

INSTITUTIONAL REVIEW BOARD MINUTES

June 18, 2015

I. Call to Order:

A. Meeting called to order at 9:04 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)	<b>X</b>					YES
Karen Ross (NS)	<b>X</b>					YES
Jonathan Taylor		<b>X</b>				YES
Gurumani Manish	<b>X</b>					YES
Joel Campbell			<b>X</b>			YES
Cozetta Shannon					<b>X</b>	YES
JeeHae (Helen) Lee					<b>X</b>	YES
William Heisler		<b>X</b>				YES
Sandra Pollock		<b>X</b>				YES
Susan Sarapin				<b>X</b>		YES
Michael Green					<b>X</b>	YES
Tom Reiner			<b>X</b>			YES
Chase Taylor (NI)(NS)				<b>X</b>		YES
Kathleen Sauer (NI)(NS)		<b>X</b>				YES
Dianne Barron (ExOfficio)(HPA)					<b>X</b>	NO
NS: Non-scientist member / NI: Non-institutional member						
Guest : Mary Anne Templeton, Associate Dean						
Dr. Campbell enters the meeting at 9:09 because of technical difficulties						

II. Approval of IRB Minutes

Approval of IRB Minutes from the May 21, 2015 meeting:

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

The motion passes. Dr. Campbell was not present for the vote.

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- B. Withdrawn: 1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. 201504009-Furr: Implications of Drug Shortage Among Alabama Certified Registered Nurse Anesthetists. Student/Troy. Full.

1. Full review of protocol begins at 9:14 am. Willie Furr and Dr. Wade Forehand were present via phone.
  - a. Willie Furr provides an overview of the study.
  - b. Willie Furr answers questions from IRB members from 9:17 to 9:22 am.
  - c. Willie Furr and Dr. Wade Forehand exit meeting at 9:22 am.
  - d. Discussion continues from 9:22 to 9:52 am.
2. Summary of Discussion and Recommendations:
  - a. Description of Participants and Recruitment
    - i. The IRB strongly recommends that the P.I. put the informed consent on the initial screen of the online survey that the participant sees. The participant should be able to indicate by clicking one of two buttons: (1) they have read the document and agree to participate in the study. In this case clicking the button will bring them to the survey questions; or (2) they do not wish to participate in the study. In this case clicking the button will bring them to an exit page. This is to make sure that every participant will read the informed consent page before proceed to answer the survey questions.
  - b. To recruitment email:

- i. Needs to move the online survey link from this email to the end of the informed consent.
    - c. Risks of participation
      - i. Needs to clearly state that some participants may feel stress or discomfort answering the survey questions. Also state that the P.I. will let the participants know that, if the participants feel stress or discomfort answering the survey questions, they may stop participating immediately.
      - ii. Needs to clearly state where and how the P.I. will store the data, how long the P.I. will store the data (Federal regulations require the data to be stored for at least three years), and who will have access to the data.
    - d. To informed consent:
      - i. Needs to make the P.I.'s self-presentation clear. What does "CRNA MSN DNP" mean?
      - ii. Needs to delete the repeated statement "By completing and submitting this survey, you are indicating your consent to participate in the study."
      - iii. Needs to revise the informed consent to reflect the revisions made to the Risks of Participation section of the application.
  - 3. Vote: Motion Not Approve as Written: Dr. Ross; Second: Dr. Pollock. Motion passes unanimously at 9:52.
  - 4. Vote: Motion for Chair to review revised Application: Dr. Heisler; Second: Dr. Manish. Motion passes unanimously at 9:53.
- B. 201505002-Lippold: Improving Pneumonia Vaccine Compliance in Older Adults. Student/Montgomery. Full.
- 1. Full review of protocol begins at 9:54 am. Krista Lippold was present for review via phone.
    - a. Krista Lippold provides an overview of the study.
    - b. Krista Lippold answers questions from IRB members from 10:02 to 10:12 am.
    - c. Krista Lippold exits meeting at 10:12 am.
    - d. Discussion continues from 10:12 to 10:38 am.
  - 2. Summary of Discussion and Recommendations:
    - a. Throughout the application, the P.I. needs to make it clear that the vaccine is recommended, not required. In addition, please avoid using the term "compliance" throughout the application since it indicates that the vaccine is required.
    - b. Dates of proposed research:
      - i. Needs to change the beginning date to a later date. The beginning time cannot predate the IRB approval.
    - c. Description of Participants and Recruitment
      - i. Participants are 65 and older. This needs to be consistent throughout the application. Sometimes it says over the age of 65.
      - ii. The flyer is advertising the education seminar. It is not clear when the P.I. will introduce the proposed research (not the seminar) to the

participants, when the P.I. will recruit them to the research, and how to recruit them. All this information is missing from the application.

iii. The P.I. needs to spell out the compensation: How much is the compensation? If the P.I. will use some gifts, what kind of gifts will the P.I. use? How to deliver the compensation? When and where to deliver the compensation?

d. Methodology

i. What kind of identifying information will be collected? When will the P.I. collect the self-addressed postcards, if the P.I. will do so as stated in the IRB meeting (the IRB will need to see a copy of the postcard if postcards are used)? Will the participants' names, home addresses, and phone number be collected? Will the P.I. connect the pre-assessment and post-assessment? If the P.I. will connect the pre- and post-assessments, what information will be used to make the connection? In addition, please clarify the time commitment (each step and the total) expected from participants.

ii. Needs to justify why it is necessary to collect the demographic information, health insurance information, and information on participants' health conditions and on whether or not the participants had other types of vaccine (e.g., shingles vaccine)?

e. Risks of Participation

i. Needs to clearly state that where and how to store data, who will have access to the data, and how long the P.I. will store the data (Federal regulations require the data to be stored for at least 3 years).

ii. Based on the clarifications (revisions #1, 3, 4, & 5), the P.I. needs to address potential risks of participation including risks of confidentiality breaching and risks of coercion.

f. To informed consent:

i. Needs to identify the P.I. in the informed consent including name, title, and institutional affiliation.

ii. Needs to revise the informed consent to reflect the revisions made to the Description of Participants and Recruitment, Methodology, and Risks of Participation sections of the application.

iii. Needs to check the informed consent checklist available on IRB webpage to make sure that all the major contents required for informed consent are included.

iv. The informed consent must have a reading level of 8 F/K or lower

3. Vote: Motion Not Approve as Written: Dr. Ross; Second: Dr. Campbell. Motion passes unanimously at 10:38.

4. Vote: Motion for Chair to review revised Application: Dr. Heisler; Second: Dr. Campbell. Motion passes unanimously at 10:43.

V. Discussion of Corrections and Updates to Research proposals under Full Review:

VI. New Business and Information Items:

Dr. Taylor presented the revised Review Form

Motion to approve the revised Review Form: Dr. Su; Second: Dr. Ross

Motion passes unanimously at 10:48.  
The Board will meet in July.

VII. Adjourn

Motion to Adjourn: Dr. Pollock; Second: Dr. Campbell.  
Motion passed unanimously.  
Meeting adjourned 10:51 am.