

**James Madison University
Institutional Review Board Minutes
June 17, 2008**

The Institutional Review Board (IRB) met Tuesday, June 17, 2008 at 5:00 p.m. in Carrier Library, Conference Room 109.

Members present: Dr. David Cockley (Chair), Mr. John Hulvey, Dr. C. Leigh Nelson, Dr. Valerie Sulfaro, Dr. Linda Sobel, Dr. Michael Hall, Dr. Eric Pyle, Ms. Helen Young, and Dr. Janet Gloeckner

Investigators present: Dr. Nicholas Swartz and Dr. Roshna Wunderlich

A sign-in sheet was circulated. The IRB meeting was called to order at 5:00 p.m. There were (6) protocols for review, all of which had previously been electronically sent to the IRB evaluators.

A motion was made to approve the minutes from the May 27, 2008 meeting. The motion was approved.

The first protocol # 07-0031, entitled "*Distractions in Hearing*", was reviewed by the full board due to a request for renewal and the involvement of external funding. The IRB requested minor modifications to the protocol and consent form regarding the compensation. The risks of research participation are reasonable in view of the potential benefits of this study. The protocol was unanimously approved pending the suggested modifications. (*Total =7; Vote: For-7, Opposed-0, Abstained-0*)

The second protocol # 09-0021, entitled "*Massanutten Municipal Incorporation – Phase I*", was reviewed by the full board due to the involvement of external funding. The IRB suggested the PI assure participants that confidentiality to academics piece of the study will be maintained. The PI stated that the clients do not care if PI's use the collected data. The risks of research participation are reasonable in view of the potential benefits of this study. The protocol was unanimously approved pending the suggested modifications. (*Total =8; Vote: For-8, Opposed-0, Abstained-0*)

The third protocol # 09-0023, entitled "*Etiology of gender differences in overuse injuries: the interaction of hormones, ligament laxity, and footwear*", was reviewed by the full board due to the involvement of external funding. The IRB questioned how the blood was being handled and disposed of. The IRB recommended that there should be more description on how the initial 10ml draw will be taken in the consent form. The IRB recommended the PI to clarify on the consent form the time limit for participation in the study. The IRB noted minor word inconsistencies regarding the references to the hurdle test. Also, the protocol says males/females, but consent form seems female driven when talking about contraceptives, etc. The IRB requested the PI make clear who is to answer which questions or who may be uncomfortable. The risks of research participation are reasonable in view of the potential benefits of this study. The protocol was unanimously approved pending the suggested modifications. (*Total =9; Vote: For-8, Opposed-0, Abstained-1 (Chair)*)

The fourth protocol # 09-0018, entitled "*The effect of motivation to change on offender recidivism*", was reviewed by the full board due to the involvement of prisoners. The IRB found multiple modifications needed with this study. A motion was made to table this review until the July 15, 2008 IRB convened meeting in hopes the PI can be present to address their concerns. The motion to table the protocol was approved.

The fifth protocol # 08-0310, entitled “*The Effect of Stigma on the Lives of the Homeless*”, was reviewed by the full board due to the involvement of the homeless. The IRB was concerned how the PI would provide the participants with final aggregate results of the study. Clarification regarding this was requested. The IRB also questioned where the interviews will take place. The IRB questioned what the PI would do if the participants could not read or write or could not speak or read English well. A request was made by the IRB for the PIs to clarify if they plan to read the consent form to the participants in such a situation. The IRB asked if other people will be present for the interview and how the PIs will maintain confidentiality if there are other people around. It was noted by the IRB that the dates referenced in the protocol reflect this past Spring. Clarification was requested regarding when data will be collected, how it will be recorded, and what is actually being done with the data. The risks of research participation are reasonable in view of the potential benefits of this study. The protocol was unanimously approved pending the suggested modifications. (Total =9; Vote: For-8, Opposed-0, Abstained-1 (Chair))

The sixth protocol # 09-0013, entitled “*Normal Lacritin Levels in Human Tears – Developing of a New Clinical Assay-JMU*”, was reviewed by the full board due to the involvement of external funding. The IRB questioned if the participants at the institution where the tear drops were being collected were informed that their data would be going to other universities? Was this data already collected? Do they have a copy of consent form? If data hasn’t been collected, does the consent form say where samples are going and what will be done with them? The IRB stated that if the data has already been collected, the PIs need to make every assurance that the participants cannot be identified. The risks of research participation are reasonable in view of the potential benefits of this study. The protocol was unanimously approved pending the suggested modifications. (Total =9; Vote: For-8, Opposed-0, Abstained-1 (Chair))

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The IRB members present were asked if there were any announcements up for discussion. Ms. Carolyn Strong stated a new student member, Mr. Adam Hall, has been added to the IRB roster. In addition, a request was received from Ms. Stefanie Warlock, East Campus Library, to join the IRB this upcoming academic year. In addition, there was a discussion regarding the newly made changes to the IRB secure web site. The IRB members present stated they were pleased with the changes. When asked if there were any other announcements to be made, the IRB members present stated there were no additional announcements to discuss at the time.

The meeting adjourned at 6:27 p.m.

Submitted by,

Carolyn Strong
IRB Research Coordinator