INSTITUTIONAL REVIEW BOARD MINUTES
May 15, 2014

I. Call to Order:

A. Meeting called to order at 9:03 am.

Members Present:

Total 9

Voting Members 9

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
Karen Ross (Chair)(NS)					**X**	YES
Xiaoli Su (Chair Elect)	**X**					YES
William Foxx			**X**			YES
Gina Mariano	**X**					YES
Joel Campbell					**X**	YES
Cozetta Shannon		**X**				YES
JeeHae (Helen) Lee					**X**	YES
William Heisler		**X**				YES
Christopher Pritchett		**X**				YES
Susan Sarapin	**X**					YES
Michael Green					**X**	YES
Dionne Rosser-Mims		**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

A. Approval of IRB Minutes from the March 20, 2014 meeting:

Approved unanimously as written by electronic vote on May 14, 2014.

B. Approval of IRB Minutes from the April 17, 2014 meeting:

Approved unanimously with revision by electronic vote on May 14, 2014.

III. IRB Productivity: Chair Comments and IRB Discussion

A. Exempt Applications: 6

B. Expedited Approvals:

1. 201404002-Rhode: Improving Follow-Up Appointments for Hypertensive Patients in a Rural Clinic. DNP Student/Troy. Dr. Lee & Dr. Ross
2. 201404003-Taylor, Frye & Anderson: Conceptual Change Theory and Learning Resistance: An Examination of Teacher Framework Theories and their Effect on In-Service Learning Resistance. Collaborative/Montgomery. Dr. Lee & Dr. Ross.
3. 201403004-McClendon: Bullying Intervention Program. DNP Student/Troy. Dr. Mariano and Dr. Ross.
4. 201404005-Whatley: Transformational Learning in Secondary Education. Student/Montgomery. Dr. Pritchett & Dr. Ross.

C. Withdrawn Applications: 0

D. Continued Review Approvals and Modifications: 1

E. Pending Full Review:

1. 201404007-Gibson: Social Skill Interventions for Parents of Children with Autism Spectrum Disorders. DNP Student/Troy.
2. 201403038-Little: Factors Contributing to the Retention Rates of Non-Traditional Students at Troy University. Staff/Troy.
3. 201404011-Hardy: Measuring the Effectiveness of Strengthening Pelvic Floor Muscles on Reducing Urinary Stress Incontinence in Women. DNP Student/Troy
4. 201405003-Warren: Improving Glycemic Control via Telemonitoring. DNP Student/Troy.

F. Full Review Approvals: 0

G. Pending Expedited Review: 0

H. Needs Revisions or Information:

1. 201402002-Railey & Hammonds: Keeping the Silver Generation Happy and Healthy; Family Involvement in Assisted Living Facilities. Collaborative/Troy.
2. 201401009-Forehand, Weed, Spurlock & Alberich: An International Collaboration Comparing Student Nurse Attitudes Toward Older People. Faculty/Troy.
3. 201405002-Westbrook: Evaluation of nursing attitudes to Delirium Assessment during implementation of the Pain-Agitation-Delirium Clinical Practice Guideline in a rural community hospital. DNP Student/Troy.
4. 201405004-Smith: Sleep Disturbances in Primary Care Patients: Evaluation of Screening Practices. DNP Student/Troy.
5. 201404009-Mann: Female Student Buying Patterns of Selected Apparel and Fashion/Luxury Goods. Staff/Student. Troy.
6. 201404010-Cotton: A primary care intervention for the obese adult. DNP Student/Troy.

IV. Review of Current Proposals for Full Review:

A. 201404007-Gibson: Social Skill Interventions for Parents of Children with Autism Spectrum Disorders. DNP Student/Troy.

1. Full review of protocol begins at 9:15am. Dr. Forehand, Dr. Farrell and Ms. Gibson enter the IRB review at 9:16 am.

a. Ms. Gibson provides an overview of the proposed study.
b. Ms. Gibson and advisors answers questions from IRB members from 9:19 to 9:26.
c. Ms. Gibson and Advisors exit meeting at 9:26.
d. Discussion continues from 9:27 to 9:30am.

2. Summary of Requirements and Revisions
   a. Purpose of the study**:**
      i. Should consider including a control group that will only use the social stories (without music) in research.
   b. Description of Participants and recruitment:
      i. On P. 9, the second paragraph is repeating the first paragraph "I am a Family Nurse Practitioner in the Doctorate of Nursing Practice … Children between the age of 4 and 7 with ASD may benefit from adding a musical element.
      ii. A letter/document should be provided to show the Lee County Autism Resource and Advocacy (LCARA) group supports the research and grants access to their members.
   c. Methodology**:**
      i. Methodology needs to be consistent with the informed consent
      ii. Stating there will be two evaluations (pretest and posttest using a social skills checklist) and the time commitment for the two evaluations.
      iii. Study mentioned follow-up questions after the evaluations, the follow-up questions need to be attached.
      iv. Change "the parents or caregivers" to "the parents or guardians" to eliminate the possibility that childcare providers (for pay) will be the one to administer the intervention. This change should be done in both the methodology section of the application, the informed consent document and recruitment materials in the attachment.
   d. Informed Consent**:**
      i. Changing "intervention" to "activities" or other words easy to understand.
      ii. The research involves a vulnerable population - children with ASD. Even though there will be no direct interaction with those children; there is a need for scripts. The scripts will be used by the parents to inform the children about the research (the research itself, the types of practices the children will be asked to do, etc.)
      iii. The telephone number of TROY IRB in informed consent is not correct. It should be 334-808-6294.
      iv. Date" should be added for signature line.
3. Vote: Motion reject proposal as written: Dr. Heisler, Second; Dr. Rosser-Mims. Motion passes unanimously at 9:31.
4. Vote: Motion to have IRB Full Review of revised protocol: Dr. Pritchett, Second; Dr. Foxx. Motion passes unanimously at 9:32.

B. 201404011-Hardy: <u>Measuring the Effectiveness of Strengthening Pelvic Floor Muscles on Reducing Urinary Stress Incontinence in Women</u>. DNP Student/Troy.

1. Full review of protocol begins at 9:33. Dr. Forehand and Ms. Hardy enter the meeting at 9:34.

2. Ms. Hardy provides an overview of the study and answers questions until 9:56 am.
3. Ms. Hardy and Dr. Forehand exit meeting at 9:56 am.
4. Discussion continues from 9:57 to 10:10.
5. Summary of discussion and recommendations:
   a. Source of funding for the protocol:
      i. The total cost of the project is $696.00 (P. 5). What is the funding source? If no other funding source, need to indicate "Self".
   b. Description of participants and recruitment:
      i. Instead of giving the recruiting flyer (P. 8) after referral, these flyers should be given to the potential participants by the physicians. This is to avoid potential coercion. It is recommended to let the physicians give the flyers and the project information (and the PI contact information) to the potential participants and let the potential participants to decide whether or not to contact the PI, instead of referral.
      ii. In the letters of supports, the length of the program should be changed from "five weeks" to "six weeks". In addition, the letters of support from the host site and from all the "referring" physicians need to be attached.
   c. Methodology
      i. Time commitments for the informational meeting, initial assessments, and training are not clearly stated, though it says participants need to keep diary for 4 weeks.
      ii. Some of the demographic information is unnecessary for the research (p. 27). For example, income, race, education. For those items, add one option "Prefer not to answer" or "do not want to answer" among the list of options of each question.
   d. Risks of participation:
      i. Since singed informed consent will be collected, this research will be confidential, not anonymous. Need to change "Anonymity" and "anonymous" to "confidentiality" and "confidential". This change also needs to be reflected in the informed consent.
      ii. On Appendix F (P. 25), it says, "Squeezing the wrong muscles can put pressure on your bladder control muscles." That means if the exercise is done incorrectly, it may aggravate the symptoms of Urinary stress incontinence. Clearly state that it is possible that the symptoms may get worse if exercise incorrectly. Also need to state that the participants need to stop the exercise if they see their symptoms worsen. Also need to give information as to who the participants need to contact and get treatment if the symptoms get worse.
      iii. In addition, the PI will use group training to teach participants how to exercise. This may pose as a risk to confidentiality. Need to incorporate into training program some statements/rules to prevent the participants from identifying each other outside of the program.
      iv. This research may have some psychological risks. Participation in this program itself is to admit that they have this type of problem. Need to have some measures against this risk, for example, add a disclaimer in your training program suggesting Urinary Stress Incontinence is a common issue for women in general and many women have this type of problem.

v. The PI is a board member of the host site. This may pose as the risk of coercion. The PI needs to clearly state this in the section of risk of participation. Emphasizes that the participation voluntary to minimize the risk of coercion.

e. Benefits of participation
i. The board agrees that the proposed research is a replication research. The PI does not need to spend time to justify its uniqueness as a group intervention.

f. To Informed Consent:
i. Need to clearly state that, if the exercise is done incorrectly, it might aggravate the symptom of urinary stress incontinence. If this occurs, the participants need to stop the exercise immediately and seek help from their physicians.
ii. The readability level of the informed consent is 9.4. Need to reword the informed consent to make the readability level no higher than 8.
iii. The informed consent should not suggest the improvement after the exercises. At this stage, Pi does not know if the exercises are effective or not.
iv. During the informed consent stage, the PI needs to let the participants read the training materials "What I need to know about Bladder Control for Women" (P. 16-25) to make sure that the participants know what exercises they will be asked to do and let them make informed decision on participation.

6. Vote: Motion reject proposal as written: Dr. Sarapin, Second; Dr. Foxx. Motion passes unanimously at 10:11.
7. Vote: Motion to have IRB Chair review revised protocol: Ms. Sauer, Second; Dr. Shannon. Motion passes unanimously at 10:13.

C. 201403038-Little: <u>Factors Contributing to the Retention Rates of Non-Traditional Students at Troy University</u>. Staff/Troy.
1. Full review of protocol begins at 10:15 am.
2. Dr. Su provides an overview of the study.
3. Discussion continues from 10:17 to 10:26 am.
4. Summary of discussion and recommendations:
a. The permission to use Datatel is not authorized by appropriate Troy Administration.
b. The application is not complete with supporting documentation. Letter of support from appropriate Troy Administration, recruiting materials, survey, etc.
c. Research starting date cannot predate the TROY IRB approval.
d. In the informed consent, the PI needs to disclose his/her identity as a recruiter of TROY University. At the same time, the PI needs to make it clarify the research is not done on behalf of the TROY University. It is a personal endeavor to meet his/her degree program requirement.
5. Vote: Motion to Not Approve: Dr. Pritchett, Second; Dr. Rosser-Mims. Motion passes unanimously at 10:27.
6. Vote: Motion for Submission of New Application: Dr.Foxx, Second; Dr. Shannon. Motion passes unanimously at 10:28am.

D. 201405003-Warren: <u>Improving Glycemic Control via Telemonitoring</u>. DNP

Student/Troy.

1. Full review of protocol begins at 9:15am. Dr. Forehand, Dr. Farrell and Ms. Gibson enter the IRB review at 9:16 am.
2. Ms. Gibson provides an overview of the proposed study.
3. Ms. Gibson and advisors answers questions from IRB members from 9:19 to 9:26
4. Ms. Warren, Dr. Forehand, and Dr. Farrell exit meeting at 9:26 am.
5. Discussion continues from 9:27 to 9:30am.
6. Summary of recommended revisions
   a. Description of Participants and Recruitment:
      i. "The DNP student will obtain permission from … physicians to review patient electronic medical records…. A cover letter and brochure will be mailed to the patients to solicit participation" (P.3). Need to show the legal permission to view patients' medical record. It is recommended that the physicians give out the cover letter and brochure (& PI's contact information) to the potential participants and let the participants decision whether or not to contact the PI.
      ii. "Participants who complete the project will be awarded a $10 Walmart gift card" on P. 3 change to "Participants …. Will be compensated a $ 10….".
      iii. On the program flyer (P. 15), remove "Participants will receive a $10 Walmart gift card at program completion" or move to a place that does not emphasize this compensation.
      iv. On P. 15, remove "Space is limited."
      v. On P. 15, "Are you interested in ….to help you improve your diabetes status?". This needs to be changed. Since this is a program whose effectiveness needs to be proved, the PI cannot advertise this program as a treatment.
      vi. Need to include a cover letter if the PI will use a cover letter and brochure to recruit the participants.
   b. Methodology:
      i. P. 4. Sample: "a sample of at least 40 adults" is not consistent with the proposed samples size 40 in the Description of Participants and Recruitment section. Keep them consistent.
      ii. Reflect the changes in the recruitment process in your methodology section.
      iii. The time commitments are inconsistent at different places, sometimes 8 weeks, sometimes 9 weeks. If the patient must come in during the 9th week, then the time commitment is 9 weeks.
      iv In physician's letter of support, "the discussed patient age group will be adults aged 18 and over with diabetes mellitus…". It needs to change to "… aged 19 and over…"
      v. Time commitment for the pre-project interview needs to be clearly stated.
   c. Risks of participation:
      i. The risk of confidentiality is an issue in this research. After the research is done, how the researchers will store the information, the participants' phone numbers, what about those messages/texting on the PI's phones, etc. This risk of confidentiality needs to be addressed
      ii. On P. 6, "The practice employs two physicians and six ancillary staff members." Will they have the access to the data collected?
      iii. The risk of coercion: need to revise the informed consent to clearly state

refusal to participate and withdrawal from the research will not affect their relationship with their physicians, affect their medical treatment, etc. (Please see the informed consent section.)

iv. Legal liability for using patients' medical record. Need to show the document that the PI has the legal permission to use patients' medical record.

v. The risk of physical injury. The intervention seems to involve exercise regimen. Need to state that the patients need to consult their physicians to make sure that their physical conditions allow them to follow the exercise regimen. Need to add measures of protections in case injury occurs during the exercise regimen – immediately stop exercise and who to contact for treatment.

vi. Need to clearly state if the program reflects accepted, standard care for diabetic patients.

d. To Informed Consent:

i. The $ 10 gift card shouldn't be treated as the benefits for participants and should not put in the paragraph discussing research benefits.

ii. The data will be stored for 3 years, not 2 years.

iii. State the length of the interview to obtain pre-project information.

iv. Will the participant still get a gift care if they withdraw from the research?

v. It is not enough to say that "You will not be denied medical care by your physician if you refuse or stop participating in the project." The PI needs to clearly state that refusing to participate and withdrawing from the research will not affect the relationship between them and the physicians. Refusal and withdrawal also does not affect their medical treatment.

vi. Need to give information about the risks of participation in the informed consent document.

7. Vote: Motion reject proposal as written: Dr. Heisler, Second; Dr. Rosser-Mims. Motion passes unanimously at 9:31.
8. Vote: Motion to have IRB Full Review of revised protocol: Dr. Pritchett, Second; Dr. Foxx. Motion passes unanimously at 9:32 am.

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

None submitted.

VI. Information Items

Dr. Su informed IRB that the IRB training videos were in final editing and that Dr. Jefferson Spurlock had agreed to assist as the voice for the scripts.

VII. Adjourn

Motion to Adjourn: Dr. Mariano, Second: Dr. Pritchett.
Motion passed unanimously.
Meeting adjourned 11:02 am.