INSTITUTIONAL REVIEW BOARD MINUTES
September 18, 2014

I. Call to Order:

A. Meeting called to order at 9:05 am.
Members Present:
Total 13
Voting Members 13
Non-scientists 2

B. Members Absent 2
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
Dr. 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 Dr. Su enters meeting at 9 :10. Dr. Shannon exits meeting at 9:50. Dr. Sarapin exits meeting at 9 :55.						

II. Approval of IRB Minutes

Approval of IRB Minutes from the August 21, 2014 meeting:
Motion to approve minutes as written: Ms. Sauer: Second: Dr. Shannon.
The Motion passes unanimously.

III. IRB Productivity: Chair Comments and IRB Discussion

A. Exempt Applications: 0
B. Expedited Approvals:
1. 201404010-Cotton: A primary care intervention for the obese adult. DNP Student/Troy. Dr. Ross & Dr. Green.
2. 201407007-Sarapin, Morris & Jackson: Trash talking incognito: Private male locker-room speech and behavior and their effect on athletes' attitudes and behavior toward women. Collaborative/Troy. Dr. Ross & Dr. Rosser-Mims.
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. Dr. Ross & Dr. Heisler.

C. Withdrawn Applications: 1
D. Continued Review Approvals and Modifications: 0
E. Pending Full Review:
1. 201407001-Pittman, Orrock & Faircloth: Hegemonic Masculinity, Depression, & its Impact on Couples. Collaborative/Troy.
2. 201409002-Smith: Sleep Disturbances in Primary Care Patients: Evaluation of Screening Practices. DNP Student/Troy.

F. Full Review Approvals: None
G. Pending Review: 0
H. Needs Revisions or Information:
1. 201405011-Johnson: Explicit Instruction of Writing Narrative Essays: A Multiple Case Study of Chinese Students' Perceptions and Performance. Dr. Ross & Dr. Su.
2. 201408001-Gourley: A Java Management Tool for Students within a Microsoft Operating System Environment. Student/Montgomery.
3. 201405005-Gibson C.: Education of Intravenous Heparin Policy/Procedure in a Community Hospital to Decrease Medication Errors. DNP Student/Troy.

I. Outside Research Pending: 1
J. Outside Research Approvals:0

IV. Review of Current Proposals for Full Review:
A. 201407001-Pittman, Orrock & Faircloth: Hegemonic Masculinity, Depression, & its Impact on Couples. Collaborative/Troy.
1. Ms. Pittman, Dr. Faircloth & Dr. Orrock enter meeting at 9:11am.
2. Researchers provide an overview of the study from 9:12 am to 9:16 am.
3. Researchers answer questions from 9:16 to 9:26 am.
4. Researchers exit meeting at 9:27am.
5. Discussion continues from 9:27 to 9:59 am.
6. Summary of discussion and requested revisions:
a. Application:
i. The title of the study should be consistent in the informed consent and the application.
ii. The title indicates the study is on couples; however, the study seems to be on heterosexual, married males. The title should reflect the population under study.
iii Date of research cannot predate IRB approval.
iv. Source of funding for the protocol: should indicate self-funded.

v. Researchers may consider reducing the value of gift cards. Giving away four 50 dollar gift cards would reduce risk of coercive effects.
vi. Description of participants and recruitment needs to include heterosexual in targeted participants.

b. Methodology:
i. Should indicate the survey should take approximately 10 minutes to complete.
ii. Needs to clearly state that there will be two icons on the informed consent which will allow potential participant either to accept and continue to the survey or to decline and go to the exit page.
iii. Revise the statement 'Identifiable information will only be shared with' …to 'only principle investigators will have access to identifiable information'.

c. Risks of Participation
i. Psychological distress should be included as potential risk of participation.
ii. Need to add that the PIs clearly state in the informed consent form that if the participants feel discomfort or distress during the survey, they should stop taking the survey immediately.
iii. Need to add that after the survey, the PIs also provide the suicide hotline number or advice individuals who have suicidal tendency to seek professional help with the contact information of the help provider.
iv. Revise the statement 'Identifiable information will only be shared with' to 'only principle investigators will have limited access to identifiable information'.
v. Need to add a statement such as "to avoid participants' family members from learning they are participating this research; the announcement of winners will not include the research title information in it."

d. Informed Consent
i. The reading level should be reduced to less than 9.0 Flesch Kinkaid.
ii. The title of the research must be consistent throughout the application and the informed consent form.
iii. The introductory sentence needs revised to indicate who is conducting the study. To use Troy University's Counseling department is misleading.
iv. Need to clarify and be consistent with the title and purpose of the study.
a. The study is on heterosexual, married males not couples. Only males are included in the study the female perspective is not under investigation.
b. Is the study about sadness or depression? Should clarify and revise methodology, purpose, title, and informed consent to reflect consistent descriptors and intentions.
v. Need to have two icons on your informed consent form. One icon is for participants to indicate that they agree to participate in the research and click this icon will lead the participants to survey; the other icon is for participant to indicate that they decline to participate in the research and click this icon will lead the participants to exit page.
vi. Should clearly state that the participants may print the informed consent if they would like a copy for their records.
vii. Need to add a statement reflecting potential for psychological distress. Should change the statement "If discomfort is felt it will be minimal" to "If

discomfort is felt we expect it will be minimal." In addition, need to clearly state "if participants experience discomfort or distress because of the survey they should stop taking the survey immediately and contact…."

viii. Should clearly state that if the participants stop the participation, there is no penalty –what does no penalty mean? Are they still eligible to win the gift card?

ix. Clearly state the first winner will come out of the first group of 75 participants and the second winner will come out of the second group of 75 participants. The announcement of winners will not include the research title information to avoid risks of confidentiality.

x. need to add information concerning Suicide Hotline in addition to contacting local mental health services or hospital should psychological distress be experienced as a result of participation in the study.

xi. Informed consent should consistently reflect revisions made in other areas of application.

xii. All links should be working properly.

e. Online Survey

i. Informed consent page needs to reflect the revision of informed consent.

ii. Demographic information needs to be on a separate page: informed consent page, then demographic information page. Cannot put them on the same page.

iii. The information for the IRB on informed consent page is not complete. The phone number is truncated and should be corrected.

iv. Need to add a page at the end of the survey to list the suicide national hotline or other services you would recommend for participants who have suicidal tendency.

f. Advertisement: Researcher's identity in advertisement should be clarified.. (Such as Assistant Professors of Counseling and Psychology at Troy University etc.).

7. Vote: Motion to Not Approve As Written and for IRB Chair to review revised application for approval; Dr. Ross, Second; Dr. Lee. Motion passes unanimously at 10:02am.

A. 201409002-Smith: Sleep Disturbances in Primary Care Patients: Evaluation of Screening Practices. DNP Student/Troy.

1. Full review of protocol begins at 10:03 am.
2. Dr. Lennen enters meeting at 10:04 and provides an overview of the study until 10:09 am.
3. Dr. Lennon answers questions about the study until 10:17am.
4. Dr. Lennon exits meeting at 10:17 am.
5. Discussion continues from 10:17 am to 10:39 am.
6. Summary of discussion and revisions to be requested

a. Application

i. Dates of proposed research: The starting date cannot predate the date of the IRB approval.

ii. Source of funding for the protocol: Should indicate no funding.

iii. Purpose of the study: The research purpose does not seem to justify the collection of demographic information. Either change the research purpose to justify the

demographic information or keep the research purpose as it is and do not collect demographic data.

iv. Description of Participants and Recruitment: The PI's advisor suggested that the sleep disorder diagnosis is mandatory in the health provider facility. The PI needs to clearly state that the sleep disorder diagnosis is mandatory at the health provider facility, every patient use the service of that health provider facility will take the sleep disorder diagnosis, not a voluntary thing.

b. Methodology

i. PI needs to clearly state that they will need to obtain the pre-intervention data. That those data will be used at aggregate level and all identification information will be protected. Need to clearly state the protection measures.

ii. The collection of demographic data is not justified. Should change the research purpose to justify the collection of the demographic data or do not collect the demographic data.

iii. On P. 8, "All providers and staff will also be asked to participate in the study of their own free will." Since the PI do not collect data on the providers and staff, the IRB board reached consensus that the providers and staff are not participants in this situation and the statement is appropriate.

iv. Instead of saying "Confidentiality will be maintained through provider/client privilege." the PI needs to clearly state who will have access to those medical records, what type of medical records the PI will have access to once the PI obtain the informed consent from the participants. The PI's advisor gave the IRB board some information as to the protection mechanism (flags for other medical records that are not related to sleep disorder will show up to prevent the PI from accessing other medical records irrelevant to this study). Should state protection measures for the confidentiality of the data

c. Risks of participation: Psychological distress may occur if some of the patients have severe sleep disorder but do not feel comfortable to disclose those information. However, since the sleep disorder diagnosis is mandatory, the psychological distress related to sleep disorder diagnosis is not caused by the current research. So the PI needs to clearly state that the sleep disorder diagnosis is mandatory in the health provider facility, not just for the current research.

d. The issue for the PI is to obtain the permission to use their medical records concerning sleep-disorder diagnosis. The PI needs to clearly state that the participant may choose to stop participating the study and withdraw their permission at any time without penalty.

e. Since the medical records of patients will be viewed in this research, confidentiality will be an issue. The PI needs to clearly state the risks concerning confidentiality and their protective measure to minimize the risks concerning confidential data (Only the PI has access to the data, data stored in a system with password, the PI does not have access to other irrelevant medical records of the participants, etc).

f. Benefits: Benefits for the participants are that their sleep problems may be better diagnosed and treated. The benefit should be added to the application.

g. Informed Consent Process:

i. Readability 11.4 is too high. The reading level should be reduced to under 9 using

Flesch Kincaid.

ii. On P. 28. The Script for Recruitment needs to be revised. "The Senior Medical Officer, Commander Smith," Need to revise to also show PI's identity as a Troy student.

iii. On P. 29: "You are being asked to participate in this study because you are an adult …" needs changed to "because you are 21 years or older..."

iv. Need to inform the patients that whether or not the provider treats them, types of treatment will be viewed by the PI. In addition, the researcher needs to keep the information confidential and clearly state how the research is going to do use the data.

v. Informed consent form needs to be revised to reflect the revisions made on the risks of participation and other parts of the application.

7. Vote: Motion to Not Approve as Written; Dr. Ross, Second: Dr. Green. Motion passes unanimously at 10:40 am.
8. Vote; Motion for IRB Chair to review revised application for approval; Dr.Ross, Second; Dr. Heisler. Motion passes unanimously at 10:42 am.

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

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

VI. Information Items

Nominations are needed for IRB Chair Elect position.

VII. Adjourn

Motion to Adjourn: Dr. Ross, Second: Dr. Manish.
Motion passed unanimously.
Meeting adjourned 10:48 am.