

Middle Tennessee State University
IRB Committee Meeting
October 12, 2005
Sun Trust Room BAS

Members Present:	Dr. Robert Kalwinsky (Chair)	Dr. Anita Crockett
	Dr. William Langston	Dr. Katherine Davis
	Dr. Peggy O'Hara Murdock	Dr. Lisa Pruitt
	Dr. Jim Nunnery	Tara Prairie, Compliance (No Vote)
	Dr. Reuben Kyle	Dr. Michael Sanger
	Dr. James Hodgson	_____
_____	_____	
_____	_____	

Members Absent:	Dr. Cheryl Flanigan	Blake DeVar (Student)
	_____	_____
	_____	_____
	_____	_____

Guests: (include affiliation)	Kim Collins (Administrator)	_____
	_____	_____
	_____	_____

The meeting convened at 2:00 P.M. with a quorum present.

1. MINUTES OF THE MEETING HELD ON (September 14, 2005).

Approved as read with the addition of the vote which would require letters from both the Superintendent(s) of a School System as well as the Principal(s) of the schools where research is done involving minors. Unless the school is a private school, which is not under a superintendent and then only the signature of the Head Master or equivalent title is required.

2. ANNOUNCEMENTS.

There were no announcements.

3. discussions.

Two issues were discussed: Who constitutes a faculty supervisor? & What constitutes a researcher for purposes of training and being listed on the form?

Who constitutes a faculty supervisor?: Dr. Langston moved, "If the individual was hired as faculty then they are faculty. A student even a graduate teaching assistant ("GTA") is a student.

To be a faculty supervisor, the individual must be a member of the faculty. For forums, both the GTA and the faculty must be listed.” Nine members voted unanimously to approve this definition.

What constitutes a researcher for purposes of training and being listed on the form?: Since there are no guidelines or policies regarding what constitutes a researcher for purposes of training and being listed on the form, Dr. Langston moved, “that a researcher is someone who works with data or contacts the participants.” Nine members voted unanimously to approve this definition.

4. INITIAL REVIEWS.

(1) Principal Investigator: Mindy Smith

Protocol Title: Disordered Eating in Preadolescent Girls: Behavior, Attitudes, and Knowledge

Protocol precis or summary: The project will evaluate the eating behaviors, attitudes, body satisfaction and knowledge of health nutrition and dieting of approximately forty (40) 4th and 5th grade girls in a local elementary school. The project is divided into two (2) sessions. The first session has the subjects independently and anonymously complete a form that includes brief demographic information, the Knowledge of Nutritional and Dieting Information, the Children’s Eating Attitude Test, and Body Size Drawings for them to choose their current and preferred body size. The data will be analyzed by the authors and group data will be summarized for use in the second session. During the second session (one week later) the authors will present the group data results and inaccuracies and misconceptions will be discussed.

(a) Discussion:

General: Is the researcher signature required on informed consent and/or assent form? Are copies required to participants?

Specific:

Scientific design: The procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits: There is no greater than minimal risk but the benefits are great. Specific faulty knowledge will be addressed in the group providing the data. There are also potential knowledge benefits for the population.

Subject selection: The population to be studied is 4th and 5th grade girls in a local elementary school. All girls will be asked to participate and they will be provided informed consent forms to be taken home to be signed by one or both parents.

Additional safeguards for vulnerable subjects.: Risky behaviors disclosed during the second session will be reported to parents.

Minimization of risks to subjects: Assent forms are provided to the students to assure their consent and risky behaviors disclosed during the second session will be reported to parents.

Privacy & confidentiality: No identifying information is being recorded.

Consent document: A written informed consent document is sent home with the subjects for one or both parents to sign and a written assent document is provided to the subjects as well.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations: 1. Need permission from the Principal of the school as well as the Superintendent of the System of which the school belongs.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of the research. The stipulations will be reviewed by the Chair.

(2) Principal Investigator: Lisa J. Pruitt
Protocol Title: Narrating Katrina Through Oral History

Protocol precis or summary: The principal investigator and faculty co-investigators will supervise up to 25 teams of undergraduate and graduate student interviewers to conduct interviews who were forced to evacuate coastal Louisiana, Mississippi, and Alabama before, during, and after Hurricane Katrina.

(a) Discussion:

General:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal in comparison to the benefits. Although there is a risk of participants of reliving potentially emotionally painful memories, there are going to be able to not only share their story but benefit agencies and organizations.

Subject selection: The primary subject group will be MTSU students who transferred and enrolled following the disaster and previously enrolled MTSU students with permanent addresses in the affected area. Other subjects will include faculty and staff of MTSU who have immediate families in the affected areas (and whose families relocated here), faculty members of institutions in the affected areas who have relocated temporarily to Middle Tennessee, and volunteer responders from local churches and organizations. Subjects will be recruited through campus wide e-mail or other forms of on campus publicity, word-of-mouth, individual referral, and local publicity.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects.

Minimization of risks to subjects: All faculty and students participating in the study will undergo three hours of training. Also an individual or individuals with expertise in post-traumatic will participate in the training and a list with contact information of local counseling resources will be provided.

Privacy & confidentiality: No social security numbers or private contact information will be recorded or published.

Consent document: A written informed consent form will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations: 1. Add ORSP information to consent form.

2. Submission of IRB Training Certificates for additional investigators.

3. Add to training information, regarding training for post traumatic stress syndrome.

(c) Recommendations: 1. Change the word “repercussions” on the consent form to negative consequences.

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

(e) IRB Decision and Vote: Nine members voted and eight members voted in favor of the research with one abstention.

(3) Principal Investigator: Karen P. Robichaud

Protocol Title: The Effects of an Exercise Program in Postnatal Women’s Psychological Well-Being

Protocol precis or summary: Under the guidance of the physicians of Wood & Cain-Swope Obstetrics and Gynecology, postnatal women will participate in a six week exercise program. The subjects will start six weeks after pregnancy and after medical clearance has been established. Prior to commencing the exercise, the women will participate in completing the Edinburgh Postnatal Depression Scale (“EPDS”) and the Lederman Postpartum Self-Evaluation Scale (“PPQ”). The exercise program consists of a 30 minute video cassette on home based walking routine. Upon completion of the exercise program, the participants will again complete the EPDS and PPQ.

(a) Discussion:

General: Prior to the meeting, the investigator informed Lisa Pruitt that she is changing the term “husband” to “partner” in the second questionnaire.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk however, there has been a request for some clarification.

Risks/benefits There is a minimum risk. The subjects may benefit from an improved sense of well-being and exercise with a minimum risk of discomfort from mild exercise.

Subject selection: The population will consist of postnatal women who are patients of Wood & Cain-Swope Obstetrics and Gynecology who are not single women living by themselves. This group was excluded because single women living by themselves are more likely to suffer from post-natal depression and therefore the depression symptomology scores would be exponentially higher. There was no inclusion/exclusion criteria list provided and upon answering questions, Peggy O’Hara Murdock explained part of the exclusion criteria meant that only women with computers could participate in the study.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects.

Minimization of risks to subjects: The investigator is an exercise scientist and will communicate weekly by e-mail with subjects. Questionnaire responses that trigger concern will be faxed to the physician.

Privacy & confidentiality: Data will be coded for confidentiality.

Consent document: A written informed consent form will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations: 1. Submit inclusion/exclusion list and justify why women without computers are excluded.

2. Add to methodology a notification of the physician if a questionnaire indicates severe depression or stress.

3. Provide control group information, i.e. how it is set up and used.

4. Clarify research design.

(c) Recommendations: 1. Modify language in 5th paragraph to read "Participation in the study is voluntary, but in order for you to participate you must complete the questionnaires. The participant can skip questions. Please disregard "Instructions to Users" #2.

2. Change the first paragraph of the consent form to read, "You are invited to participate in this study. Your physician said you were eligible."

(d) Controverted Issues & Resolutions: A discussion ensued between equity/justice versus researcher autonomy. It was decided to hold this discussion at a later date.

(e) IRB Decision and Vote: Dr. Kalwinsky moved to table the protocol until the necessary stipulations were remedied. Of the eight members, five voted for the table, two voted against, and one abstained.

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

(A) Principal Investigator: There were no expedited reviews reported at the meeting.

Title and type of expedited action:

Date approved by IRB Chair or designee:

Description of expedited action:

6. CONTINUING REVIEWS.

There were no continued reviews reported at the meeting.

(A) Principal Investigator:

Protocol Title:

Protocol Number:

Expiration Date:

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion:

(b) Stipulations

- (c) Recommendations
- (d) IRB Decision and Vote

7. AMENDMENTS.

There were no amendments reported at the meeting.

- (A) Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:

Description of the amendment:

- (a) Discussion:
- (b) Stipulations
- (c) Recommendations
- (d) IRB Decision and Vote

8. REPORT OF ADVERSE EVENT(S).

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

Principal Investigator:
Protocol Title:
Protocol Number:
Date of Adverse Event(s):

Description of the adverse event(s):

9. ADJOURNMENT

The meeting adjourned at 4:15 P.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD

Middle Tennessee State University
IRB committee meeting
November 16, 2005
Sun Trust Room BAS

Members Present:	Dr. Robert Kalwinsky (Chair)	Dr. Vince Smith
	Dr. William Langston	Dr. Katherine Davis
	Dr. Peggy O'Hara Murdock	Dr. Lisa Pruitt
	Dr. Cheryl Flanigan	Tara Prairie, Compliance (No Vote)
	Dr. Reuben Kyle	Dr. Michael Sanger
	Dr. James Hodgson	_____
	_____	_____
	_____	_____
Members Absent:	Blake DeVar (Student)	Dr. Anita Crockett
	_____	_____
	_____	_____
	_____	_____
	_____	_____
Guests:	_____	_____
(include	_____	_____
affiliation)	_____	_____

The meeting convened at 2:00 P.M. with a quorum present.

1. MINUTES OF THE MEETING HELD ON (November 16, 2005).

Approved as read.

2. ANNOUNCEMENTS.

a. Please give notice to Kim Collins if you will be out of the office so expedited reviews can be forwarded to other members and are not delayed.

b. When filling out the IRB form, investigators may answer "Not Applicable" (N/A) when it applies to filling out the exclusion criteria section.

c. The Compliance Officer made a reminder that expedited protocols may be reviewed/approved upon receipt. Reviewers do not have to wait until to Committee Meeting.

3. discussions.

Several issues were discussed.

a. Conflict of Interest Recommended Procedure: The PI must step out until the committee members get the issues finalized. Then the PI is invited in to discuss the protocol and answer questions. After questioning, the PI is asked to leave while the committee continues the discussion and votes. Nine members voted unanimously to approve this procedure.

b. Are we going to request letters from all entities/institutions on a go forward or just schools, i.e. Superintendent and Principal? It was decided unanimously by nine members that this issue would be handled on a case by case basis.

c. Are we going to require all Informed Consent forms on letterhead? It was voted unanimously by nine members that the Compliance Officer would create templates for informed consent and assent forms as well.

d. Lisa Pruitt brought up that the CME Training Link is not as easily accessible and asked that it be placed under the Education Links, which that has been requested.

4. INITIAL REVIEWS.

(1) Principal Investigator: Hollie Fisher

Protocol Title: The Effects of Vending Machine Use of Student Behavior and Health

Protocol Number: 06-081

Protocol precis or summary: The study is designed to research the effects of vending machine use on students' health and behavior. Participants are in the 8th grade at a rural middle school. Themselves, their parents and teachers will fill out a survey regarding the student's eating habits.

(a) Discussion:

The protocol was tabled until the stipulations set forth below are met.

Stipulations:

Page 3 of the application is missing – please submit this page.

The student survey questionnaire skips from question 9 to 21; please correct this and resubmit

Will disabled students be able to provide assent without modification of the process?

There are many grammatical issues, including an error in the title ('use on' not 'use of'). Since this is an official document that reflects on this school, please check the grammar throughout the document and make suitable corrections.

You need a letter from the superintendent of the school.

Please change the language on the parental consent form to read – “you and your child are invited to” not simply “you are invited” - so the parent does not have the impression that they alone are participating.

In the parental questionnaire there are many leading questions. Words such as ‘non-nutritional’ (as in #8) or terms that reinforce presupposed attitudes (#14) ensure that negative effects will result – nonbiased approaches are necessary for research. Please modify these questions so they are not leading.

The committee, including the teachers on the committee, want you to understand that what you are requesting of the teachers is somewhat demanding.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of tabling the protocol until the stipulations are met. Once the stipulations are met, the protocol will be reviewed at the next available meeting.

(2) Principal Investigator: Sandra “Sandy” Spicer

Protocol Title: Educating adolescent students about good nutrition habits through the content area of Reading

Protocol Number: 06-082

Protocol precis or summary: This study is designed to intervene in the negative nutrition habits of adolescent students. They will be instructed on good nutrition habits according to the Health Textbook that is provided by the Dickson County Board of Education and currently used at Charlotte Middle School. The participating students will fill out an anonymous questionnaire and will keep a journal on their chosen nutrition each day. Participating students will be allowed to consume snacks and drinks during the Reading class from which observations will be made.

(a) Discussion:

General:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: The subject pool involves students in the PI’s Reading class.

Additional safeguards for vulnerable subjects: Informed Consent forms will be provided to parents and assent forms will be provided to minors.

Minimization of risks to subjects: The level of risk is minimal and the PI will be providing informed consent forms to the parents and assent forms to the children.

Privacy & confidentiality: No personal identifiers will be used.

Consent document: Written informed consent and assent forms will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations: 1. The PI needs to provide the Informed Consent and Assent forms.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of the research upon receipt of the informed consent and assent forms.

(3) Principal Investigator: Amy K. Lowe

Protocol Title: Positive Effects of Inclusion on the Student with Mental Retardation

Protocol Number: 06-083

Protocol precis or summary: This study is to determine the positive effect an inclusionary environment has on children with mental retardation. There will be a determination by observation the positive impact an inclusionary environment has on special education students with mild to moderate mental retardation. Negative aspects will be observed as well. The investigator will look for more age appropriate behavior and keep tally sheets to track specific behaviors.

(a) Discussion: The protocol was tabled until the stipulations set forth below are met.

Stipulations:

You are presupposing positive effects for inclusion – the study’s conclusions are already made. It is not research if you are seeking validation of a presupposition. Thus your title should be “Effects of Inclusion” rather than “Positive Effects of Inclusion.” One example of negative effects is the research demonstrating the psychological stress from subtle ridicule and teasing that has a toll on moderately retarded children in an inclusive classroom.

In terms of confidentiality, there is no need to use first names of the students – please use a pseudonym or a number.

What happens if permission is not granted?

Verbal assent is required for all students.

Please submit readable copy of your protocol.

Please submit a letter from the relevant superintendent of schools.

Please describe your data collection process.

The consent form is incomplete - please see the standard form on the IRB website or call Tara Prairie at 8918 for assistance.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of the research upon receipt of the informed consent and assent forms.

(4) Principal Investigator: Sunshine Pinell

Protocol Title: Looking at African Immigration in the Normandy Region of France

Protocol Number: 06-099

Protocol precis or summary: To acquire first hand information concerning the process of African assimilation, and aim to uncover the trials and triumphs experienced through the processes of immigration and integration. The investigator's goals are to discover the country of origin and ethnicity of immigrants, their motivation for relocation, differences between their native lands and France, as well as barriers facing immigration integration. The investigator will then incorporate the data into an exploration of their notion of identity.

(a) Discussion:

General:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be selected purely on availability. No payment will be granted to the subjects and the investigator plans to seek the subjects within the open market, as well as any informal/public facilities that cater to African immigrants.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects in this study.

Minimization of risks to subjects: The risks of participating in the interviews are minimal to the subjects.

Privacy & confidentiality: No personal identifiers will be published and all original recordings, field notes, consent forms, and other related materials will be collected, compiled and placed in a sealed envelope, which will then be stored in the investigator's personal file cabinet for a minimum of three years.

Consent document: The consent document is to be revised and the investigator will confirm the informed consent document will be provided in French and on MTSU letterhead.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Stipulations:

The consent form is incomplete – please see the standard form on the IRB website or call Tara Prairie at 8918 for assistance.

Please provide a statement that the consent form will be provided in French and on official MTSU letterhead;

Please indicate what happens to the collected material after 3 years.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Seven members voted unanimously in favor of the research upon the above stipulations.

Old Business:

(5) Principal Investigator: Karen P. Robichaud

Protocol Title: The Effects of an Exercise Program in Postnatal Women's Psychological Well-Being

Protocol precis or summary: Under the guidance of the physicians of Wood & Cain-Swope Obstetrics and Gynecology, postnatal women will participate in a six week exercise program. The subjects will start six weeks after pregnancy and after medical clearance has been established. Prior to commencing the exercise, the women will participate in completing the Edinburgh Postnatal Depression Scale ("EPDS") and the Lederman Postpartum Self-Evaluation Scale ("PPQ"). The exercise program consists of a 30 minute video cassette on home based walking routine. Upon completion of the exercise program, the participants will again complete the EPDS and PPQ.

(a) Discussion:

General:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk however, there has been a request for some clarification.

Risks/benefits There is a minimum risk. The subjects may benefit from an improved sense of well-being and exercise with a minimum risk of discomfort from mild exercise.

Subject selection: The population will consist of postnatal women who are patients of Wood & Cain-Swope Obstetrics and Gynecology who are not single women living by themselves. This group was excluded because single women living by themselves are more likely to suffer from post-natal depression and therefore the depression symptomology scores would be exponentially higher. There was no inclusion/exclusion criteria list provided and upon answering questions, Peggy O'Hara Murdock explained part of the exclusion criteria requires women to not have computers.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects.

Minimization of risks to subjects: The investigator is an exercise scientist and will communicate weekly by e-mail with subjects. Questionnaire responses that trigger concern will be faxed to the physician.

Privacy & confidentiality: Data will be coded for confidentiality.

Consent document: A written informed consent form will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations:

1. In the fifth paragraph of the informed consent letter please change "Funds to compensate for physician visits due to injury or distress are not routinely available by this study." to "Funds to compensate for physician visits due to injury or distress are not available from this study."

(c) Recommendations: There were no recommendations.

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

(e) IRB Decision and Vote: Dr. Kalwinsky moved to table the protocol until the necessary stipulations were remedied. Six members voted unanimously in favor of the research upon the correction on the informed consent form.

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

A list of all approved expedited protocols since the last meeting (November 16, 2005) was provided to the Committee and there was no discussion or controverted issues.

6. CONTINUING REVIEWS.

- (A) Principal Investigator: Don W. Morgan
Protocol Title: Underwater Treadmill Training in Spastic Diplegia
Protocol Number: 05-085
Expiration Date: 12/1/06

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion:

What became of the IRB request for a change in the manner of compensation, so that the payment would not be withheld until the completion of the study? Are we required to have a letter from either Vanderbilt or, the outpatient clinic where the patients are recruited, since they are outside institutions? If the answer to the first is that the policy has been changed, and the answer to the second is that the letters are not required, I will vote for the protocol to be approved."

Approval seems appropriate to me. A couple of issues did crop up in reading over the material. Both are probably easily dealt with. My vote in favor isn't contingent on how they are resolved. No evidence that two issues raised in letter from Hood to PI (dated 11/19/04) were addressed. Those issues were:

1. Withholding of reimbursement until the end of the study
2. HIPAA authorization/waiver

Can we assume that they were resolved to the committee's satisfaction? I didn't read all of the many apparently identical versions of this proposal packed into the pdf, but I did scan them for evidence of adjustments. None were spotted.

(b) Stipulations Although there is an approval letter in the file, there is no documentation of the changes so the investigator will be providing the necessary documents to assure the changes were made.

(c) Recommendations

– Consent form errors (minor sort)

1. p. 4 of 7; Item 3 ("Your child will incur not costs...".)
2. p. 5 of 7; Item 5 ("...facilities and professional which are available will not be provided free of charge...".)

[Consent form was written in a style many parents are likely to find obscure.]"

(d) IRB Decision and Vote Vote was done through e-mail and seven members voted unanimously to allow the investigator to continue research.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 3:22 P.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD

Middle Tennessee State University
IRB committee meeting
December 14, 2005
Sun Trust Room BAS

Members Present: Dr. Robert Kalwinsky (Chair) Dr. Vince Smith
 Dr. William Langston Dr. Katherine Davis
 Dr. Peggy O’Hara Murdock Dr. Lisa Pruitt
 Dr. Cheryl Flanigan Tara Prairie, Compliance (No Vote)
 Dr. Reuben Kyle Dr. Michael Sanger
 Dr. James Hodgson Dr. Anita Crockett

Members Absent: Blake DeVar (Student) _____

Guests: Dr. Anthony Farone (Faculty Advisor)
John Jackson (Graduate Student)

The meeting convened at 2:00 P.M. with a quorum of seven present. Dr. Kathy Davis and Dr. James Hodgson arrived at 2:10 P.M. and Peggy O’Hara Murdock arrived at 2:24.

1. MINUTES OF THE MEETING HELD ON (November 16, 2005).

Approved as read unanimously with seven (7) votes.

2. ANNOUNCEMENTS.

The Compliance Office announced that subsequent to attending the PRIM&R Conference, that along with Lisa Pruitt of Oral History and the Folklore, Anthropology, and Sociology Departments are working to create IRB Policies and Procedures language pertaining to Oral History.

3. discussions.

Several issues were discussed.

a. As we require letters from the Superintendent of public schools, are we going to request letters from the Tennessee Association of Independent Schools in regards to private schools? Nine members voted unanimously to keep it as an as needed basis.

b. Do you need oral assent from children under the age of seven (7)? Dr. Kalwinsky will research this matter.

c. Reviewers will continue to send approval letters. The Compliance Officer will send templates for the letters.

4. INITIAL REVIEWS.

Dr. Langston moved to discuss and vote on 06-109 since Dr. Anthony Farone and John Jackson were guests in regards to the protocol. The motion was unanimously approved with nine (9) votes.

Dr. Anthony Farone and John Jackson stepped out for discussion.

(1) Principal Investigator: John Jackson
Protocol Title: Isolation and Characterization of Diarrheagenic Bacteria in Robillard, Haiti
Protocol Number: 06-109

Protocol precis or summary: The investigator will invite patients in Robillard, Haiti, who are complaining of diarrhea and those who are not (control group) to participate in the study, which would require the investigator to dip a swab into the stool sample that a doctor and/or nurse collects. The investigator will then attempt state side to isolate the different bacteria and genetically analyze them in order to determine which strains are present.

(a) Discussion:

General:

Dr. Langston recommended that the IRB not be listed on the informed consent and that a local Haitian contact be provided in addition to the Murfreesboro contact. It should also be confirmed that the patients may withdraw at any time.

Dr. Pruitt questioned how the samples will be matched once they are state side.

Dr. Hodgson questioned the circumstances of the clinic.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be selected purely on availability.

Additional safeguards for vulnerable subjects: Informed consent and assent will be obtained either written or oral. In case of oral consent/assent, it will be documented. Forms will be provided in French as well as Creole and there will be interpreters on site as well.

Minimization of risks to subjects: The investigator will be contacting either Père Michele, Dr. Metellus, and/or the trained medical providers to disclose any dangerous bacteria or parasites that may be found. Antibiotics as well as deworming medicine is provided to patients as a standard of care.

Privacy & confidentiality: No personal identifiers will be published and all data collected will be stored in a locked file cabinet in the faculty advisor's office for a minimum of three years.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Dr. Kalwinsky invited the investigator and the faculty advisor back into the conference room to answer questions.

Dr. Langston asked Mr. Jackson what the network of communication is. Mr. Jackson responded that Dr. Metellus from Cap Haitian frequents the clinic and works with locals to train them as medical providers. Also, Père Michele handles the majority of the communication and has access to e-mail as well as a cell phone.

Dr. Crockett asked how Mr. Jackson planned to obtain fecal swabs that were not diarrhea. Mr. Jackson responded by choice patients can either allow him to swab the samples at the clinic or the patients can leave and bring back a sample.

Dr. Hodgson inquired about an age range. Mr. Jackson responded that he wanted to see if there is a significant difference between adult and children as far as what bacteria is present in their system in order to target future treatment.

Dr. Hodgson then inquired to how the data/samples would be disposed. Mr. Jackson responded that the samples will be stored and grown in a Biosafety II container. Most of the samples will be destroyed in an autoclave.

Dr. Nunnery inquired as to how Mr. Jackson will be able to determine the causative agent. Mr. Jackson responded he will be looking for strains of disease causing genes of specific bacteria. He said the majority of cases involve parasites, which he also may be able to identify. Mr. Jackson stated that the standard of care is to provide patients deworming medicine.

Dr. Kalwinsky inquired as to how Mr. Jackson plans to retain confidentiality. Mr. Jackson responded that he will number the samples upon collection along with the name and age so he can cross reference the data. He would destroy the links.

The investigators stepped out for voting.

Stipulations:

1. On the consent and assent forms, have the header identify the investigator's group from MTSU and not the IRB. The investigator has authored the document and it is more appropriate for clients to identify their group with the assent/consent document.

2. On the consent form, some local contacts for clients need to be added (i.e., it is unlikely they will be able to call a 615 area-code phone number). The investigator might suggest they contact the parish priest via e-mail, or return to the clinic with questions and/or possible injury, or provide them a local phone number – any or all of these, or any other methods of local contact they deem helpful.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Ten members voted unanimously in favor of the protocol pending stipulations are met.

(2) Principal Investigator: Mark Abolins

Protocol Title: Development, Implementation, Evaluation and Dissemination of GeoBrain curricula

Protocol Number: 06-108

Protocol precis or summary: The investigators seek to develop three two-hour undergraduate activities. They will build the activities around GeoBrain software and data. They will utilize a successful model for computer-based curricula (SAUARO) developed by the National Science Foundation (NSF). The investigators will develop, implement, and evaluate the activities at Middle Tennessee State University. They will extensively involve undergraduates in development and implementation. The investigators will disseminate evaluation results at meeting and through a journal manuscript. They will disseminate beta versions of the activities on CDs at meetings and final versions through the Digital Library for Earth System Education (www.dlese.org).

(a) Discussion:

General: Dr. Langston moved that upon the committee providing recommendations, that the Compliance Officer can approve the protocol as expedited review.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be students enrolled in sections of Geol 1030 (Intro. to Earth Science), Geol 2000 (Intro. to Regional Geology), Geol 4020 (Geomorphic Regions of the US), and Geog 4490 (Remote Sensing).

Additional safeguards for vulnerable subjects: There are no vulnerable subjects.

Minimization of risks to subjects: The level of risk is minimal.

Privacy & confidentiality: Study data will reside in a single, password-protected computer at a location inaccessible to personnel uninvolved in the study. Study data will not be transmitted by computers by ftp or e-mail. Questionnaires will be anonymous.

Consent document: Written informed consent forms will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations:

1. On page 2 of the questionnaire, for the questions starting with “On average,” the investigator may want to lengthen the answer lines;
2. The consent form needs to be on official MTSU letterhead and the investigator can add the Compliance Officer’s contact information as well [irb@mtsu.edu, (615) 494-8918]; and,
3. On page 2, indicate what the actual ranking is for 1-5, i.e. difficulty and interest.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Ten members voted unanimously in favor of the research to be labeled as expedited upon the above stipulations.

(3) Principal Investigator: Katrina McMullen

Protocol Title: Bridging the Gap Between Teachers’ Views and School Psychologists’ Views of Behavior Management

Protocol Number: 06-110

Protocol precis or summary: Teachers (approx. 50) in Cannon County elementary schools grades K-5 will be asked to fill out surveys regarding behavior management in their classrooms. Teacher attitudes and practices will be compared to School Psychologist’s training and practices regarding behavior management.

(a) Discussion: General: Dr. Langston moved that upon the committee providing recommendations, that the Compliance Officer can approve the protocol as expedited review.

Stipulations:

1. Provide letters from the Principals of each Cannon County elementary school you intend to do research expressing their acknowledgement of same;
2. In regards to the letter from the Cannon County Board of Education, confirm who Marcia Melton is;
3. In the second paragraph of the Oral Consent Script, after “Are there any questions?” the investigator should add their contact information as well as the Compliance Officer’s (irb@mtsu.edu (615) 494-8918); and,
4. Need a copy of Dr. Wallace’s certificate of training.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Ten members voted unanimously in favor of the research to be labeled as expedited upon the above stipulations.

(4) Principal Investigator: David Moeding

Protocol Title: Comparison of Bone Mineral Density of Pre and Post Test Surgery

Protocol Number: 06-111

Protocol precis or summary: The purpose of the study is to examine differences in bone mineral density of pre and post surgical participants who are using crutches post-surgery. Participants will have their height, weight, and bone mineral density measured. Body weight will be measured to the nearest 0.1 lb with a calibrated digital scale (SECA 770). Height will be measured to the nearest 0.25 inch with a stadiometer and bone mineral density will be measured using a DEXA densitometer (Hologic 4500 QDR). Post test measures will be taken upon release of the crutches by the participants physician. Pre and post test measures will be compared to determine if the use of the crutches impacted bone mineral density of the upper and lower body limbs.

(a) Discussion:

General: Dr. Pruitt stated that the investigator has not taken into consideration if patients who may be cognitively impaired were introduced into the study. Upon follow up with the faculty

advisor after the meeting, she confirmed that no patients with cognitive impairment will be allowed to participate in the study.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: The participants will be volunteers directed to the investigator by Michael Jordan of the Tennessee Orthopaedic Alliance. Participants undergoing a lower body surgery that will result in the participant being non-weight bearing (on crutches) for 4-8 weeks will be referred for study participation.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects in this study.

Minimization of risks to subjects: The risks are minimal to the subjects.

Privacy & confidentiality: All participants will be coded by number to ensure anonymity. All data and information will be stored for three years by the researcher in a locked cabinet in the exercise physiology lab at MTSU. After three years, files will be shredded and all computer data destroyed.

Consent document: Written informed consent forms will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Stipulations:

1. The grammatical or typing errors made some aspects of this proposal difficult to comprehend (e.g., please see page 2, “measure will be taken up release from the use of crutches...”). Specifically, under section 4 of page 11 (E) Research involving ... – the last sentence of the page ends with ‘During’ – yet there is nothing on the next page to follow (‘Dr. Jennifer Caputo and Dr. Richard Farley’). Is there a page missing?
2. Dr. Richard Farley is a researcher in this study and thus must be included in the application as an investigator. The IRB will need a certificate of training and he is to be included on the first page as an investigator.
3. A letter is needed from both Dr. Tom Johns and Dr. Michael Jordan - the investigator included the one from Dr. Jordan but there is not one from Dr. Johns.

(c) Recommendations: There are no recommendations.

(d) Controverted Issues & Resolutions: There was discussion on whether asking the investigator to consider the possibility of cognitively impaired patients being introduced to the study was unreasonable. The Committee decided to go ahead and vote on the protocol. Subsequently, the faculty advisor confirmed that cognitively impaired patients would be excluded from the study.

(e) IRB Decision and Vote: Ten members voted with seven (7) members voting in favor of the protocol and three (3) members voting against the protocol.

Old Business:

(5) Principal Investigator: Karen P. Robichaud

Protocol Title: The Effects of an Exercise Program in Postnatal Women's Psychological Well-Being

Protocol Number:

Protocol precis or summary: Under the guidance of the physicians of Wood & Cain-Swope Obstetrics and Gynecology, postnatal women will participate in a six week exercise program. The subjects will start six weeks after pregnancy and after medical clearance has been established. Prior to commencing the exercise, the women will participate in completing the Edinburgh Postnatal Depression Scale ("EPDS") and the Lederman Postpartum Self-Evaluation Scale ("PPQ"). The exercise program consists of a 30 minute video cassette on home based walking routine. Upon completion of the exercise program, the participants will again complete the EPDS and PPQ.

(a) Discussion:

General:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk however, there has been a request for some clarification.

Risks/benefits There is a minimum risk. The subjects may benefit from an improved sense of well-being and exercise with a minimum risk of discomfort from mild exercise.

Subject selection: The population will consist of postnatal women who are patients of Wood & Cain-Swope Obstetrics and Gynecology who are not single women living by themselves. This group was excluded because single women living by themselves are more likely to suffer from post-natal depression and therefore the depression symptomology scores would be exponentially higher. There was no inclusion/exclusion criteria list provided and upon answering questions,

Peggy O'Hara Murdock explained part of the exclusion criteria requires women to not have computers.

Additional safeguards for vulnerable subjects: There are no vulnerable subjects.

Minimization of risks to subjects: The investigator is an exercise scientist and will communicate weekly by e-mail with subjects. Questionnaire responses that trigger concern will be faxed to the physician.

Privacy & confidentiality: Data will be coded for confidentiality.

Consent document: A written informed consent form will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations:

1. In the fifth paragraph of the informed consent letter please change "Funds to compensate for physician visits due to injury or distress are not routinely available by this study." to "Funds to compensate for physician visits due to injury or distress are not available from this study."

(c) Recommendations: There were no recommendations.

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

(e) IRB Decision and Vote: Dr. Kalwinsky moved to table the protocol until the necessary stipulations were remedied. Six members voted unanimously in favor of the research upon the correction on the informed consent form.

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

A list of all approved expedited protocols since the last meeting (November 16, 2005) was provided to the Committee by e-mail after the IRB meeting and there was no discussion or controverted issues.

6. CONTINUING REVIEWS.

(A) Principal Investigator: John Coons

Protocol Title: Sex and Race Differences in the Assessment of Skeletal Symptoms of Marfan Syndrome

Protocol Number: 04-217

Expiration Date: 06/06/05

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion: There was a discussion about the duty to disclose and to research the federal regulations pertaining to continued review and renewals.

(b) Stipulations:

1. While implicit in your description, please add a statement that ensures us of the following: if a patient appears to have Marfan's syndrome, the researchers will notify the patient and/or the patient's parents that while the test is not diagnostic, there is an indication of the disease and that physician follow-up is warranted.

2. You list seven researchers on this study, yet we only have certificates of training for three. Please submit copies of the other researchers' certificates to comply with federal regulations

(c) Recommendations: To review the protocol for grammatical errors.

(d) IRB Decision and Vote Ten members voted and there was a unanimous vote in favor of the continued review pending the above stipulations.

(A) Principal Investigator: John Coons
Protocol Title: Sex and Race Differences in the Assessment of Skeletal Symptoms of Marfan Syndrome
Protocol Number: 04-217
Expiration Date: 06/06/05

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion: There was a discussion about the duty to disclose and to research the federal regulations pertaining to continued review and renewals.

(b) Stipulations:

1. While implicit in your description, please add a statement that ensures us of the following: if a patient appears to have Marfan's syndrome, the researchers will notify the patient and/or the patient's parents that while the test is not diagnostic, there is an indication of the disease and that physician follow-up is warranted.

2. You list seven researchers on this study, yet we only have certificates of training for three. Please submit copies of the other researchers' certificates to comply with federal regulations

(c) Recommendations: To review the protocol for grammatical errors.

(d) IRB Decision and Vote Ten members voted and there was a unanimous vote in favor of the continued review pending the above stipulations.

(B) Principal Investigator: Ginger Holmes Rowell
Protocol Title: STEPMT, STEPMT Phase II, STEPMT Phase III
Protocol Number: 05-139, 05-221, 05-224
Expiration Date: 04/20/06

Protocol Precis or Summary (if not provided in discussion at (a) below):

(a) Discussion: The investigator needs to provide the certificates of training for the additional investigators. Language confirming same will be added to the approval letter form that goes out to all investigators.

(b) Stipulations:

1. The investigator indicated in their renewal that there are several other researchers involved in the study, including student workers who have signed confidentiality agreements. A researcher is anyone who deals with clients or the data during the course of the research (research is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”.) The IRB will need certificates of training from all of these individuals to comply with federal regulations.

(c) Recommendations: There were no recommendations.

(d) IRB Decision and Vote Ten members voted and there was a unanimous vote in favor of the continued review pending the above stipulation.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 3:30 P.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD

MIDDLE TENNESSEE STATE UNIVERSITY
IRB COMMITTEE MEETING
January 18, 2006
BAS (SUN TRUST ROOM)

Determination of Quorum:

Members present: Dr. Anita Crockett, Cheryl Flanigan, Dr. Reuben Kyle, Dr. Vince Smith, Dr. Lisa Pruitt, Dr. Peggy O'hara-Murdock, Dr. James Nunnery, Kathryn Davis, Dr. Michael Sanger, Compliance Office Tara Prairie and Kim Collins (non-voting)

Call to Order

Meeting called to order at 2:00 p.m. by Ms. Tara Prairie, Compliance Officer

Approval of Minutes

Minutes for December 14, 2005 meeting were approved.

Disclosure of Any Conflicts of Interest

No conflicts of interest were reported

Old business

New Business

Guests were introduced to committee members: Dr. Ida Fadzillah, Dr. John Pennington and Justin Drey. The guests each had a protocol being reviewed and were present to answer any questions regarding their submissions.

Protocol 06-118: Submitted by Christopher Pell; unanimously approved with changes.

Primary reviewer: Dr. Anita Crockett

Secondary reviewer: Dr. Vince Smith

Protocol 06-119: Submitted by Justin Ryan Drey; unanimously approved with changes.

Primary reviewer: Dr. Reuben Kyle

Secondary reviewer: Cheryl Flanigan

Protocol 06-120: Submitted by Dr. Ida Fadzillah; unanimously approved with minor changes.

Primary reviewer: Dr. Will Langston

Secondary reviewer: Dr. Peggy O'hara-Murdock

Protocol 06-121: Submitted by Michael J. Bolen with Faculty Advisor Dr. John Pennington present; unanimously approved with minor changes

Primary reviewer: Dr. Michael Sanger

Secondary reviewer: Dr. Lisa Pruitt

Meeting adjourned at 4:10 p.m.

Protocol 06-028 was part of the agenda to be reviewed for changes, i.e. the addition of six (6) questions. However the meeting ran over and the protocol had to be deferred for approval. The IRB Committee members were e-mailed and quorum was reached. The additional questions were unanimously approved.

Dr. Langston moved to discuss and vote on the protocols of guests who are present (06-145, 06-147, 06-143). The motion was unanimously approved with twelve (12) votes.

All investigators stepped out for discussion.

(1) Principal Investigator: Joseph M. Baker
Protocol Title: Lexical Pop-Out: The Effect of Emotion on Automatic Attention Words
Protocol Number: 06-145

Protocol precis or summary: The proposed research intends to generalize the pop-out effect to lexical, or word based, stimuli. The investigator intends to demonstrate that emotional (e.g. threatening or taboo) words will pop-out of a background grid of non-emotional, or neutral words. They intend to present computer-generated stimuli of nine word grids to undergraduate students. A single target word will be displayed, in the center of the computer screen, before each trial. These target words will differ randomly between emotional words and non-emotional words. Participants will be instructed to press the “f” key if the target word is present within the grid, and to press the “j” key if the word is not present. The participants will be instructed to make their decision as quickly as possible.

(a) Discussion:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be obtained due to expressed interest from the psychology pool.

Additional safeguards for vulnerable subjects: Vulnerable subjects will not be used.

Minimization of risks to subjects: The level risk is minimal however, informed consent will be obtained from all subjects.

Privacy & confidentiality: At no time will a subject’s name be directly attached to his/her test results. All consent forms will be kept within a single file folder and will be kept under the investigator’s possession until the data is no longer needed, at which time all data will be destroyed.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Dr. Kalwinsky invited the investigator into the conference room to answer questions.

Dr. Sanger recommended that Article 5 and Article 8 be removed from the informed consent document as they were not applicable.

Dr. Pruitt recommended that the word “emotional” be excluded and include “taboo” or “emotionally charged.”

It was also recommended that during the selection system (psychology pool), participants should be made aware that some of the key words will be emotionally charged.

The investigator stepped out for voting.

Stipulations:

In the sign-up material, please reflect the concern that participants will be exposed to potentially offensive words. You should reiterate this in the consent form as well.

Please make it clear that participants can stop at any time.

In #8, please delete the information about alternative treatment (i.e., n/a is sufficient).

Please eliminate the wealth of general information in the consent form, so participants are not unduly influenced – you do not want to inadvertently lead the respondents.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Twelve members voted unanimously in favor of the protocol pending stipulations are met.

(2) Principal Investigator: Jaclyn Walker

Protocol Title: Measurement of Caloric Expenditure in Elementary Students to Determine Level of Physical Activity

Protocol Number: 06-147

Protocol precis or summary: The purpose of the study is to quantify the amount of physical activity performed by elementary school students in a single physical education class. First and fourth graders at Lascassas Elementary School will wear NL-2000 pedometers to determine the number of steps they accumulate and caloric expenditure. Along with step activity data, each child’s height, weight, and age will be programmed into the pedometers to estimate the number of calories expended during the physical education class.

(a) Discussion:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: One first and one fourth grade physical education class will be observed from Lascassas Elementary School, which will be pre-selected based on availability and the teacher's willingness to participate. After informed consent and assent is obtained, students will be given a pedometer to wear during the duration of the class. Each student will be assigned a number and will receive a pedometer with the corresponding number.

Additional safeguards for vulnerable subjects: In addition to obtaining informed consent from the parents, assent will be obtained from the students as well.

Minimization of risks to subjects: The level of risk is minimal.

Privacy & confidentiality: The research team will assign numbers to each child that participates in the study. All data will be recorded in a spreadsheet with the child's number. Jaclyn Walker, the primary investigator will be in charge of all the data. After the research is completed, the Faculty Advisor, Don Morgan will keep the data in his possession for three years. After three years has passed the data will be destroyed.

Consent document: Written informed consent and assent forms will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Dr. Kalwinsky invited the investigator into the conference room to answer questions.

It was recommended to the investigator that their faculty advisor keep the data rather than the investigator.

It was also stated that verbal assent is appropriate for children who are unable to sign an assent form, i.e. those under the age 7.

The investigator stepped out for voting.

(b) Stipulations:

An MTSU faculty member must be the one responsible for safeguarding, retaining and properly disposing of the data; it generally is the task of the primary investigator(s)/supervisor/advisor. It can not be a student. Please submit a revision to this effect.

On the informed consent form, at the very bottom is a reference to Myra Norman. She is no longer serving as the participant's contact for the IRB. The compliance officer for MTSU is Tara Prairie; her phone number is 494-8918. Please revise this section and resubmit the form. Please note that verbal assent will be satisfactory for any student seven years old or younger. For future reference, there are form templates on the www.mtsu.edu/~irb website that use standard language and ensure inclusion of all items.

- (c) Recommendations: There are no recommendations.
- (d) Controverted Issues & Resolutions: There were no controverted issues.
- (e) IRB Decision and Vote: Twelve members voted unanimously in favor of the protocol pending stipulations are met.

(3) Principal Investigator: Sherri L. Jones
Protocol Title: The Effects of Proprioceptive Training on Balance as Measured on the Biodex Balance System
Protocol Number: 06-143

Protocol precis or summary: The research project will consist of balance testing and proprioceptive training. The purpose of the study is to determine if proprioceptive training will improve balance in high school athletes. There will be two groups, a training group and a control group. Both groups will be tested at the beginning and at the end of a six week period on the Biodex Balance System using the protocols that are provided by the manufacturer. Testing will require the athletes to perform dynamic balance testing and dynamic limits of stability testing. During testing, the participant will be asked to balance while standing on the platform with both legs and also while standing on the platform with each individual leg. The control group will continue with their regular activities during the six week period. The training group will participate in proprioceptive training. The training will consist of a circuit of five activities that will each be performed by the participants for three minutes, which will equal fifteen minutes of training. The five activities are as follows: square board motion, square board balance with squatting, elastic band four direction kicking, blue mat balance with eyes closed, and blue mat balance with throwing.

(a) Discussion:

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be obtained by requesting volunteers from the students that participate in organized athletics at Smyrna High School. Requests will be distributed through the coaching staff and the general announcements at the school. The volunteers who reply will be divided randomly and equally into two groups: a training group and a control group. Some consideration may be made to make the groups equal in number and in distribution of male and female volunteers.

Additional safeguards for vulnerable subjects: In addition to obtaining informed consent from the parents, assent will be obtained from the students as well.

Minimization of risks to subjects: The level of risk is minimal.

Privacy & confidentiality: All information will be initially taken using a coding system. An identification number will be assigned to each participant at the time that he or she volunteers. On all subsequent paperwork, that number will identify the volunteer and the testing data will be collected using that number. When the data is recorded, the results will be coded numerically and will not include the initials or names of the subjects. Data will be kept in a locked cabinet and only the researcher will have access to the information. At the conclusion of the testing and training, the subject may obtain a copy of the data. If the subject is a minor, the parent or guardian may also obtain a copy. Three years following the completion of the written thesis process all personal information will be shredded and thrown away.

Consent document: Written informed consent and assent forms will be provided to all subjects and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Dr. Kalwinsky invited the investigator into the conference room to answer questions.

It was recommended to the investigator that precaution for safety monitor needs to be added since the Informed Consent document states that there is a possibility of injury. It was recommended to the investigator that a description of the Biodex machine also needs to be added to the Informed Consent document. Also, the Compliance Officer's information needs to be added to the informed consent document.

The investigator stepped out for voting.

Stipulations:

Please explain the Biodex Balance machine's operation and include some summary of this – how it works and perhaps some safety assurances – in the parental consent form.

Please revise the control consent form to state that this group receives a t-shirt and length of theraband as well, to avoid influencing decision-making.

Tara Prairie's phone number has changed. Please update the consent forms to reflect this. Her new number is 494-8918.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Twelve members voted unanimously in favor of the protocol pending stipulations are met.

(4) Principal Investigator: Robyn L. Ridgley

Protocol Title: The Effect of a Planning Process on the Amount and Quality of Embedding

Protocol Number: 06-144

Protocol precis or summary: This study examines the effect of a planning process on the amount and quality of embedding learning opportunities within an early childhood classroom. Two early childhood teachers, two teaching assistants, and three children ages 18 months to two years old in each class room will participate. In the first phase of the study, data will be collected to determine that the children have not acquired the targeting skills. The teachers and teaching assistants will then teach each child the first targeted skill using methods that they typically use to plan and implement instruction. In the second phase, after the teachers have collected data confirming that each child has not learned the second targeted skill, the teachers, teaching assistants, and researcher will meet to utilize a process to determine how the skills will be taught.

(a) Discussion:

Need to work on population selection process

Informed consent document that is sent to parents is worded to vaguely

Consent form needs to have the Office of Compliance contact information

The investigator needs to clarify the student population

A letter from Project Help is needed

Tentative completion date on consent form is needed

Teacher's aid needs to provide consent

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: The teachers and teaching assistants have volunteered to participate in the research project. The program in which the teachers work is an inclusive early childhood program on MTSU's campus. Therefore, families who have children with and without disabilities will be asked to allow their children to participate. The study procedures will not differ based on whether the child has a disability or not.

Additional safeguards for vulnerable subjects: Consent will be obtained from the parents, however, the informed consent document needed to be revised.

Minimization of risks to subjects: The risks are minimal to the subjects.

Privacy & confidentiality: Each classroom and child will be assigned a code at the time the informed consent document is obtained. This code will be used on all data collection forms to guard the anonymity of each participant. Any reports or publications related to the study will not

include the names of the participants. The consent forms, data collection sheets, and other study materials will be kept in a locked cabinet in 122 EHSA.

Consent document: Written informed consent forms will be provided to all subjects however they are not appropriate for this study and the investigator was asked to revise them to make them appropriate.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Stipulations:

Please explain the research potential given such a small number of participants? Is this a pilot study?

What is the time frame for targeted skill acquisition?

On the parental consent form, please offer some examples of specific skills.

You need appropriate contact information on the parental consent form (i.e., If you should have any questions about this research study or possibly injury, please feel free to contact (INSERT NAME OF RESEARCHER) at (INSERT RESEARCHER'S PHONE NUMBER) or my Faculty Advisor, (INSERT NAME OF FACULTY ADVISOR) at (INSERT FACULTY ADVISOR'S NUMBER). For additional information about giving consent or your rights as a participant in this study, please feel free to contact Tara Prairie at the Office of Compliance at (615) 494-8918).

For future reference, there are form templates on the www.mtsu.edu/~irb website that use standard language and ensure inclusion of all items.

Are there girls included in this study? If so, the consent form should reflect this (only the pronoun 'he' is used in that form).

- (c) Recommendations: There are no recommendations.
- (d) Controverted Issues & Resolutions: There were no controverted issues or resolutions.
- (e) IRB Decision and Vote: Twelve members voted to table this protocol for clarification.

(5) Principal Investigator: John Howse
Protocol Title: The Effects of Task Mastery Orientation and Positive Self-Monitoring on Learning a Motor Skill
Protocol Number: 06-148

Protocol precis or summary: The study seeks to examine the effectiveness of positive self monitoring (PSM) on learning a motor skill and on the influence of goal orientation in a PSM condition. During the pilot test, students will toss 12 darts and complete the Task and Ego Sport Questionnaire (TESQ). The student's error score will consist of the average, in centimeters, of the 12 throws from the bull's eye. Student's possessing error scores in the lower fiftieth

percentile will be eligible for the study. Student's selected for the actual study will receive a twenty minute lesson concerning proper dart-tossing. A total of four groups will be constructed based on TESQ task mastery scores. A total of four groups will be constructed: high and low task mastery experimental groups and high and low task mastery control groups. Participants will throw twenty darts one at a time. The experimental group will use a PSM checklist, a sheet of correct techniques taught from the lesson, to check off performed techniques that correspond with the checklist. Students will perform the dart-tossing task again after two days. The control groups will not use a PSM checklist during the research. A 2 (treatment v. control) x (high v. low goal orientation) x 2 (pre & posttests) ANOVA with repeated measures on the last factor will be used to determine if significant group differences exist.

(a) Discussion:

Too many grammatical errors present

What kind of darts are being used?

Consent form needs to have the Office of Compliance contact information

There needs to be more information on how participants will be screened.

Should experiment be geared toward fifth graders, as oppose to sixth graders?

Specific:

Scientific design: The procedures are consistent with sound research design however could unnecessarily expose subjects to risk.

Risks/benefits The level of risk is slightly more than minimal.

Subject selection: The sample will consist of male and female 5th and 6th grade students, ages to 11 to 13 attending a public elementary school located in Middle Tennessee.

Additional safeguards for vulnerable subjects: Consent will be obtained from the parents, however, the informed consent document needed to be revised. Assent will be obtained from the subjects.

Minimization of risks to subjects: The risks are slightly above minimal to the subjects.

Privacy & confidentiality: Both during and after the study, all written data will be kept in a locked room to which only the primary investigator will have access. All data will be coded by number rather than by name and no participant will be identified by name when the data is reported. After five years of storage, the information will be shredded.

Consent document: Written informed consent and assent forms will be provided to all subjects. However the informed consent form was not appropriate for this study and the investigator was asked to revise it.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Stipulations:

Please indicate if you are using a Velcro dart or a pointed dart. If the latter, there are safety issues you need to address.

Please submit the approval letter from Dr. Don Odom to Dr. Baskin for an approval letter from his school.

How will you assess if there is a disability present?

Please revise the consent form so the contact for questions regarding rights as a participant in the research is not the Chair of the IRB but the compliance officer: Tara Prairie, at 494-8918.

It was noted that 5th graders are often 10 years old. To exclude them might be problematic for a variety of reasons. One solution would be to study 6th graders only, or 6th and 7th graders, etc. Please address this issue.

In the questionnaire, questions 22-24 are redundant. If you intend to determine respondent consistency, each individual question needs to be separately interwoven among other questions in the questionnaire, not listed together as a group. If there is another rationale, please explain. Are there 12 or 22 darts (it is presented differently in various places, so the issue is one of consistency)?

There are many grammatical errors. For example, the second sentence in the description (page 2). In particular, the consent form is distributed to parents and reflects MTSU's reputation, therefore it must be well written. For example, 4th paragraph:

...John House will assign identification number (should be numbers or 'assign an identification number').

Sixth paragraph: grammar in the first sentence – 'I understand the...' – missing verb.

Other side, first sentence– 'I understand that in case of injury, If (should be lower case 'i' in if) Assent form – simply write 'understand that my parent(s) have given permission'

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Twelve members voted to table this protocol for clarification and too many grammatical errors.

Old Business:

There was no old business.

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

A list of all approved expedited protocols since the last meeting (January 18, 2006) was not provided to the Committee and will be provided at the next meeting.

6. CONTINUING REVIEWS.

(6) Principal Investigator: Mary Beth Templeton

Protocol Title: Individualized Reading Intervention for Student with Dyslexia

Protocol Number: 05-149

Expiration Date: 11/04/05

Protocol precis or summary: A student diagnosed with dyslexia will be provided interventions and services recommended by the Center for the Study and Treatment of Dyslexia at Middle Tennessee State University. The student's progress will be monitored up to two times per week for a school year and supplement the school based services in an attempt to increase the student's reading level and spelling achievement. Progress will be measured through a review of work samples and curriculum based measures. The Woodcock Johnson Test of Achievement III and the Comprehensive Test of Phonological Processing at the end of the intervention will also be administered. The primary purpose of this research is to determine which recommendation or combination of recommendations best support increases in reading and spelling achievement.

(a) Discussion:

General: The protocol expired 11/04/05. The Progress Report needs to be submitted and the two tests need to be provided. Also any data obtained between 11/04/05 and the present cannot be used. Also, this can be expedited.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits There is a minimum risk.

Subject selection: The participant's parent contacted school psychology faculty about getting assistance for her child's reading problem. The parent subsequently volunteered the participant to participate in thesis research.

Additional safeguards for vulnerable subjects: Consent was obtained from the parent and assent was obtained from the child.

Minimization of risks to subjects: This is standard educational practices and consent and assent was obtained.

Privacy & confidentiality: Confidentiality of the subject's identity will be maintained at all times. Any documents that contain identifying material will be locked in the faculty advisor's office and will be kept separate from the research data and completed thesis. A pseudo name will be used

in place of the participant's name in the thesis. All documents will be stored for three years and will be shredded and disposed of after the three year period.

Consent document: A written informed consent and assent form was provided to the participant and it is appropriate for this study.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations:

1. The investigator must file a Final Report for this protocol. The investigator later confirmed that this is a new study in addition to the originally approved protocol. She submitted a Final Report and a new protocol, 06-181.

(c) Recommendations: There were no recommendations.

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

(e) IRB Decision and Vote: Twelve members voted unanimously to have the investigator submit a Final Report and a new protocol for review and approval.

(7) Principal Investigator: Merissa A. Waddey
Protocol Title: Children's Perceptions of and Reactions to Peers' Emotional Displays
Protocol Number: 05-115
Expiration Date: 12/16/05

Protocol Precip or Summary: First and third grade children from Homer Pittard Campus School will be interviewed to determine their reactions to story characters who display emotions in situations where they would be expected to hide their feelings to protect their self-esteem. The participants will be interviewed at school and will listen to three scenarios. Sketches will be proved along with the scenarios. After listening to each scenario, participants will answer questions regarding the appropriateness of the target child's emotional display, intensity of the felt emotion, their own response, predicted responses of the teacher and target child's classmates, the likeability of the target child, and how the target child should have behaved. Investigators also will rate the target child on various traits using Likert-type scales. The three emotions to be studied will be studied disappointment, embarrassment, and fear.

(a) Discussion: There was a discussion about approving retroactive continued review.

(b) Stipulations: There were no stipulations.

(c) Recommendations: There were no recommendations.

(d) IRB Decision and Vote Twelve members voted unanimously in favor of the continued review.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 10:15 A.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD

Middle Tennessee State University
IRB committee meeting
March 16, 2006
Sun Trust Room BAS

Members Present:	Dr. Robert Kalwinsky (Chair)	Dr. Vince Smith
	Dr. William Langston	Dr. Katherine Davis
	Dr. Peggy O'Hara Murdock	Dr. Lisa Pruitt
	Joe Hawkins	Tara Prairie, Compliance (No Vote)
	Dr. Reuben Kyle	Dr. Michael Sanger
	Dr. Aleka Blackwell	Kristin Brown (No Vote)
	_____	_____

Members Absent:	Dr. Stacy Borasky	Dr. Anita Crockett
	Dr. Cheryl Flanigan	Dr. Jim Nunnery
	Dr. Jim Hodgson	_____
	_____	_____

Guests: Dan Roberts and John Howse

The meeting convened at 9:00 A.M. with a quorum of seven present.

1. MINUTES OF THE MEETING HELD ON (February 16, 2006).

Approved as read unanimously.

2. ANNOUNCEMENTS.

There were no announcements.

3. discussions.

There was a motion made by Dr. Langston, seconded by Dr. Pruitt to include a debriefing box in the Informed consent Instructions. The motion was unanimously approved with nine (9) votes.

4. INITIAL REVIEWS.

(1) Principal Investigator: Daniel Alexander Roberts

Protocol Title: The Effect of Reduced Oxygen Breathing Induced Hypoxia on Pilot Error in Civilian Aviation Simulators.

Protocol Number: 06-180

Protocol precis or summary: The investigator will look at civilian pilots (in civilian simulators) and what effect hypoxia has on the pilot's error rate while flying the simulator. Pilots will be asked to take-off, fly a specific course, and land (using a precision landing system) in the simulator. During the stimulation, the Reduced Oxygen Breathing Device will be used to induce hypoxia, and the changes in error rates will be noted.

(a) Discussion:

General:

Dr. Sanger recommended that treatment be checked in addition to observation since the oxygen levels will be changing. Also, supplemental information is needed to detail what the onset of hypoxia feels like.

Dr. Smith questioned if students age seventeen (17) and under will be excluded.

Dr. O'Hara Murdock questioned what type of calibration the equipment will go through prior to the study.

Dr. Sanger noted that the informed consent document states that once subject exceeds mild hypoxia the subject will be changed to breathing room air, however the supplemental information states that once the subject reaches a SPO2 of 65%, the test will be terminated and the participant will be recovered on 100% oxygen. Is recovering at 100% oxygen and being changed to breathing room air the same thing?

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will be selected purely on availability.

Additional safeguards for vulnerable subjects: Informed consent and assent will be obtained either written.

Minimization of risks to subjects: There will be constant oxygen saturation monitoring, lower limit cut off at 65% saturation, and there will be an EMT in attendance.

Privacy & confidentiality: Participants will be assigned numbers and only investigators will have access to the names. .

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Dr. Kalwinsky invited the investigator back into the conference room to answer questions.

Dr. Sanger questioned once mild hypoxia is reached, how will the subject be treated. Mr. Roberts responded that the subject will drop their mask once mild hypoxia is achieved. Mr. Roberts also noted that there is little difference in dropping mask and gaining 100% oxygen. Dr. Smith questioned if students age seventeen (17) or under will be excluded. Roberts responded that students seventeen (17) and under will be excluded from the study. Dr. O'Hara Murdock questioned the calibration of the equipment. Roberts responded that all equipment have been calibrated by the company.

The investigators stepped out for voting.

Stipulations:

1. In the supplemental information, state that once mild hypoxia is obtained, the subject's mask will be dropped and detail what the onset of hypoxia feels like.

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of the protocol pending stipulations are met.

Old Business:

(1) Principal Investigator: John Howse

Protocol Title: The Effects of Task Mastery Orientation and Positive Self-Monitoring on Learning a Motor Skill

Protocol Number: 06-148

Protocol precis or summary: The study seeks to examine the effectiveness of positive self monitoring (PSM) on learning a motor skill and on the influence of goal orientation in a PSM condition. During the pilot test, students will toss 12 darts and complete the Task and Ego Sport Questionnaire (TESQ). The student's error score will consist of the average, in centimeters, of the 12 throws from the bull's eye. Student's possessing error scores in the lower fiftieth percentile will be eligible for the study. Student's selected for the actual study will receive a twenty minute lesson concerning proper dart-tossing. A total of four groups will be constructed based on TESQ task mastery scores. A total of four groups will be constructed: high and low task mastery experimental groups and high and low task mastery control groups. Participants

will throw twenty darts one at a time. The experimental group will use a PSM checklist, a sheet of correct techniques taught from the lesson, to check off performed techniques that correspond with the checklist. Students will perform the dart-tossing task again after two days. The control groups will not use a PSM checklist during the research. A 2 (treatment v. control) x (high v. low goal orientation) x 2 (pre & posttests) ANOVA with repeated measures on the last factor will be used to determine if significant group differences exist.

(a) Discussion:

Dr. Davis noted that the faculty advisor's information is needed on the front page. There are numerous typographical errors. The top 25% needs to be taken away since there are only 45 subjects.

The permission letter from Rutherford County School Board is still missing.

The assent form does not have researcher's information

What will non-participating students be doing while the study is being conducted?

A statement about non-participation will not effect child's grade in class.

Parental consent is not written at an 8th grade reading level.

How can the study be explained and witness if the consent forms will be sent home with the students?

Dr. Davis suggested that students need to be ten (10) feet behind the actual dart thrower to ensure safety.

Font needs to be consistent though out survey.

Specific:

Scientific design: The procedures are consistent with sound research design however could unnecessarily expose subjects to risk.

Risks/benefits: The level of risk is slightly more than minimal.

Subject selection: The sample will consist of male and female 5th and 6th grade students, ages to 11 to 13 attending a public elementary school located in Middle Tennessee.

Additional safeguards for vulnerable subjects: Consent will be obtained from the parents, however, the informed consent document needed to be revised. Assent will be obtained from the subjects.

Minimization of risks to subjects: The risks are slightly above minimal to the subjects.

Privacy & confidentiality: Both during and after the study, all written data will be kept in a locked room to which only the primary investigator will have access. All data will be coded by number rather than by name and no participant will be identified by name when the data is reported. After five years of storage, the information will be shredded.

Consent document: Written informed consent and assent forms will be provided to all subjects. However the informed consent form was not appropriate for this study and the investigator was asked to revise it.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

(b) Stipulations: There were sufficient questions that the IRB committee has requested a revised protocol to be evaluated at the next meeting. The investigator was asked to meet with Dr. Katherine Davis and/or Dr. Peggy O'Hara Murdoch to obtain the items they need to address and for assistance in correcting the committee's specific concerns.

(c) Recommendations:

1. Need letter from Rutherford County Public School System.
2. Informed consent needs to be written at an 8th grade letter.
 3. Protocol needs further clarification.
 4. Font size in survey needs to be consistent.
 5. Need to talk to faculty advisor.

(d) Controverted Issues & Resolutions:.

(e) IRB Decision and Vote: Ten members voted unanimously in favor of the research to be deferred until the next meeting.

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

All expedited protocols are available for view on the Docushare account for which committee members have the username and password.

6. CONTINUING REVIEWS.

(A) Principal Investigator: Karen Metius-Howse
Protocol Title: Survey of the Cedar Glades
Protocol Number: 05-169
Expiration Date: 06/06/05

Protocol Precis or Summary: Utilizing 2nd and 5th grade classes from Homer Pittard Campus School, the investigators will introduce the cedar glades ecosystem with a focus on endemic species via lecture and interactive field experiences. The goal of the projects is to integrate hypothesis-based strategies into the unit study on cedar glades. Students will attempt to determine growing conditions required for selected glade plants through class activities and

observation. Students will complete a pre and post-test on the concepts covered. Anecdotal information will be collected from the classroom teachers for insights related to the lesson plans, student interest, and science knowledge.

(a) Discussion: Dr. Langston moved to approve.

(b) Stipulations:

1. Dr. O'Hara-Murdock asked that the investigator clarify the participation data.

(c) Recommendations: There were no recommendations.

(d) IRB Decision and Vote Nine members voted and there was a unanimous vote in favor of the continued review pending the above stipulation.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 10:25 A.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD

Middle Tennessee State University
IRB Committee Meeting
April 20, 2006
Gore Conference Room, Todd Hall

Members Present: Dr. William Langston Dr. Peggy O'Hara Murdock
 Dr. Kathy Davis Dr. Reuben Kyle
 Dr. Aleka Blackwell Dr. Lisa Pruitt
 Dr. Jim Nunnery Dr. Cheryl Flanigan
 Kristin Brown (no vote)

_____ _____
_____ _____

Members Absent: Dr. Robert Kalwinsky Dr. Anita Crockett
 Joe Hawkins Dr. Jim Hodgson
 Dr. Michael Sanger Dr. Vince Smith
 Tara Prairie

_____ _____
_____ _____

Guests: Sandra Poirier

The meeting convened at 9:00 A.M. with a quorum of seven present.

1. MINUTES OF THE MEETING HELD ON (March 16, 2006).

Approved as read unanimously.

2. ANNOUNCEMENTS.

There were no announcements.

3. discussions.

There was no discussion.

4. INITIAL REVIEWS.

(1) Principal Investigator: Dr. Kathryn L. Davis
Protocol Title: OPIE-Obesity Prevention Intervention and Education
Protocol Number: 06-223

Protocol precis or summary: The purpose of this project is to develop a school-based intervention model, Obesity Prevention Intervention and Education (OPIE), which will combine physical activity, strength and conditioning, and nutrition education components to determine the impact of an eighteen (18)-week OPIE intervention program for kindergarten children. The outcome measures that will be used during the pre-testing and post-testing periods during the 2007-2008 school year to evaluate the effectiveness of the OPIE intervention program include a half-mile run, measurement of body mass index, abdominal curl-up tests and modified pull-up tests, and a flexibility test.

(a) Discussion:

General:

Dr. Will Langston noted that the level of risk involved is minimal. There was a technical error in which a banana was classified as a vegetable, as oppose to a fruit.

Dr. O'Hara Murdock what activities or alternative exercises will be provided to non-consenting students or students who do not return the informed consent document.

Dr. O'Hara Murdock questioned that since the subjects are at such a young age group (5 years of age) with little experience with strength and conditioning exercises, should a strength and conditioning consultant be consulted for proper techniques when working with such a young age group. In addition, Dr. O'Hara Murdock questioned if there is written justification for the strengthening and condition exercises being administered to the subjects.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: Subjects will consist of kindergarten children from two elementary schools in the MCESD. The children and the kindergarten classroom teachers will be selected for participation by virtue of their membership in the kindergarten classes at the time of the study

Additional safeguards for vulnerable subjects: Informed consent and assent will be obtained either written.

Minimization of risks to subjects:

Privacy & confidentiality: The teachers' and the students' identity will remain anonymous. Data will be collected for research purposes only. Participants will be identified only by ID numbers in all reports. Data will be stored in a lock file accessible only to the investigators.

Additional considerations: Ionizing radiation; collaborative research; etc.
do not apply.

Dr. Langston invited the investigator back into the conference room to answer questions.

Dr. Langston questioned what activities will be available to non-consenting students. Dr. Davis responded that non-consenting students will be participating with another physical education class. This method has been practice before at these two school systems.

Dr. Langston asked if a person that specializes in strength and conditioning training will be available since the subjects are a young age group. Dr. Davis responded that Dr. Helen Brinkley, one of the investigators, is certified in strength and conditioning.

Dr. Langston asked if there were written justification for the different types of activities that will be used with this protocol. Dr. Davis responded yes. .

The investigators stepped out for voting.

Stipulations: There are no stipulations

(c) Recommendations: There are no recommendations.

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of the protocol approval.

Old Business:

(1) Principal Investigator: John Howse

Protocol Title: The Effects of Task Mastery Orientation and Positive Self-Monitoring on Learning a Motor Skill

Protocol Number: 06-148

Protocol precis or summary: The study seeks to examine the effectiveness of positive self monitoring (PSM) on learning a motor skill and on the influence of goal orientation in a PSM condition. During the pilot test, students will toss 12 darts and complete the Task and Ego Sport Questionnaire (TESQ). The student's error score will consist of the average, in centimeters, of the 12 throws from the bull's eye. Student's possessing error scores in the lower fiftieth percentile will be eligible for the study. Student's selected for the actual study will receive a twenty minute lesson concerning proper dart-tossing. A total of four groups will be constructed based on TESQ task mastery scores. A total of four groups will be constructed: high and low task mastery experimental groups and high and low task mastery control groups. Participants will throw twenty darts one at a time. The experimental group will use a PSM checklist, a sheet of correct techniques taught from the lesson, to check off performed techniques that correspond with the checklist. Students will perform the dart-tossing task again after two days. The control groups will not use a PSM checklist during the research. A 2 (treatment v. control) x (high v.

low goal orientation) x 2 (pre & posttests) ANOVA with repeated measures on the last factor will be used to determine if significant group differences exist.

(a) Discussion:

Dr. Langston noted that all provisions previously questioned have been satisfied.

Parental consent form is still long and assent form is still not written at an eighth (8th) grade reading level. Dr. Langston commented that the consent form can not be reduced any further.

Tara Prairie's name is spelled incorrectly on Parental consent form.

Parental consent form is on the incorrect letterhead.

Dr. Langston will contact the PI, have him e-mail the documents that need any technical changes (i.e. informed consent document, assent document) and make any necessary changes.

The survey has been edited to have the correct font throughout.

Dr. Davis contact faculty advisor and spoke of all necessary changes.

Specific:

Scientific design: The procedures are consistent with sound research design however could unnecessarily expose subjects to risk.

Risks/benefits: The level of risk is slightly more than minimal.

Subject selection: The sample will consist of male and female 5th and 6th grade students, ages to 11 to 13 attending a public elementary school located in Middle Tennessee.

Additional safeguards for vulnerable subjects: Consent will be obtained from the parents. Assent will be obtained from the subjects.

Minimization of risks to subjects: The risks are slightly above minimal to the subjects.

Privacy & confidentiality: Both during and after the study, all written data will be kept in a locked room to which only the primary investigator will have access. All data will be coded by number rather than by name and no participant will be identified by name when the data is reported. After five years of storage, the information will be shredded.

Consent document: Written informed consent and assent forms will be provided to all subjects.

Additional considerations: Ionizing radiation; collaborative research; etc.
do not apply.

(b) Stipulations: There are no stipulations

(c) Recommendations:

1. Edit for all technical errors.

Incorrect spelling of Tara Prairie

Correct letterhead for Parental informed consent document

Change Chief Investigator on Informed consent Document to read Investigator

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

(e) IRB Decision and Vote: Nine members voted unanimously in favor of protocol approval pending changes.

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

All expedited protocols are available for view on the Docushare account for which committee members have the username and password.

6. CONTINUING REVIEWS.

There are no continuing reviews reported at the meeting.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 9:25A.M.

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

Tara Prairie explained that this is standard procedure among IRBs at various institutions and the agreement was adapted from Vanderbilt University. Also, the implications of breaching confidentiality are listed in the Policies and Procedures and simply entail loss of membership. However, a meeting was set up with J. David Hays, Esq. to discuss the Confidentiality Agreement.

New Business

The Delaware Study: It was brought to Tara Prairie's attention that THEC & TBR have mandated faculty participate in this study. It has been argued that this in fact is not research and therefore can be mandated upon faculty. Tara Prairie included her memo in response to this statement, which concluded that the Delaware Study is in fact research as defined by The Common Rule. The Delaware Study was discussed and Will Langston made a motion to have the IRB determine if it is in fact research. The IRB voted and eight members unanimously voted that the Delaware Study is research.

* Since departmental resources are allocated depending upon faculty's responses to the study, there were issues of confidentiality as the Chairs will know the results, i.e. which faculty member returned which survey. The question was brought up if the data could be aggregated prior to Department Chairs receiving data.

Tara Prairie states she address confidentiality issues with Dr. Kaylene Gebert and Dr. Robert Carlton, which was e-mailed June 30, 2006.

4. INITIAL REVIEWS.

(1) Principal Investigator: Tiago Barriera

Protocol Title: Does Resistance Training Increase Bone Mineral Density (BMD) in Female Collegiate Swimmers?

Protocol Number: 06-271

Protocol precis or summary: The purpose of this investigation is to compare the BMD of the whole body, distal radius, lumbar spine, and femoral head amongst a subject cohort of NCAA Division I female swimmers that take part in resistance training, NCAA Division I Swimmers that do not take part in resistance training, and inactive females. Participants will fill out questionnaires about their physical activity history, health history, and eating habits. Height and weight will be measured on a balance scale. A 7-site skinfold measurement will be taken prior to the participants changing into the specific clothing necessary for a BMD test. They will then have their body fat percentage and BMD of the whole body, femur, radius, and lumbar spine measured by a GE Lunar Prodigy Dual Energy X-Ray Absortometry machine (DEXA).

(a) Discussion:

General:

Dr. Hodgson provided the Health History Questionnaire which was originally left out.

Dr. Hodgson moved to approve the protocol with the insertion of the questionnaire and qualifications of Dr. Wayland Tseh, the faculty advisor at University of North Carolina, Wilmington.

Dr. Hodgson moved the protocol be approved pending discussion.

Lisa Pruitt seconded.

Dr. Pruitt noticed discrepancies between all protocols using a DEXA machine as far as what the radiation exposure is. Dr. Jetton stated the differences could be due to citing different sources or perhaps using different machines. However, all readings are negligible.

Dr. Nunnery questioned how many scans will be done.

Dr. Hodgson states that the hypothesis is not clear cut.

Dr. Sanger noticed inconsistencies in acronym, i.e. DXA v. DEXA. Dr. Jetton stated that DXA is an older acronym while DEXA is the newer one.

Dr. Langston noticed that they did not discuss the storage of data.

Dr. Jetton did state that you can detect changes in fat composition and/or muscle composition however not BMD.

Specific:

Scientific design: Yes, the procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits The level of risk is minimal.

Subject selection: The study will consist of three groups of fifteen (15) participants. The first group will consist of Division I collegiate female swimmers from UNC Wilmington (UNCW). The second group will consist of Division I collegiate swimmers already members of the UNCW swim team for one or more years. The third group will be composed of female volunteers from the UNCW student population.

Additional safeguards for vulnerable subjects: No vulnerable subjects are targeted for this study.

Minimization of risks to subjects: Identity is decoupled from individual data by code; secure storage of data and code, operator(s) of DEXA machine are qualified.

Privacy & confidentiality: There is reporting of group results only, data is codified, secure storage of data and code, and data will be destroyed after three (3) years.

Additional considerations: Ionizing radiation; collaborative research; etc.
do not apply.

Dr. Kalwinsky invited Gina Evans, who was serving as proctor for Tiago Barriera, back into the conference room to answer questions.

Dr. Kalwinsky asked how is the data going to be disposed? Ms. Evans answered the electronic data will be purged and paper data will be shredded after 3 years.

Dr. Kalwinsky asked how recruitment for the control group will take place? Ms. Evans responded that Dr. Tseh teaches basic classes and will likely recruit through them.

The investigator stepped out for voting.

Stipulations:

Please submit a written statement indicating that you will exclude participants who are on Vitamin D or who are taking estrogen.

You may wish to correct spelling and grammatical errors in the questionnaire "For Swimmers Only," (e.g., item one ('long' not 'ling')).

- (c) Recommendations: There are no recommendations.
 - (d) Controverted Issues & Resolutions: There were no controverted issues.
 - (e) IRB Decision and Vote: Seven members voted unanimously in favor of the protocol approval with the amendments. One member opposed the study.
- (2) Principal Investigator: Stephanie Otto
Protocol Title: Correlation Between Bone Mineral Density and Physical Activity Among Women Who Use Depo-Provera
Protocol Number: 06-278

Protocol precis or summary: The purpose of this study is to investigate the correlation between weight bearing physical activity and bone mineral density (BMD) among females who are taking Depo Provera. Numerous studies have indicated BMD loss among women taking this form of contraception. Research also indicated that weight bearing activity can increase bone mineral density. Participants will be asked to wear an activity monitor which will count the number of steps they are taking. Following a seven day monitoring period participants will undergo a DEXA scan to determine BMD. Participants will also complete a three day diet record so their level of calcium intake can be determined. Height, weight, blood pressure, and skin fold measurements will also be collected and used in final analysis. Data will be used from 04-230.

(a) Discussion:

Since Dr. Nunnery did not receive his packet, Dr. Sanger as secondary reviewer volunteered to discuss the protocol as primary reviewer.

Dr. Sanger pointed out that adolescent should be dropped from the description since only adults (18+) will be recruited. He also asked how prevalent is Depo Provera use?

In regards to the Informed Consent document, Dr. Sanger recommended that the following language be added to #10, "Please advise if you do so."

Dr. Sanger moved that the protocol be approved pending discussion.

Dr. Langston seconded.

Dr. Hodgson inquired where are scans done and who does them?

Dr. Langston inquired whether or not the person performing the scans will be qualified.

Dr. Sanger felt that the use of radiation should be elaborated upon in the informed consent document.

Specific:

Scientific design: The procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits: The level of risk is minimal.

Subject selection: Subjects will be selected from the Murfreesboro community and MTSU student population.

Additional safeguards for vulnerable subjects: No vulnerable subjects are being targeted for this study.

Minimization of risks to subjects: The risks are minimal to the subjects. Individuals operating the DEXA machine are trained.

Privacy & confidentiality: No names or identifying information will be collected and data will be coded by number. All data will be stored in the Human Performance Lab for three (3) years at which time, the hard copies will be destroyed. The facility is locked unless supervised by a member of the exercise science staff.

Consent document: Written informed consent forms will be provided to all subjects.

Additional considerations: Ionizing radiation; collaborative research; etc. do not apply.

Stipulations:

You indicate that you are studying adolescent females, yet also state the participants are over 18 years of age. Please clarify.

In the informed consent document, item 10 – please add a statement requesting that the participant inform you if they do stop the Depo-provera.

Please indicate who will be conducting the scans and how the individual(s) are qualified.

Is it possible to administer an overdose of radiation with the DEXA scan (i.e., if not well calibrated, etc.)?

(c) Recommendations:
There were no recommendations.

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

(e) IRB Decision and Vote: Eight members voted unanimously in favor of protocol approval pending changes.

(3) Principal Investigator: Stephanie Otto
Protocol Title: The Relationship Between Physical Activity, Blood Pressure, Body Composition, and Bone Mineral Density Among Children and Adolescents
Protocol Number: 06-279

Protocol precis or summary: The purpose of this study is to determine if a relationship exists between physical activity, blood pressure, body composition, and bone mineral density (BMD) among children and adolescents. Specifically, the investigator is interested in how appropriate the 10,000 step recommendation is for children and adolescents. If a relationship is found, studies such as this one may provide guidance as to how much physical activity is needed for children and adolescents to achieve health benefits. Data will be collected on 7th-12th grade students from Middle Tennessee Christian School. Blood pressure, body composition, and physical activity will be gathered from previous data. BMD will be measured using a DEXA scanner and participants will be asked to complete a three day diet record to determine average calcium intake. All data collection for this portion of the study will take place at MTSU in the Human Performance Lab by certified DEXA technicians. Partnered w/06-282, PI Jennifer Caputo, Exempt Review approved 06/13/06.

(a) Discussion:

Tara Prairie noted that Richard Farley did submit his Certificate of Training for 06-282.

Dr. Smith asked that it be clarified who the DEXA technicians will be as referred to on page 2. In regards to the exclusion/inclusion criteria, what about disabled students? On page 6, in regards to calibration, if when and how does it take place? Please define reduce/eliminate this risk. There is a concern that the permission letter from Middle Tennessee Christian School (MTCS) is not broad enough to cover the DEXA scans. On the informed consent document, on #10, the investigator should delete "may." The letter to parents needs to be put on letterhead. The investigator did not inform that data obtained from 06-282 will be used in the study. There is a concern as to whether or not parents will understand the radiation levels.

Dr. Smith moved to approve the protocol with the amendments. Dr. Pruitt seconded the motion.

Tara Prairie explained that the data obtained from 06-282 becomes pre-existing data and since there are no identifiers used, the investigator does not need permission from parents to use the data.

Dr. Hodgson had a concern regarding whether students would be pregnant and the risks to exposure of radiation.

Dr. Jetton stated that since radiation exposure is less than a dental x-ray, there is little risk however, pregnancy in adolescents would compromise the data anyways as it effects bone density.

Dr. Langston stated that the DEXA scan is considered “fitness data” in regards to the permission letter from (MTCS) and that the principal asked for the study to happen at his school and therefore should be aware of the DEXA scans.

Dr. Sanger stated that “Academy” through out the document as well as “MTCA” should be changed to “School” and “MTCS.” The informed consent document may be more helpful if said “parental consent.”

Dr. Pruitt noted that on the consent document to parents, instead of stating, “you are being asked to participate”, it should state, “we are asking for your permission to allow your child to participate.”

Dr. Sanger feels that # 4 in the informed consent document should be elaborated upon i.e., radiation levels from the DEXA and minimal risk. At the end of the second line, take out university as it already states MTSU.

Dr. Smith feels that instead of “picture” on the assent form that the word x-ray should be used.

Dr. Sanger questions whether the radiation exposure was based per day, week, year, etc.

Dr. Hodgson would like the IRB to require more thorough permission letters from the investigator.

Specific:

Scientific design: The procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits: The level of risk is minimal.

Subject selection: Subjects will be selected from the grades 7-12 at MTCS and is open to all students from this population

Additional safeguards for vulnerable subjects: Consent will be obtained from parents and assent will be obtained from the children participants.

Minimization of risks to subjects: The risks are minimal to the subjects. Individuals operating the DEXA machine are trained.

Privacy & confidentiality: No names or identifying information will be collected and data will be coded by number. All data will be stored in the Human Performance Lab for three (3) years at which time, the hard copies will be destroyed. The facility is locked unless supervised by a member of the exercise science staff.

Consent document: Written informed consent and assent forms will be provided to all subjects.

Additional considerations: Ionizing radiation; collaborative research; etc.

do not apply.

Dr. Kalwinsky invited Stephanie Otto into the conference room to answer questions.

Dr. Kalwinsky asked who the DEXA technicians are and Ms. Otto responded Dr. Jennifer Caputo and Dr. Richard Farley.

Dr. Kalwinsky asked about pregnant and/or disabled participants. Ms. Otto confirmed that pregnant subjects will be excluded however, individuals wheelchair bound would not necessarily have to be excluded.

Dr. Kalwinsky asked about calibration and Ms. Otto responded that all Graduate Assistants are trained in regards to calibration.

Dr. Kalwinsky asked if it is possible to overdose the subjects and Ms. Otto was not aware of the possibility.

Dr. Kalwinsky confirmed with Ms. Otto that she needs to change “Academy” to “School.”

Dr. Kalwinsky asked whether the radiation exposures were based on pure day, year, etc. and Ms. Otto understood it to be per scan.

The investigator stepped out for voting.

Stipulations:

All letters going out (to parents, etc.) must be on official letterhead. Note this does not mean the informed consent document.

If anyone is involved in a study, whether a graduate assistant or an undergraduate student – i.e., anyone – they must present documentation of training. There will be spot checks of research in the future, and violation of training protocol is a serious breach of federal guidelines, so please be thorough in listing and training everyone involved.

If parents are giving informed consent, the document must be tweaked to reflect this change (i.e., the parents can not be addressed or listed as the participants but rather their child).

You indicated that the DEXA technicians are Drs. Caputo and Farley. Thus these are the only individuals who can utilize the DEXA scanner.

Please revise the exclusion/inclusion criteria (page 3) to delineate exclusion criteria (e.g., pregnancy, any form of disability, etc.)

If graduate assistants are part of the study, they need to provide documentation of training. This applies to all studies undertaken.

Can you please provide some details concerning “calibration of all testing equipment” to reduce risk – who will do it, when, how, etc.? (from number 3 of A. Subjects at Risk).

What is the time scale on the radiation dose (e.g. per hour, per day, per month)? Thus is background radiation of 8.0 μ SV for one hour, one day, one year, etc.?

In the informed consent document, please change the wording to reflect that this document is to the parent. Thus the first sentence under 1, Purpose of the Study, should reflect the fact that it is the student and not the parent who is being asked to participate (e.g., a change akin to “As a student at Middle Tennessee Christian School, your child is being asked to participate...”). You will have to go through the document and make these changes since the parent is not the participant and will not be in the study.

Under informed consent, item 10 – please change the wording to :...”the Principal Investigator will withdraw you” – the ‘may’ is not acceptable given federal guidelines.

In the parental consent form, item 4 – please add a brief explanation of ‘2.6 μ SV’ and ensure the paragraph breaks at a point that does not truncate the explanation of radiation (so that the information on background radiation is not on a separate page). The best way would be to ensure the paragraph contains no page breaks.

In the informed consent, item 13 – please eliminate the word ‘University’ from “MTSU University Institutional Review...” since it is redundant.

All letters going out from MTSU (e.g., the letter to parents) must be on official letterhead – please provide appropriate copies. Note this does not include informed consent documents; the letter to the parents, however, does require letterhead.

Please be consistent in referencing the school; it appears the name should be Middle Tennessee Christian School (MTSC), not Academy. Please make the appropriate changes in the document.

(c) Recommendations:

There were no recommendations.

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

(e) IRB Decision and Vote: Eight members voted unanimously in favor of protocol approval pending changes.

Dr. Kalwinsky had to leave for a class at 12:50 P.M. and Dr. Langston, who is Vice-Chair, took over as Chair.

(4) Principal Investigator: Gina Sobrero Evans

Protocol Title: Effects of a 12-Week Strength Training Intervention Among Community-Dwelling Eating Disordered Females

Protocol Number: 06-281

Protocol precis or summary: To determine the effects of a 12-week resistance training intervention on bone mineral density (BMD), body composition (BC), strength, depression, and eating disordered tendencies in community-dwelling females with eating disorders. All participants will complete a risk stratification questionnaire including questions regarding menstrual status, duration of eating disorder, current medications, and supplements. Pre- and post-intervention, all participants will complete the Beck Depression Inventory 2, the Eating Disorders Inventory 3, the Impact Food Frequency Questionnaire, and the AHA/ACSM Health Fitness Facility Preparticipation Screening Questionnaire. All participants will have BC, BMD of the lumbar spine, hip, and forearm assessed by dual energy x-ray absorptiometry (DEXA) and chest and leg strength (estimated 1-RM) will be measured. Height and weight will be recorded to calculate body mass index (BMI). Participants will be randomly assigned to either the experimental or the control group. Participants in the experimental group will complete a resistance program prescribed at a frequency of three (3) times per week at MTSU or a designated site in Nashville. All training sessions will be in a supervised group format. The resistance program will utilize machines and dumbbells, and include eight exercises covering major muscle groups. Each exercise will be performed at a weight that can be lifted for two (2)

sets of 10-12 repetitions. Resistance will progressively be increased. Control participants will continue with standard care and will not receive an exercise prescription. All participants will record all planned physical activity and cardiovascular activity during the 12-week period, as well as any bouts of over exercising, over- or under-eating, purging, and other unplanned activities.

(a) Discussion:

Dr. Langston question what is eating disorder not otherwise specified? There will be DEXA scans before and after the study to do a comparative analysis 12 week strength training. Safety precautions are in place for over exercise and eating disorders, i.e. taken out of the study and/or to the ER depending on the level of risk. Will participants know what EDNOS or osteopenia means? The investigator needs to clarify that the records will be stored with the faculty advisor. Will the name sections be taken off the EDI-3 & BDII to assure confidentiality? On #10 of the informed consent form, it should read “she is” instead of “she are.” Is the assent language appropriate for 16 year olds? Recruitment needs to be limited to the two (2) facilities stated in the protocol application.

Dr. Langston moved that the protocol be approved with the amendments and Dr. Flanigan seconded the motion.

Dr. Flanigan stated that letters to participants should be on letter head.

Dr. Pruitt noted that neither mentally ill or physically ill was checked as a population targeted in the study.

Dr. Sanger noted that males are excluded from the study. Also, none of the consent forms address radiation exposure. For #10, elaborate what “necessary steps” are i.e. emergency room.

Dr. Nunnery asked if there is data showing that BMD can make changes in such a short period of time.

Dr. Ida Fadzillah left the meeting at 1:10.

Dr. Jetton noted that pregnant females should be excluded from the study.

Dr. Hodgson asked if it was okay for chair/vice-chair to approve the protocol without bringing in the investigator to ask questions.

Specific:

Scientific design: The procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.

Risks/benefits: The level of risk is minimal.

Subject selection: Eligible candidates will be identified from professionals dealing with the population.

Additional safeguards for vulnerable subjects: Informed consent will be obtained from parents/guardians and assent from participants.

Minimization of risks to subjects: If any health problems appear or if reported exercise is too high, appropriate measures will be taken.

Privacy & confidentiality: No names or identifying information will be collected and data will be coded by number. All data will be stored in the Human Performance Lab for three (3) years at which time, the hard copies will be destroyed. The facility is locked unless supervised by a member of the exercise science staff.

Consent document: Written informed consent and assent forms will be provided to all subjects.

Additional considerations: Ionizing radiation; collaborative research; etc.
do not apply.

Stipulations:

What is "eating disorder no otherwise specified"?

On the questionnaire, will participants know what EDNOS and osteopenia mean?

The PI needs to clarify that the records will be stored with the Faculty Advisor.

Need to have name section taken off of EDI-3 & BDII to protect confidentiality.

On #10 of the Parental Consent form it states, "she are" instead of "she is."

Recruitment must be limited to the two (2) facilities listed in the application.

Mentally ill and/or physically ill not checked as a targeted population on application.

Has the investigator considered the fact that she is excluding males?

None of the consent forms address radiation exposure.

Is there data available that will show that changes in bone density can be seen within 12 weeks time.

Exclusion of pregnant females.

(c) Recommendations:

There were no recommendations.

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

(e) IRB Decision and Vote: Seven members voted unanimously in favor of protocol approval pending changes.

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

All expedited protocols are available for view on the DocuShare account for which committee members have the username and password.

6. CONTINUING REVIEWS.

There are no continuing reviews reported at the meeting.

7. AMENDMENTS.

There were no amendments reported at the meeting.

8. REPORT OF ADVERSE EVENT(S).

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

9. ADJOURNMENT

The meeting adjourned at 1:00 P.M.

Signed and Approved by: _____, Chair
Robert Kalwinsky, PhD