Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

• Call to order 3:05PM

• Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.  
  o Also in attendance: Jonathan Good

• The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

• Full Review of an IRB application submitted by Greg Wimer and Jonathan Good entitled, “Effect of wearing a cooling vest on thermoregulation and exercise performance in the heat.”
  o The board met without the researchers present to discuss the application
    ▪ Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  o The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  o After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  o The board recommended that the researchers make the following changes:
    ▪ Use disposable one-time use thermistors
    ▪ Acquire a portable defibrillator to be present during all research sessions
    ▪ Train all researchers in CPR and defibrillator use
    ▪ Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    ▪ Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    ▪ Ensure the privacy of participants while in the research room using the rectal thermistor
    ▪ Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    ▪ Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - [www.armstrong.edu/IRB](http://www.armstrong.edu/IRB)

- The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

- Call to order 3:05PM

- Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
  - Also in attendance: Jonathan Good

- The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

  - The board met without the researchers present to discuss the application
    - Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  - The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  - After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  - The board recommended that the researchers make the following changes:
    - Use disposable one-time use thermistors
    - Acquire a portable defibrillator to be present during all research sessions
    - Train all researchers in CPR and defibrillator use
    - Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    - Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    - Ensure the privacy of participants while in the research room using the rectal thermistor
    - Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    - Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - www.armstrong.edu/IRB

- The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting
November 10, 2011
Conference Room #109 – Burnett Hall

• Call to order 3:05PM

• Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
  o Also in attendance: Jonathan Good

• The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

• Full Review of an IRB application submitted by Greg Wimer and Jonathan Good entitled, “Effect of wearing a cooling vest on thermoregulation and exercise performance in the heat.”
  o The board met without the researchers present to discuss the application
    ▪ Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  o The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  o After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  o The board recommended that the researchers make the following changes:
    ▪ Use disposable one-time use thermistors
    ▪ Acquire a portable defibrillator to be present during all research sessions
    ▪ Train all researchers in CPR and defibrillator use
    ▪ Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    ▪ Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    ▪ Ensure the privacy of participants while in the research room using the rectal thermistor
    ▪ Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    ▪ Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - www.armstrong.edu/IRB

- The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

- Call to order 3:05PM

- Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.  
  o Also in attendance: Jonathan Good

- The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

  o The board met without the researchers present to discuss the application  
    ▪ Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  o The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  o After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  o The board recommended that the researchers make the following changes:
    ▪ Use disposable one-time use thermistors
    ▪ Acquire a portable defibrillator to be present during all research sessions
    ▪ Train all researchers in CPR and defibrillator use
    ▪ Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    ▪ Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    ▪ Ensure the privacy of participants while in the research room using the rectal thermistor
    ▪ Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    ▪ Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - www.armstrong.edu/IRB

- The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

- Call to order 3:05PM

- Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
  - Also in attendance: Jonathan Good

- The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

  - The board met without the researchers present to discuss the application
    - Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  - The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  - After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  - The board recommended that the researchers make the following changes:
    - Use disposable one-time use thermistors
    - Acquire a portable defibrillator to be present during all research sessions
    - Train all researchers in CPR and defibrillator use
    - Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    - Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    - Ensure the privacy of participants while in the research room using the rectal thermistor
    - Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    - Have the participants clearly document their level of fitness in the screening procedure
• Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
• Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

• Informational item on department head and deans signatures on IRB application
  o Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  o The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

• John Kraft presented the latest version of the IRB webpage.
  o Now housed under Academic Affairs.
  o [www.armstrong.edu/IRB](http://www.armstrong.edu/IRB)

• The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

• Call to order 3:05PM

• Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.  
  o Also in attendance: Jonathan Good

• The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

• Full Review of an IRB application submitted by Greg Wimer and Jonathan Good entitled, “Effect of wearing a cooling vest on thermoregulation and exercise performance in the heat.”  
  o The board met without the researchers present to discuss the application  
    - Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.  
  o The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.  
  o After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.  
  o The board recommended that the researchers make the following changes:  
    - Use disposable one-time use thermistors  
    - Acquire a portable defibrillator to be present during all research sessions  
    - Train all researchers in CPR and defibrillator use  
    - Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services  
    - Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures  
    - Ensure the privacy of participants while in the research room using the rectal thermistor  
    - Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant  
    - Have the participants clearly document their level of fitness in the screening procedure
• Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
• Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

• Informational item on department head and deans signatures on IRB application
  o Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  o The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

• John Kraft presented the latest version of the IRB webpage.
  o Now housed under Academic Affairs.
  o www.armstrong.edu/IRB

• The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

• Call to order 3:05PM

• Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.  
  o Also in attendance: Jonathan Good

• The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

• Full Review of an IRB application submitted by Greg Wimer and Jonathan Good entitled, “Effect of wearing a cooling vest on thermoregulation and exercise performance in the heat.”
  o The board met without the researchers present to discuss the application
    ▪ Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  o The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  o After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  o The board recommended that the researchers make the following changes:
    ▪ Use disposable one-time use thermistors
    ▪ Acquire a portable defibrillator to be present during all research sessions
    ▪ Train all researchers in CPR and defibrillator use
    ▪ Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    ▪ Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    ▪ Ensure the privacy of participants while in the research room using the rectal thermistor
    ▪ Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    ▪ Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - [www.armstrong.edu/IRB](http://www.armstrong.edu/IRB)

- The meeting adjourned at approximately 4:30 pm
Call to order 3:05PM

Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
   ○ Also in attendance: Jonathan Good

The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

   ○ The board met without the researchers present to discuss the application
     ▪ Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
   ○ The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
   ○ After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
   ○ The board recommended that the researchers make the following changes:
     ▪ Use disposable one-time use thermistors
     ▪ Acquire a portable defibrillator to be present during all research sessions
     ▪ Train all researchers in CPR and defibrillator use
     ▪ Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
     ▪ Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
     ▪ Ensure the privacy of participants while in the research room using the rectal thermistor
     ▪ Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
     ▪ Have the participants clearly document their level of fitness in the screening procedure
• Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
• Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

• Informational item on department head and deans signatures on IRB application
  o Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  o The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

• John Kraft presented the latest version of the IRB webpage.
  o Now housed under Academic Affairs.
  o www.armstrong.edu/IRB

• The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

- Call to order 3:05PM

- Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
  - Also in attendance: Jonathan Good

- The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

  - The board met without the researchers present to discuss the application
    - Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  - The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  - After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  - The board recommended that the researchers make the following changes:
    - Use disposable one-time use thermistors
    - Acquire a portable defibrillator to be present during all research sessions
    - Train all researchers in CPR and defibrillator use
    - Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    - Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    - Ensure the privacy of participants while in the research room using the rectal thermistor
    - Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    - Have the participants clearly document their level of fitness in the screening procedure
- Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
- Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

- Informational item on department head and deans signatures on IRB application
  - Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  - The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

- John Kraft presented the latest version of the IRB webpage.
  - Now housed under Academic Affairs.
  - [www.armstrong.edu/IRB](http://www.armstrong.edu/IRB)

- The meeting adjourned at approximately 4:30 pm
Institutional Review Board meeting  
November 10, 2011  
Conference Room #109 – Burnett Hall

- Call to order 3:05PM

- Members present: Joyce Bergin, Patricia Holt, Sean Eastman, John Kraft (chair), John Markham, Delana Nivens, Zaphon Wilson, Sara Plaspohl, and Greg Wimer.
  - Also in attendance: Jonathan Good

- The minutes of the October 6, 2011 meeting were approved without change and John Kraft volunteered to take minutes for the November meeting.

  - The board met without the researchers present to discuss the application
    - Major concerns involved the use of a rectal thermistor, assessment of rectal inflammation and screening of other health problems, potential for adverse reactions, use of less intrusive measures, gender issues, training of use of thermistor, use of first-aid equipment by trained personnel.
  - The board met with both researchers for a question and answer dialog session where the above issues were discussed. The researchers provided detailed responses to the board members’ questions and offered to change the protocol to address concerns.
  - After consultation without the researchers present, the board unanimously voted to defer approval of the project. The IRB application will have to be modified and resubmitted for full review in order to receive approval.
  - The board recommended that the researchers make the following changes:
    - Use disposable one-time use thermistors
    - Acquire a portable defibrillator to be present during all research sessions
    - Train all researchers in CPR and defibrillator use
    - Develop a written action plan for possible adverse events including, but not limited to, the use of CPR, defibrillator use, and availability of a phone in the research room to call emergency services
    - Create a stringent protocol for such issues as sterilization (if necessary), disposal of thermistors, attaching the cord to the participant's leg, binding of thermistor to determine when to stop inserting, and other critical procedures
    - Ensure the privacy of participants while in the research room using the rectal thermistor
    - Ensure that the researcher who trains the participant on thermistor insertion is the same sex as the participant
    - Have the participants clearly document their level of fitness in the screening procedure
• Change the informed consent form to warn against participation of anyone with rectal inflammation or pathology
• Change the informed consent form to be more specific about the type of “medical care” provided if an adverse event is experienced

• Informational item on department head and deans signatures on IRB application
  o Reportedly concern was expressed at the last Senate meeting about the purpose of the signatures.
  o The board is waiting to hear from the Senate committee about the specific issues and any suggestions they may have

• John Kraft presented the latest version of the IRB webpage.
  o Now housed under Academic Affairs.
  o www.armstrong.edu/IRB

• The meeting adjourned at approximately 4:30 pm