

## INSTITUTIONAL REVIEW BOARD MINUTES

June 19, 2014

I. Call to Order:

A. Meeting called to order at 9:04 am.

Members Present:

Total 11

Voting Members 11

Non-scientists 2

B. Members Absent 4

Quorum met, Attendance was as follows:

Members	In Person	Via Phone	Via Vtel	Absent	Absent with notice	Voting Member
Karen Ross (Chair)(NS)	<b>X</b>					YES
Xiaoli Su (Chair Elect)	<b>X</b>					YES
William Foxx			<b>X</b>			YES
Gina Mariano	<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
Christopher Pritchett					<b>X</b>	YES
Susan Sarapin	<b>X</b>					YES
Michael Green					<b>X</b>	YES
Dionne Rosser-Mims		<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						

II. Approval of IRB Minutes

Approval of IRB Minutes from the May 15, 2014 meeting:

Motion to approve minutes: Dr. Mariano: Second: Dr. Shannon.

The Motion passes unanimously.

III. IRB Productivity: Chair Comments and IRB Discussion

A. Exempt Applications: 8

B. Expedited Approvals:

1. 201401009-Forehand, Weed, Spurlock & Alberich: An International Collaboration Comparing Student Nurse Attitudes Toward Older People. Faculty/Troy. Dr. Ross & Dr. Mariano.
- C. Withdrawn Applications: 2
- D. Continued Review Approvals and Modifications: 2
- E. Pending Full Review:
1. 201403033-Sarapin & Jackson: Trash talking incognito: Private male locker-room speech and behavior and their effect on athletes' attitudes and behavior toward women. Collaborative/Troy.
  2. 201404007-Gibson J.: Social Skill Interventions for Parents of Children with Autism Spectrum Disorders. DNP Student/Troy.
  3. 201405005-Gibson C.: Intravenous (IV) administration of heparin and the development of a consistent protocol across a five-hospital health system. DNP Student/Troy.
  4. 201405008-Faison: An Evaluation of a Diabetes Patient Centered Support Program to Improve Health Related Quality of Life. DNP Student/Troy.
  5. 201406001-Walters: Life Skills Interventions to Improve Social Confidence, Self-Management, and Drug Resistance Skills in Elementary School Aged Children. DNP Student/Troy.
  6. 201405003-Warren: Improving Glycemic Control via Telemonitoring. DNP Student/Troy.
- F. Full Review Approvals: None
- G. Pending Expedited Review: 1
- H. Needs Revisions or Information:
1. 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.
  2. 201405004-Smith: Sleep Disturbances in Primary Care Patients: Evaluation of Screening Practices. DNP Student/Troy.
  3. 201404010-Cotton: A primary care intervention for the obese adult. DNP Student/Troy.
  4. 201404011-Hardy: Measuring the Effectiveness of Strengthening Pelvic Floor Muscles on Reducing Urinary Stress Incontinence in Women. DNP Student/Troy. Full Review.
  5. 201405011-Johnson: Explicit Instruction of Writing Narrative Essays: A Multiple Case Study of Chinese Students' Perceptions and Performance. Dr. Ross & Dr. Su.
- I. Outside Research Pending: 1
- J. Outside Research Approvals: 2
- IV. Review of Current Proposals for Full Review:
- A. 201403033-Sarapin, Morris & Jackson: Trash talking incognito: Private male locker-room speech and behavior and their effect on athletes' attitudes and behavior toward women.
1. Full review of protocol begins at 9:09am. Dr. Sarapin is present for review.
    - a. Dr. Sarapin provides an overview of the revisions to the study.
    - b. Dr. Sarapin answers questions from IRB members from 9:11 to 9:54.
    - c. Dr. Sarapin exits meeting at 9:54.

- d. Discussion continues from 9:54 to 9:1006am.
- 2. Summary of Discussion and Recommendations:
  - a. The survey and interview questions seem skewed, negative, and leading.
  - b. The number of research questions seem excessive; some of which are not in PI's expertise/training.
    - i. Recommend narrowing the focus of the project to the expertise of the faculty member.
  - c. Risks to the participants and undergraduate interviewer are too high in comparison to potential benefits and not justified. In addition, some IRB members had concerns about an undergraduate with no expertise or experience leading such interviews and possibly placing this student at risk.
    - i. Recommend eliminating telephone interview.
    - ii. Should not ask about illegal activity without federal certificate of confidentiality.
  - d. In each of the letters to ADs and communications to professional organizations, the stated purpose of the study did not match the purpose as written in the application.
  - e. On the letters and consent docs, should reword the discussion of possible discomfort. The PIs wrote that the risks are "insignificantly small" and all discomfort will dissipate within two months. Cannot guarantee that, even if lingering distress is unlikely. Would be better to delete "insignificantly" and reword "...but the distress typically disappeared within 2 months." In addition, the board felt that two months of discomfort was not a minor risk.
  - f. Recommend providing counseling resources at end of survey.
  - g. The IRB recommends that the PIs do not approach Ads. Could consider using other communication sources such as social media or professional organizations.
- 6. Vote: Motion to reject as written: Dr. Rosser-Mims, Second; Dr. Campbell. Motion passes unanimously at 10:07.
- B. 201406001-Walters: Life Skills Interventions to Improve Social Confidence, Self-Management, and Drug Resistance Skills in Elementary School Aged Children.
  - 1. Full review of protocol begins at 10:08 am.
  - 2. Dr. Hamilton and Ms. Walters enters meeting.
  - 3. Ms. Walters provides an overview of the study and answers questions from the IRB from 10:09 to 10:17 am.
  - 4. Discussion continues from 10:17 to 10:23 am.
  - 5. Summary of discussion and recommendations:
    - a. Risk section:
      - i. Details about protecting electronic and paper data such as where it will be stored and for how long needs to be provided.
    - b. Benefits section:
      - i. Should include the potential benefits to larger community/society.
    - c. Parental Informed consent document:
      - i. The reading level is high. Needs to be FK 8.9 or lower.
      - ii. Should add a sentence to inform parents what demographic data will be collected, that no names will be attached to that information, and only the researcher will see the answers.
      - iii. The telephone number of IRB is incorrect and Dr. Hamilton's contact

- information needs to be included.
- iv. The signature line should read parent/legal guardian.
- v. The total time commitment needs to be clear and consistent.
- d. Child assent script:
  - i. The statement “Your parent said you may take the class.” should be deleted.
- 5. Vote: Motion to Not Approve as Written and for Chair to review revised Application; Dr. Foxx, Second; Dr. Mariano. Motion passes unanimously at 10:24.
- C. 201405008-Faison: An Evaluation of a Diabetes Patient Centered Support Program to Improve Health Related Quality of Life.
  1. Full review of protocol begins at 10:25 am. Dr. Burns enters the IRB review at 10:25 am.
  2. Ms. Faison provides an overview of the proposed study by phone.
  3. Ms. Faison answers questions from IRB members from 10:26 to 10:36.
  4. Dr. Burns and Ms. Riley exit meeting at 10:36 am.
  5. Discussion continues from 10:37 to 10:40 am.
  6. Summary of recommended revisions:
    - a. Source of Funding:
      - i. Need to indicate that the project is self-funded.
    - b. Inclusion criteria in methodology section:
      - i. Add the participants must be at least 19 years of age.
    - c. Recruitment materials:
      - i. On the flyer and the brochure indicate that this is research, not treatment.
      - ii. State that you are a DNP student at Troy, research, purpose of research. Can be very brief.
    - d. The Informed consent document does not comply with Troy University IRB policy and/or federal guidelines. Please see templates and checklist on the IRB website.
  5. Vote: Motion to Not Approve as Written and for Chair to review revised Application; Dr. Campbell, Second; Dr. Su. Motion passes unanimously at 10:40.
- D. 201405003-Warren: Improving Glycemic Control via Telemonitoring. DNP Student/Troy.
  1. Full review of protocol begins at 10:41am. Dr. Riley enters the IRB review at 10:41 am.
  2. Dr. Riley provides an overview of the proposed study.
  3. Ms. Riley answers questions from IRB members from 10:46 to 10:51.
  4. Dr. Riley exit meeting at 10:51 am.
  5. Discussion continues from 10:52 to 10:55 am.
  6. Summary of recommended revisions
    - a. Benefits section
      - i. PI should add potential benefits to broader community/society.
    - b. Recruitment materials
      - i. The PI needs to indicate that this is research, not treatment.
      - ii. PI should state she is a DNP student at Troy the research and purpose of

research. The statement could be very brief (a couple of sentences – “I am a graduate student in nursing at Troy University and I am studying if text messaging can improve diabetes management.”).

c. Informed consent document

- i. There needs to be consistency when referring to self (Warren) say “I will...” (rather than “the student” )
- ii. Potential participants should be informed they will be expected to follow dietary and exercise program/recommendations.
- iii. Include faculty advisor’s information (telephone number and email)

7. Vote: Motion reject proposal as written and have Chair review revised protocol: Dr. Mariano, Second; Dr. Su. Motion passes unanimously at 10:56 am.

E. 201405005-Gibson C.: Intravenous (IV) administration of heparin and the development of a consistent protocol across a five-hospital health system.

1. Full review of protocol begins at 10:57. Dr. Farrell, Dr. Whitted and Ms. Gibson enter the meeting at 10:58
2. Ms. Gibson provides an overview of the study and answers questions until 11:18 am.
3. Ms. Gibson, Dr. Farrell, and Dr. Whitted exit meeting at 11:18 am.
4. Discussion of protocol resumes from 11:43 to 11:57.
5. Summary of discussion and recommendations:
  - a. The PI needs to clearly state that the five hospitals in this health system are undergoing a change to standardize heparin protocols, to comply with current national best practices, independent of the PI’s DNP project. According to the answers the PI gave during the meeting, currently each hospital in the system has its own heparin administration protocol. The new, standardized protocol is the 2012 standard protocol recommended by the American College of Chest Physicians and represents accepted and best practices in this field. The protocol will be adopted by all five hospitals.
    - i. The IRB would like to see a clear statement that the protocol represents accepted medical practices and/or best practices as recommended by the proper authorities. The new protocol is not untested or experimental.
    - ii. Although the PI is involved in this transition as a nurse manager for the health system (Piedmont Health System), the decision to adopt a single, standard protocol was made by the Piedmont Health System and is not for the sake of the PI’s research project. In other words – indicate that the care that patients in these hospitals receive will not be affected as a result of Ms. Gibson’s research, but rather due to an administrative decision.
  - b. Please explain that informed consent of patients is not being sought because the PI will not be interacting with patients directly and no individually identifiable information on patients will be collected.
  - c. Risks:
    - i. None to patients due to the PI’s research. The protocol change is a system-wide change happening whether or not the PI collects information about errors rates.
    - ii. Some risk to the reputation of the Piedmont Health System exists if the error rates increase, but that is not the concern of the IRB and the Piedmont Health System administrator has given the PI permission.
6. Vote: Motion to not approve proposal as written: Dr. Su, Second; Dr.

Heisler. Motion passes unanimously at 12:02.

7. Vote: Motion to have IRB Chair review revised protocol: Ms. Sauer, Second; Dr. Mariano. Motion passes unanimously at 12:03.

F. 201404007-Gibson, J.: Social Skill Interventions for Parents of Children with Autism Spectrum Disorders.

1. Full review of protocol begins at 11:20 pm. Dr. Farrell enters meeting by phone.
  - a. Dr. Farrell provides an overview of the proposed study.
  - b. Ms. Gibson enters meeting by phone and continues to discuss study with IRB and Dr. Farrell from 11:34 until 11:37.
  - c. Ms. Gibson and Dr. Farrell exit meeting at 11:37.
  - d. Discussion continues from 11:38 to 11:42.
2. Summary of Requirements and Revisions
  - a. Participants:
    - i. Should indicate that some participants are 19+ years of age on application. (check the “19 and over” line)
  - b. Potential benefits:
    - i. What are the potential benefits to society?
  - c. The IRB needs to see the letter of permission from the Lee County Autism Resource and Advocacy group.
  - d. Informed Consent:
    - i. The parents should be informed some demographic data, including education, family information, etc. will be collected and an explanation of why should also be provided.
    - ii. Indicate that the data will be stored three years.
3. Vote: Motion not approve proposal as written and allow revised application to be reviewed by Chair: Dr. Heisler, Second; Dr. Rosser-Mims.  
Motion passes unanimously at 11:43 am.

V. Discussion of Corrections and Updates to Research proposals under Full Review:  
None submitted.

VI. Information Items

Dr. Su informed the IRB that the IRB training videos are complete and available on the IRB website.

VII. Adjourn

Motion to Adjourn: Dr. Mariano, Second: Dr. Foxx.

Motion passed unanimously.

Meeting adjourned 12:08 pm.