

# INSTITUTIONAL REVIEW BOARD MINUTES

## June 21, 2012

I. Call to Order:

Meeting was called to order at 9:02am

Members Present:

|                |    |
|----------------|----|
| Total          | 10 |
| Voting Members | 9  |
| Non-scientists | 2  |

Quorum was met, Attendance was as follows:

| Members   | In Person | Via Phone | Via Vtel | Absent | Absent with notice | Voting Member |
|---|-----------|-----------|----------|--------|--------------------|---------------|
| Tim Buckner (chair)(NS)                                 | X         |           |          |        |                    | YES           |
| William Foxx  |           |           | x        |        |                    | YES           |
| Shari Hoppin (NS)                                       | X         |           |          |        |                    | YES           |
| Glenda Avery  |           |           | X        |        |                    | YES           |
| Gina Mariano  | X         |           |          |        |                    | YES           |
| Emma Peden  |           |           |          |        | x                  | YES           |
| Eddie Clark   |           |           |          |        | x                  | YES           |
| Christopher Pritchett                                   |           |           | X        |        |                    | YES           |
| Frank Hammonds  | x         |           |          |        |                    | YES           |
| Richard Caldarola                                       |           |           |          |        | x                  | YES           |
| Dionne Rosser-Mims                                      |           |           | X        |        |                    | YES           |
| Robert Abbey  |           | X         |          |        |                    | YES           |
| Susan R. DuBose (NI)                                    |           |           |          |        | x                  | YES           |
| Chase Taylor (NS)(NI)                                   |           |           |          |        | x                  | YES           |
| Janet McNellis (HPA)                                    | X         |           |          |        |                    | NO            |
| NS: Non-scientist member / NI: Non-institutional member |           |           |          |        |                    |               |

II. Approval of IRB Minutes from the last meeting on April 19, 2012:

A. Correction to minutes

1. Change Frank Hammonds to voting member on roster
2. Correct Janey to Janet on roster
3. Change on to one in section V.

Motion to approve all minutes: Dr. Abbey

Second: Dr. Hoppin

The Motion Passed Unanimously

III. Chair Comments on IRB Productivity:

|                                  |               |
|----------------------------------|---------------|
| Report on Applications:          | <u>Annual</u> |
| <u>Total</u>                     | <u>73</u>     |
| Expedited                        | 57            |
| Exempt                           | 3             |
| Full Review                      | 7             |
| Pending                          | 3             |
| Cancelled                        | 2             |
| <u>Other University Approval</u> | <u>1</u>      |
| Student                          | 17            |
| Faculty                          | 20            |
| Student/Faculty                  | 36            |

IV. Current proposals for full review:

A. Protocol# 201206001-Gillespie: Positive Reminiscence as an Evidence-based Intervention for Coping with Terminal Illness in Hospice Care

1. Ms. Gillespie and advisor, Dr. Patsy Riley enter meeting at 9:13
2. Explanation of Project 9:13 to 9:17
3. Questions 9:17 to 9:36

-Could you explain who will be signing the informed consent form?

The patients will be signing the written consent form and verbally attesting to consent. If the patient has established a Power of Attorney, the attorney will also sign the informed consent.

-Why the mention of Power of Attorney if patients are competent to sign the informed consent? The population selected for this research have terminal diagnosis. Given the nature of the diagnosis, often the patients establish Power of Attorney to facilitate their needs should their competencies diminish. Patients selected for this study will not include those with a diagnosis of Dementia. Patients incapable to sign the informed consent will not be recruited.

- What if a patient who originally was competent to sign the informed consent form deteriorates during the course of the study and is no longer capable of consent? Such a patient would be terminated from the study. The primary terminal diagnosis is as set forth by Medicaid. I assess and recertify the patients according to an specific checklist. One item on the diagnosis check list for assessment is dementia. Should a patient present with dementia they would no longer be deemed as participants in the project.

-Do you believe having the patients give verbal assent would be beneficial in light of the potential for diminished competency during the course of the research?

yes

-Could the rate of attrition affect research's completion? It is for this reason a large data base (300t) is required. Also, the terminal diagnosis sets a six month approximation for life expectancy however, many of our patients live much longer.

-How will Patients who experience adverse effects from the study receive

intervention or assistance? Various forms of counseling or assistance will be readily available to the patient. The hospice company I work for and affiliated with this study, employs numerous social workers and chaplains who are dispatched from over 7 agency sites in the Gulf Coast Region. The patients also have access to hospice aides and are seldom without support of some type. The patients will have support persons present after the visits are conducted such as family members, hospice workers, social workers or chaplains.

-How will you keep the data anonymous? I will be using no names, no identifiers, the data will be stored in a locked and private location, HIPPA and corporate guidelines will be strictly followed. I am bound by laws of confidentiality.

-Will you be reporting to this company? Will the data be disseminated by site or location? Yes, I will be reporting to the company. There is a Memorandum of Understanding (MOU) signed which necessitates all changes and findings in reference to the research, be reported to the corporation. The company is now the largest home health company in the nation.

-What form of data coding will you be using? Aggregate

-Are the questions on page 30 examples? They are exact guidelines. The guidelines are literature based and found to lead to positive reminiscence rather than general.

-Given the questions, some could generate positive or negative outcomes: Isn't the research to illicit positive reminiscence? Any question could potentially illicit positive or negative outcomes or response. The questions selected have been shown in literature to primarily produce positive reminiscence.

-Are the questions asked randomly? The questions are asked randomly in that what questions asked will vary by patient and current circumstances. The questions will be random due to delivery.

-Will the participants be in Troy? They will be in Pike County, but based on referrers the applicant and advisor believe the participants will mostly be from Troy.

-Have you considered how cultures affect habits? Yes, it's actually in her literary review.

-The cost is \$460, but there isn't any funding so where is the money coming from? Donations. Applying for a grant (Sigma Theta Tau Nursing Honors Society).

Applicant and Advisor exit at 9:39

Summary:

-Add "hour long" time factor to methodology and consent form.

-In the consent form specify participation is voluntary and that the participant can withdraw at any time.

-The consent form should mention the participant will have to wear a pedometer.

-The consent form should include potential for injury.

-Do not use waiver in study.

-Include Institutional Review Board information in study.

-Update wording that sounds like you are asking for parent participation.

-Change grade level of reading documents being read to participants/children to first or second grade reading level.

Vote: Motion to not approve as written and allow the IRB chair to review changes and approve: Dr. Clark, Second: Dr. Mariano, Passes unanimously  
Applicant and Advisor enter again at 9:42  
Applicant and Advisor exit 9:43

V. Discussion of protocols approved under Expedited Review

VI. Report from Human Protections Administrator

- A. The IRB has received an application for research to be conducted in Pakistan. Dr. McNellis is currently working with the International Activities Division of the Federal Office of Human Resource Protections and the National Bioethics Committee for the government of Pakistan to ensure the proposed research is reviewed and approved by the governments and institutions involved.
- B. A new Graduate Assistant has been assigned to work with the IRB, Rhonda Young.
- C. Dr. McNellis will be sending letters to members whose terms of IRB service expire in July of 2012.
- D. Dr. McNellis reported no official, policy changes received in reference to the Human Protections Administration.

VII. Training Needs

With the Fall 2012 semester approaching, Dr. McNellis indicated she would conduct IRB training for incoming faculty and students as needed.

VIII. Discussion of Prior Meetings Full Review Research Proposal

- A. Protocol# 201204007-Outlaw: A Family based Intervention for Management of Childhood Obesity
  - 1. All revisions were completed as the board stipulated
  - 2. Protocol received approval on June 13, 2012
- B. Protocol# 201203003-Jones: Effects of Caffeine Consumption on Strength Performance in the Lower Body
  - 1. All revisions were completed as the board stipulated
  - 2. Protocol received approval on June 5, 2012
- C. Protocol# 201202008-Lindsay: Alabama Law Enforcement Officer's Alcohol Consumption Study
  - 1. All revisions were completed as the board stipulated
  - 2. Protocol received approval on June 6, 2012

IX. New Business

None to report

X. Adjourn

Motion to Adjourn: Dr. Mariano  
Second: Dr. Abbey  
Meeting adjourned 10:20