

Jacksonville State University

Institutional Review Board

2006 Annual Report

I. General Information

a. Name. The name of this committee is Jacksonville State University Institutional Review Board (IRB).

b. Purpose and Scope. The Institutional Review Board (IRB) is a committee that reviews all JSU research involving human participants and is responsible to the President. The purpose of the IRB is to assure that research is conducted in an ethical manner, specifically in accordance with Department of Health and Human Services regulations (45 CFR 46 Protection of Human Subjects). This includes ensuring that risks to participants are minimized, the selection of participants, is equitable and participants are informed fully of what their participation will entail.

The policy on the use of human subjects in research applies to any activity deemed to be research at Jacksonville State University. The applicability of this policy is to all entities of the university: faculty, administration, staff, students and contracted consultants. This policy applies to any research activity using human subjects that is directly or indirectly supported by the university.

The full text of JSU's "Policy on Use of Human Subjects in Research" is available on the Academic Affairs web site at <http://www.jsu.edu/depart/avpasa/humansubjects.html> and is reviewed and updated annually.

c. Membership. For 2005-2006, the committee consisted of the following membership:

Dr. Joe Delap, Secretary (Ex Officio)
Dr. Joann Williams, Chair
Dr. Jennifer Gross
Dr. Bob Hymer
Dr. Martha Merrill
Dr. Michael Clayton
Dr. Kay Williams
Dr. Laura Weinkauff

d. Records. Committee Records are maintained by the Secretary and housed in the Office of the Associate Vice President for Academic Affairs, 201 Bibb Graves Hall.

II. Activities and Significant Accomplishments

a. Applications. The IRB reviewed 22 research proposals during the academic year 2005-2006. Of these, 17 were exempt, 1 was expedited, 1 was renewed and 3 were fully reviewed. Minutes of fully reviewed applications are included in "III.a." The names of all applicants and projects are attached in "III.b." All applications were eventually approved.

b. FWA. In November of 2003, with the generous support of the President's Office and others, JSU applied for and was awarded the FWA. The Office of the AVPAA continues to sustain the university's FWA through careful record keeping and reporting.

III. Appendix

a. Minutes of IRB Meetings 2005-2006

Institutional Review Board (IRB) meetings (Meetings were conducted by electronic mail).

Meeting of March 31, 2006, to consider **two** applications entitled "Comparative Study of Brain Activity Patterns between violent crime and property crime offenders using Quantitative Electroencephalography." PI's: Keller and MacMillan (submitted **2** identical applications, considered together).

From Member Dr. Claudia McDade: I have no problem with the IRB apps you sent over this week, as I know Ron Mellon is competent to supervise these research projects. (No response needed.)

From Member Dr. Al Nichols: In regard to this application, as long as the subjects are volunteers and the questionnaire responses are kept confidential, I don't have a problem with the proposal. (No response needed.)

From Member Dr. Robert Hymer:

Re: Comparative Study of brain activity patterns between violent crime and property crime offenders using Quantitative Electroencephalography

The assurances given by the investigator and the faculty sponsor seem adequate.
The study will be closely supervised by well qualified faculty.
I have no objection to the study.

Re: Comparative Study of brain activity patterns using Quantitative Electroencephalography of violent sex offenders and a control population.

The assurances given by the investigator and the faculty sponsor seem adequate.
The study will be closely supervised by well qualified faculty.
I have no objections to the study. (No responses needed).

Drs. Gross and Weinkauff, contacted by telephone, had no objections to the study.

From the Chair, Dr. Joann Williams: The authors did an excellent job of describing the equipment to be used and its administration. Therefore, I have no questions regarding the threat of physical harm to these individuals. I do have some questions regarding several other aspects of the methodology.

1. What specific information will you be pulling from the prisoners' record?
2. You state that the prisoners will be interviewed to determine interest in the participation. What are the questions you will be asking? How will this interview be conducted? It would be helpful if you provide us with detail procedures including a script that will be used
3. In selecting your control (student) population, what questions will you be asking? How will this interview be conducted? Again, it would be helpful if you provide us with detail procedures including a script that will be used.
4. For both prisoners and control, you have provided the consent form. There are three aspects of this form that I would like to review.
 - a. The written description that these individuals will be reading is not attached. Would you please submit this description?
 - i. In regards to the prisoner group, what are the procedures if the person is illiterate or unable to comprehend English?
 - ii. In regards to the prisoner group, you need to make sure that this description includes wording that indicates that they will gain nothing from participation.
 - b. Regarding the verbal explanation, what will you tell these potential subjects regarding the procedure? It would be helpful if you provide us with a script regarding these procedures.
 - c. You mentioned responding to questions. What are the potential or frequently asked questions regarding this procedure? What are the typical responses?
5. The individual has signed the consent; yet, during the study they decide they do not wish to continue. What procedures do you have in place to discontinue the study at the request of the individual?
6. The individual has signed the consent; yet, during the study they appear to becoming agitated or having an unforeseen reaction. What procedures do you have in place to discontinue the study and to respond to any potential reaction?
7. Will you be collecting any other type of data? (e.g. demographics, questions). If yes, would you please submit this information?
8. Since this study will be conducted within prison facility with potentially violent individuals, what procedures are in place to protect the researcher during data collection?

Responses from the Co-PI's:

1. What specific information will you be pulling from the prisoners' record?
 - We would be pulling the Age, Current Offense, and Prior Offenses.
2. You state that the prisoners will be interviewed to determine interest in the participation. What are the questions you will be asking?
 - Please see attached Questionnaire Form. Please note that the Questionnaire will not be given until after consent to the research has been ascertained.
 - How will this interview be conducted?

- The interviews will be conducted according to the Calhoun County Sheriff's Office protocol.

It would be helpful if you provide us with detail procedures including a script that will be used:

- Please see attached Research Description

3. In selecting your control (student) population, what questions will you be asking?

- Please see attached Questionnaire Form.

How will this interview be conducted?

- The interview will be conducted by the P.I. and Dr. Mellen in his office.

Again, it would be helpful if you provide us with detail procedures including a script that will be used:

- Please see attached Research Description.

4. For both prisoners and control, you have provided the consent form. There are three aspects of this form that I would like to review.

a. The written description that these individuals will be reading is not attached. Would you please submit this description?

i. In regards to the prisoner group, what are the procedures if the person is illiterate or unable to comprehend English?

- The person will not be included if he does not comprehend English and/or is illiterate

ii. In regards to the prisoner group, you need to make sure that this description includes wording that indicates that they will gain nothing from participation.

- Please see new Consent Form.

b. Regarding the verbal explanation, what will you tell these potential subjects regarding the procedure? It would be helpful if you provide us with a script regarding these procedures.

- We will be reading the Research Description, Analysis Description and the Informed Consent Form as they read it silently.

c. You mentioned responding to questions. What are the potential or frequently asked questions regarding this procedure? What are the typical responses?

- The most frequent questions anticipated have been covered in the Analysis Description. The Research Description should cover all other anticipated questions. We have left the inmates and students the opportunity to ask questions in order to clarify concerns they may have about the analysis.

The analysis has proven to be the most "troubling" part of the research for the participant, when we asked random students. This is due to the idea of sensors being connected to the head. When we explained that the sensors are not attached to the head and there is no discomfort felt during the analysis, they said it is something they "wouldn't mind participating in."

5. The individual has signed the consent; yet, during the study they decide they do not wish to continue. What procedures do you have in place to discontinue the study at the request of the individual?

- We will discontinue the analysis reading, remove all equipment from the individual, and let them leave. (Inmates will have to be escorted back out with the officer that is present)

6. The individual has signed the consent; yet, during the study they appear to becoming agitated or having an unforeseen reaction. What procedures do you have in place to discontinue the study and to respond to any potential reaction?
 - We will follow the same procedure as above and file an incident report for the university. (No allergic reactions are expected from the equipment, as it is all medical grade equipment)
7. Will you be collecting any other type of data? If yes, would you please submit this information?
 - No other data will be collected besides the analysis reading and the information on the questionnaire form.
8. Since this study will be conducted within prison facility with potentially violent individuals, what procedures are in place to protect the researcher during data collection?
 - We will be following Calhoun County Sheriff's Office protocol, which usually includes an officer present with us at all times.

The Co-PI responses were copied to all committee members. The application was approved by all members and signed by the IRB Chair.

Meeting of April 25, 2006, to consider the research proposal entitled "The Application of Alpha-Stim SCS as a Treatment Modality for Reducing Anxiety and Depression in Law Enforcement Officers," Dr. Ron Mellen, PI.

Concerns expressed by the Chair, Dr. Joann Williams:

1. The consent form states that the individual has read a description of the study and understand the procedure. What exactly are the procedures that the researcher will describe to the subject? This script needs to be provided.
2. The section on risk/benefits state that the risk are minimal and provide the various risk associated with this procedure. Yet, I do not see where you inform the subjects regarding these risks. These risks must be reviewed with the subject and the subject needs to acknowledge that they are aware of the risks in the consent form.
3. I appreciate the inclusion of the IRB Incident report. Yet, what are the immediate procedures if an incident occurs to minimize potential harm to the subject.
4. What are the procedures for a subject to voluntarily remove him/herself from the study or the researcher to remove a subject from study? These procedures need to be outlined and provided to the IRB committee.

Dr. Williams subsequently received a copy of a revised consent form and reported that she was satisfied with the application.

From Dr. Hayden Center: My concerns have been addressed and I am satisfied.

From Dr. Robert Hymer: The instrumentation used is approved by the FDA for treating anxiety, depression and insomnia. The principal investigator is a well qualified faculty member. I have no objections to the study.

From Dr. Al Nichols: In regard to this application, as long as the subjects are volunteers and the questionnaire responses are kept confidential, I don't have a problem with the proposal.

From Dr. Jennifer Gross: Once again, I find myself with no comments or questions on an IRB application.

The application was approved and signed by the IRB Chair.

FACULTY NAME	DEPT.	TITLE OF PROJECT	NEW	RENEW	DATE REC'D.	ACTION REQUESTED	APPROVED
Evans, Robert	CJ	Comparison of self-concepts of male juvenile sex offenders and male juvenile non-sex offenders and the relationship of self-concept to family marital status using the Tennessee Self-Concept Scale	X		3/1/6	Expedited Review	Expedited Review 3/1/6
Evans, Robert	CJ	The Relationship of Factors That Influence Criminal Justice Majors Choice of Concentration & the Variables Ages, Gender, Ethnicity & Class Standing	X		3/27/6	Exempt	Exempt 3/27/6
Keller, Shawn (student)	CJ	Comparative Study of Brain Activity Patterns Between Violent Crime and Property Crime Offenders Using Quantitative	X		4/12/6	Full Review	Full Review 4/12/6
MacMillan, Scott (student)	CJ	Comparative Study of Brain Activity Patterns Using Quantitative Electroencephalography of Violent Sex Offenders and a Control Population	X		4/12/6	Full Review	Full Review 4/12/6
Richey-Bentley, Charity	West Anniston Foundation	For Your Life! (Community Programs to Improve Minority Health)	X		4/13/6	Renewal	Renewal 4/13/6
Mellen, Ron	CJ	The Application of Alpha-Stim SCS as a Treatment Modality for Reducing Anxiety and Depression in Law Enforcement Officers	X		4/25/6	Full Review	Full Review 4/25/6

FACULTY NAME	DEPT.	TITLE OF PROJECT	NEW	RENEW	DATE REC'D.	ACTION REQUESTED	APPROVED
Hardy, Ben	FEAC	Impact of Desert Palace, Inc. V. Costa	X		5/20/6	Exempt Review	Exempt 5/10/6
Bryson, Jeff	PSY	The relationship between subjective sleep characteristics and GPA among social organization students.	X		6/13/6	Exempt Review	Exempt 6/13/6
Bryson, Jeff	PSY	New Methods for Teaching Dreaming in Introductory Psychology Courses	X		6/14/6	Exempt Review	Exempt 6/14/6
Phillips, Tommy	FCS	An Investigation of the Influence of the Parent- Child bond on College Students' Interpersonal Rejection Beliefs and Feast of Intimacy	X		7/21/6	Exempt Review	Exempt 7/21/6
Phillips, Tommy	FCS	Pilot Test & Initial Validation of a Parental Coalition Scale	X		8/7/6	Exempt Review	Exempt 8/7/6

Submitted 1 August 2007 by Joe Delap, Executive Secretary, JSU IRB