearly state that participants’ physical activities should be approved by their physicians. This is to avoid physical injury.

- ii. This proposed research is confidential, not anonymous. Needs to give more details on how to link the pre- and post-intervention assessments for comparison and analysis. Will the P.I. assigned coded numbers to the participants to link the assessments?
 - c. Risks of Participation
 - i. Needs to clearly state where and how data will be stored, how long data will be stored, and who will have access to the data. (Federal Regulations require data to be stored for at least three years).
 - ii. Needs to clearly state that there are risks of physical injury during physical activities. Needs to clearly state that the P.I. will decrease the risks through informing the participants that they have to obtain physicians' approval before they change their physical activity plans.
 - d. Informed Consent Process
 - i. Needs to make sure that the informed consent readability level be consistent with the participants' reading level. If the P.I. use 5th grade reading level as the criterion of participants recruitment, the informed consent needs to have 5th grade readability level. If there is no reading level criterion used in selecting participants, the readability level of informed consent cannot be higher than 8.
 - e. Informed Consent
 - i. Needs to add P.I.'s and faculty advisor's identifying information including name, title, and institutional affiliation.
 - ii. Needs to clearly state the time commitment expected from participants (e.g., how long will the counseling session be? How long the project will last?)
 - iii. Needs to clearly state how the participants' confidentiality will be protected (will participants' name be collected? Will the P.I. assigned coded numbers to participants to link the pre- and post- assessments for comparison and analysis?)
 - iv. Needs to revise the informed consent to reflect the revisions made to the Risks of Participation section
 - v. Needs to add a statement "I have read and understood the above information. By signing this form, I agree to participate in the above-mentioned research." before participant's signature line.
 - vi. Needs to add lines for P.I.'s signature and date.
 - vii. Readability level of informed consent needs to be consistent with the participants' reading level.
 - 3. Vote: Motion Not Approve as Written: Dr. Pollock; Second: Dr. Sarapin. Motion passes unanimously at 11:27.
 - 4. Vote: Motion for Chair to review revised Application: Dr. Heisler; Second: Dr. Taylor. Motion passes unanimously at 11:27.
- V. Discussion of Corrections and Updates to Research proposals under 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. Approved.

- B. 201505005-Crittenden: The Impact of Health Coaching on Lifestyle Modification in the Management of Hypertension in a Primary Care Setting. Student/Troy. Approved.
- C. 201505001-Smith: Pediatric Sleep Assessment and Educational Intervention for Parents. Student/Troy. Approved.

VI. New Business and Information Items:
None

VII. Adjourn
Motion to Adjourn: Dr. Manish; Second: Dr. Taylor.
Motion passed unanimously.
Meeting adjourned 11:29 am.