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**MIDDLE
TENNESSEE**
STATE UNIVERSITY

July 11, 2008

Dr. Kaylene Gebert
CAB 111

Dr. Michael Allen
Box 52

Re: FY 08 Annual Report of the Institutional Review Board (IRB)

Dr. Gebert:


Attached are the minutes from the IRB last year. Please note, there were no meetings from November 2007 through May, 2008. This is due to following the Common Rule. Applications that were previously approved under full review actually fall under expedited and/or exempt, which do not require a full review meeting.

In regards to the research protocols, there were a total of 341. Of those 341 protocols; 4 were full review, 123 were expedited review, and 214 were exempt review. 62 protocols have received a Final Report and are closed. There were no adverse events reported.

Sincerely,



Tara M. Prairie
Research Compliance Officer



Dr. William Langston
Fiscal Year 2008 Chair



A Tennessee Board of Regents University

MTSU is an equal opportunity, non-racially identifiable, educational institution that does not discriminate against individuals with disabilities.

MIDDLE TENNESSEE STATE UNIVERSITY
IRB COMMITTEE MEETING
SEPTEMBER 25, 2007
JAMES WALKER LIBRARY

Members Present: William Langston (Chair) Lisa Pruitt (Vice Chair)
Cheryl Flannigan Robert Kalwinsky
Joe Hawkins Tim Graeff
Michael Sanger Melinda Korzaan
Jim Hodgson Aleka Blackwell
Michelle Blaylock-Howser Leigh Ann McInnis
Reuben Kyle (Community Member) Tara Praire (no vote)

Members Absent: Gore Ervin Lita Warise
Ida Fazillah Victoria Dawn Shelar
Vincent Smith Robert Rogers
James Nunnery

Guests: Joe Baker

The meeting convened at 1:36 A.M. with a quorum of nine (11) voting members present.

1. MINUTES OF THE MEETING HELD ON (April 24, 2006).

Last minutes approved over summer. No approval of minutes.

2. ANNOUNCEMENTS.

Tara introduced her "IRB Reminder List" poster
Tara announced her intention to locate an IRB Fellow.

All people present introduced themselves.

3. DISCUSSIONS.

We now have four (4) alternate community members.

www.yourmorals.org was introduced as a good source by which to guide IRB decisions when the committee is undecided or in conflict in deciding an issue.

Concerning Dexa X-Ray Scans:

Dexa use is considered expedited in a number of institutions outside of MTSU
Motion to allow Dexa to be approved as expedited (Open to discussion):

-Questions remain concerning the cumulative effect of radiation exposure from the Dexa machine

-Experts suggest that cumulative effects are minimal.

-Perhaps study should be conducted addressing the issue of total cumulative radiation exposure on persons both operating the machines, and on subjects of tests, which require Dexa scans.

-Language concerning the unknown long-term exposure risks to radiation from the Dexa machine should be included in any future studies consent form that require Dexa scans

-Studies should acknowledge risk for technicians who will be exposed multiple times.

-If made expedited it must be up to the reviewer of any protocol that includes Dexa scans to make sure the risk is acknowledged.

-Should a medical expert be included on every protocol in which the Dexa machine will be used?

-It should be up to the reviewer of any protocol that includes Dexa scans to determine if the protocol should be reviewed as expedited or full based on the capacity in which the machine will be used.

Interview with Health & Human Performance Representatives:

-Concerning the risk of multiple exposures:

-Studies using the Dexa machine tend to be very population specific, so there is a very low chance of any one student participating in multiple Dexa scan studies

-Language concerning possible risks of multiple exposures to radiation emitted from the Dexa machine will be added to all consent forms in which the machine will be used.

-Concerning diagnosis of possible ailments after Dexa scan:

-Legally, researchers using the Dexa machine cannot diagnose any ailment that may be found throughout the scanning process.

-The x-ray dosage used in a Dexa scan is too low to diagnose any ailment outside those of bone density issues.

-Researchers may infer medical conditions, and subsequently imply that a subject visit a doctor, but they cannot share with the participants any specific diagnosis that is found.

-X-ray pictures are shared with the subjects, and often times are given to the participants as a 'gift', but any data that may be used to diagnose any ailments will not be shared.

-Language will be added to all consent forms using Dexa scans concerning the legal inability of the researchers to diagnose.

-Concerning the cumulative effect of radiation over time:

-There are very few exposures to radiation in any Dexa experiment conducted at MTSU relative to common hospital usage.

-In a single Dexa scan, both the subject and the technician/experimenter are subject to roughly the same amount of radiation.

-Language will be added to all consent forms using Dexa scans concerning possible risks to multiple exposures to radiation to Dexa machines.

IRB Decision and Vote: Eleven (11) members voted unanimously to approve Dexa scans as qualifying for expedited review.

4. NEW BUSINESS.

There is no new business.

5. INITIAL REVIEWS.

(1) Principal Investigator: Amy Tyler Petty

Protocol Title: Perceptions towards and misuse of prescription drugs.

Protocol Number: 08-036

Protocol precis or summary: The purpose of this project is to explore the use and attitudes that college students have towards prescription drug abuse.

(a) Discussion:

- Primary reviewer was unsure whether or not the survey will be conducted in or out of class.
- All data must be kept within the advisors office.
- Does asking an 18 year old about illegal activity in which they were engaged one year prior (i.e. when they were 17 years old) equate to asking a minor about illegal activity?
 - i. No
- Demographic questions are very limited.
- Because of the nature of the survey's demographic questions, MTSU's online psychology subject pool, and the need to retain information concerning each participant's identity for class credit purposes, the confidentiality of each participant is compromised.

- i. Confidentiality is compromised concerning who participated in the study, however, specific answer to any particular question on the survey can in no way be matched to any particular subject.
- Because the study cannot ensure complete anonymity the experimenters must delete the confidentiality language in the protocol proposal.
- In an effort to make those questions that are negatively worded less confusing, the experimenter should rewrite those questions so that they are positively worded.
- Consent form modifications:
 - i. Re-write #4 in the first person tense.
 - ii. Fix typo within the template of question #12.
 - iii. Remove questions 6 & 8.
 - iv. In question #2, erase "to complete" at the end.

Discussion with Investigators:

-Concerning Demographic Questions:

-“White” & “Black” were used because they make up the majority of students attending MTSU.

-Using demographics from lesser-represented ethnic groups may possibly compromise those individuals identity.

-“Freshman” and “Other” were used for the same reason.

-Concerning the negatively worded questions:

-Will express the committee’s concerns to her advisor.

(b) Stipulations: There were no stipulations.

(c) Recommendations: There were no recommendations

(d) Controverted Issues & Resolutions:. There were no controverted issues.

(d) IRB Decision and Vote: Eleven (11) members voted unanimously to approve.

(2) Principal Investigator: Joy Pollard

Protocol Title: Peer-mediated techniques with toddlers with autism

Protocol Number: 08-034

Protocol precis or summary: This study investigates whether or not toddlers can be trained as peer mediators to children with autism

(b) Discussion:

- The experimenter will train two groups of three normally developing peers individually over the course of 5 sessions.
- The script seems too wordy to be followed by and responded to by 18-36 month old peers.
- Special instructions/qualifications for the experimenter should be listed.
- There is a small amount of risk involved in the study but none that could be expected outside of those in everyday life.
- Experimenter may want to increase number of subjects.
- Can assent be given by an 18 month old?
 - Assent will be given verbally and all experimental activity will be ceased should the child show any signs of discomfort.

Discussion with Investigators:

- Concerning whether or not 18-36 month olds can follow the script:
 - This is the thesis in question.
- Concerning the number of subjects:
 - The current number should suffice, however, the number of subjects will be increased.

- (b) Stipulations: There were no stipulations.
- (e) Recommendations: There were no recommendations
- (d) Controverted Issues & Resolutions: There were no controverted issues.
- (f) IRB Decision and Vote: Ten (10) members voted unanimously to approve.

(1) Principal Investigator: Kari Campbell

Protocol Title: Baseline characteristics of ALERT and non-ALERT schools using the Global School-Based Health Survey in Ghana, West Africa.

Protocol Number: 08-035

Protocol precis or summary: This study will investigate the baseline characteristics of ALERT and non-ALERT schools using the Global School-Based Health Survey in Ghana, West Africa.

(c) Discussion:

- Consent form cannot be signed by 15 year old participants.
 - i. Current consent form for 15 year old participants must be changed to assent form.

- Be more specific regarding the potential discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in the study (#4 on consent form).

(b) Stipulations: There were no stipulations.

(g) Recommendations: There were no recommendations

(d) Controverted Issues & Resolutions: There were no controverted issues.

(h) IRB Decision and Vote: Ten (10) members voted unanimously to approve.

(3) Principal Investigator: Dr. Jwa Kim

Protocol Title: Psychometric validation of the social support scale for children and adolescents.

Protocol Number: 08-033

Protocol precis or summary: Psychometric validation of the social support scale for children and adolescents.

(d) Discussion:

- Assent must be given before questionnaire is handed out.
- Clarification on the purpose of the study is needed.
 - i. Currently asks nothing concerning social support, religiosity, etc.
 - ii. Current language may be construed as offensive and/or adverse.
- A number of the questions are double-barreled.
- Consent form needs clarification.

(b) Stipulations: The above discussion topics must be clarified.

(i) Recommendations: There were no recommendations

(d) Controverted Issues & Resolutions: There were no controverted issues.

IRB Decision and Vote: Ten (10) members voted unanimously to table the protocol until the above stipulations are adjusted.

6. EXPEDITED INITIAL REVIEWS, EXPEDITED CONTINUING REVIEWS OR EXPEDITED AMENDMENTS

There were no expedited initial reviews, expedited continuing reviews, or expedited amendments.

7. CONTINUING REVIEWS.

There were no continuing reviews.

8. AMENDMENTS.

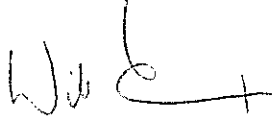
There were no amendments

9. REPORT OF ADVERSE EVENT(S).

There were no adverse event(s) reported at the meeting.

10. ADJOURNMENT

The meeting adjourned at 3:11 P.M.

Signed and Approved by:  _____, Chair
William Langston, PhD

MIDDLE TENNESSEE STATE UNIVERSITY
IRB COMMITTEE MEETING
OCTOBER 30, 2007
JAMES WALKER LIBRARY

Members Present: William Langston (Chair) Lisa Pruitt (Vice Chair)
Tim Graeff Patrick Geho
Michael Sanger Leigh Ann McInnis
Melinda Korzaan Aleka Blackwell
Victoria Dawn Shelar James Nunnery
Tara Prairie (no vote)

Members Absent: Gore Ervin Lita Warise
Ida Fazillah Vincent Smith
Robert Rogers Cheryl Flannigan
Robert Kalwinsky Joe Hawkins
Jim Hodgson Michelle Blaylock-Howser
Reuben Kyle (Community Member)

Guests: Joe Baker

The meeting convened at 1:36 P.M. with a quorum of ten (10) voting members present.

1. MINUTES OF THE MEETING HELD ON (September 25, 2007).

Suggested changes: Meeting began 1:36 P.M
Dexa= DEXA

Minutes approved per suggested changes.

2. ANNOUNCEMENTS.

Dr. Geho was introduced as the newest member of the IRB.

The Student Government Association will decide which students will be assigned to the IRB as student members.

3. DISCUSSIONS.

Should innocuous cognitive tests be included under exempt review?

-Motion to approve: Nine (9) members voted to approve the addition of innocuous cognitive tests under exempt review. One (1) member abstained from voting.

4. NEW BUSINESS.

DEXA Informed consent:

- Question #10: Last sentence is ambiguous.
Should state: "Pregnant women cannot participate" as opposed to "advise against pregnant women participating".
- Question #6: Should be deleted.
- Question #1: Consent form should state exactly what the DEXA procedure measures.
- Question #4: Researchers must make clear that multiple exposures to radiation are cumulative.

5. INITIAL REVIEWS.

There were no initial reviews.

6. EXPEDITED INITIAL REVIEWS, EXPEDITED CONTINUING REVIEWS OR EXPEDITED AMENDMENTS

(1) Principal Investigator: Dr. Jwa Kim

Protocol Title: Psychometric validation of the social support scale for children and adolescents.

Protocol Number: 08-033

Protocol precis or summary: Development of a psychometric validation of the social support scale for children and adolescents.

- a. Discussion: This proposal has only been submitted for the completion of a grant.
- b. Stipulations: Must submit all materials to the Committee before data can be collected
- c. Recommendations:
- d. Controverted Issues & Resolutions:
- e. IRB Vote & Decision: Ten (10) members voted unanimously to approve the protocol per stipulations.

7. CONTINUING REVIEWS.

There were no continuing reviews.

8. AMENDMENTS.

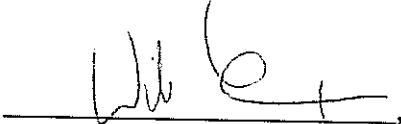
There were no amendments

9. REPORT OF ADVERSE EVENT(S).

There were no adverse event(s) reported at the meeting.

10. ADJOURNMENT

The meeting adjourned at 2:19 P.M.

Signed and Approved by: , Chair
William Langston, PhD