INSTITUTIONAL REVIEW BOARD GUIDELINES

BRENAU UNIVERSITY
Gainesville, GEORGIA

TABLE OF CONTENTS

Brenau University Institutional Review Board

Mission

The mission of research at Brenau University is to improve the human condition. Human subject's research requires approval of the Institutional Review Board (IRB).

Purpose of the IRB

The purpose of the Brenau University Institutional Review Board (IRB) is to insure the protection of any human subjects involved in research projects conducted under the auspices of the university in any capacity.

Policy Statement

Any research activity that involves human subjects (including instructor directed activities), whether conducted on a large or a small scale, whether preliminary or fully designed research study, whether conducted by students or faculty, whether funded or not, and whether it involves minimal risk or more than minimal risk, is subject to the IRB Guidelines.

Brenau University's Institutional Review Board (IRB) strives to comply with guidelines as defined by the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), and to put into practice principles outlined in the Belmont Report. These guidelines are also extended to include review and oversight of any activity that involves Human Subjects or participants. The policy also applies to visitors of the University, and/or use of non-public records associated with the university to identify, contact, or recruit human subjects.

Failure to complete an IRB application for a research project involving human subjects will result in notification to the appropriate department chair and the Vice President for Academic Affairs who will determine the appropriate disciplinary action.

The IRB has the authority to suspend or terminate approval of any research that is not being conducted in accordance with the IRB requirements or that has been associated with serious and/or unexpected harm to the subjects. A statement of the reasons for suspension or termination by the IRB will be given to the PI, the department chair, the VP for Academic Affairs or a designee, sponsors and/or funding sources.

Composition of the IRB

The Vice-President for Academic Affairs appoints and supervises the IRB members per the guidelines put forth by the Faculty Welfare and Ethics Committee. The committee chair is appointed for a term of three years and the 6 committee members serve 2-year terms. The chairperson acts as a liaison to the VPAA and is also responsible for being a liaison between the PI, their advisor (if appropriate) and the committee. All members have full voting rights. No IRB members participate in the review of any study on which they are an advisor, an investigator or a co-investigator. The IRB provides training to new faculty and to students as requested by faculty members. The IRB communicates with Deans and Department Heads regarding the activities of the IRB. The IRB is currently housed in the School of Health and Science and receives administrative support from their office manager.

The IRB may invite individuals with expertise in special areas (consultants) to assist in the review of complex issues that require expertise beyond, that available on the committee. The consultant does not take part in voting. Principle investigators (PI's) may request or be invited to attend IRB meetings to discuss issues concerning their proposed research. PIs are excused from the IRB meeting prior to members voting on the decision about the proposal Investigators and/ or consultants do not take part in IRB deliberations or voting.

Meetings and recordkeeping:

1. The IRB shall meet at regularly scheduled intervals not less than once per semester and all meetings are open to the public except in cases where the chair deems that confidentiality is necessary
2. Voting of the IRB requires a quorum, including at least one member who has non-scientific interests. The chair does not vote except in case of a tie vote among members. Voting may be done by secret ballot or by show of hands. Reporting of decisions of IRB is done in writing by the chair (or designated office support personnel) to the PI in a timely fashion. In case of a non-unanimous vote, the minority opinion is documented and shared with the PI.
3. The IRB must have minutes documenting all meetings which include members present and actions taken. IRB records must also include copies of all proposals and attached

documents submitted to it, regardless of decision about proposals. Copies must be kept of all correspondence sent to PIs regarding decisions and status of research projects. Copies of all ongoing reports sent to the IRB by PIs during the progress of research must also be in the IRB files.

4. The IRB must review all research in progress on a regular basis, determined by the level of risk to subjects, but not less than annually. The IRB shall have a protocol for seeking and reviewing ongoing reports of such research. Approval of research may be canceled at any time, depending upon findings of risk to subjects during the progression of the research. The IRB may also continue approval with stipulations and/or non-binding recommendations at any time during the progress of research, depending on findings of risks to subjects during the research process.
5. Reporting of decisions of IRB is done in writing by the Chair and/or the office manager (Dean of Health and Science) to the PI in a timely fashion. Once the paper copies are received in the office, most communication will occur via e-mail.

Recordkeeping

The IRB must have minutes documenting all meetings which include members present and actions taken. The IRB will maintain a "project log" for each academic year in order to accurately keep track of the research projects conducted at Brenau University. IRB records must also include copies of all proposals and attached documents submitted to it, regardless of decision about proposals. Copies must also be kept of all correspondence sent to PIs regarding decisions and status of research projects. Copies of all ongoing reports sent to the IRB by PIs during the progress of research must also be in the IRB files. IRB files will be maintained for five years and subsequently shredded.

The IRB must review all research in progress on a regular basis, determined by the level of risks to subjects, but not less than annually. The IRB shall have a protocol for seeking and reviewing ongoing reports of such research. Approval of research may be cancelled at any time, depending upon findings of risks to subjects during the progression of the research. The IRB may also continue approval with stipulations and/or non-binding recommendations at any time during the progress of research, depending on findings of risks to subjects during the research process. Repeated infractions or failure to act upon the recommendations of the IRB will result in notification to the Vice President for Academic Affairs.

Definition of Terms

Human Subject: A living individual about whom an investigator (either student or employee of the university) conduction research acquires: identifiable private information, or data through interaction or intervention with the individual.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Privacy of human subjects must be respected by disguising pertinent information such as names, social security numbers, addresses, or any other characteristics that are not pertinent to the research goals. While many studies, particularly qualitative research cannot insure complete anonymity, researchers should make every attempt to insure confidentiality.

Interaction: includes interpersonal contact and communication between the investigator and the subject.

Intervention: includes both physical procedures and manipulation of the subject or the subjects environment for the purpose of performing research.

Legally Authorized Representative: an individual, judicial, or other body authorized by law to consent on behalf of a potential subject to the subject's participation in the proposed research.

Minimal Risk: means that the risks of harm anticipated by the research are not greater, considering probability and magnitude, than those encountered in daily life or during routine physical or psychological examination or tests.

Research: systematic investigation intended to develop or contribute to knowledge.

Collaborative Research

Ethical scientific practices must be adhered to in the case of collaborative research. Collaborative relationships should be identified as clearly as possible prior to the implementation of research. Collaborative research may include but is not limited to:

1. Examination of patients
2. Collection or receipt of specimens
3. Visits to institutions to perform research activities or clinical work
4. Supplying reagents
5. Performing tests

6. Analyzing data

7. Exchange of data containing personal or potential identifiers (such as codes)

8. Preliminary data-collection involving human subjects

9. Substantial intellectual contributions to protocol design

It is important that there is mutual agreement regarding the participation of each investigator, the shared authorship of the results of the study, and the order of authors in resulting publications. Not all collaboration is defined in advance. The need for collaboration may develop during the study. Collaboration that is not defined before the study begins must be reviewed by the IRB.

Cooperative Research

In the event that research in which the university and another institution or party cooperate in the conduct of all or part of the research the IRB, in concurrence with the Vice President for Academic Affairs or a designee, may use joint review, or rely on the review of another qualified IRB.

PI's need to take into account the time that may be required for approval from a cooperating agency. In some cases the cooperating agency may state that they want Brenau IRB approval prior to their IRB approval. In this case, the IRB may request a letter from the cooperating agency to insure that they are in agreement about the project. This letter can be on official letterhead or from an official e-mail account. For example, an EDS student doing a project in their own classroom may get a letter from their principal authorizing them to complete their research in their school and this will suffice as "cooperation" if attached to the IRB application.

Instructor directed activities

Any activity done through a course conducted at Brenau University that involves the use of human subjects will be considered course directed activities. Such activities might include surveys, case studies, and interviews. These activities are typically not written up in research journals or presented at professional meetings. Instructors are held accountable for data that is obtained via course assignments. Instructors should use the "Instructor directed activities" form to notify the IRB of projects involving the use of human subjects.

Requirements for Approval of IRB Application

Research can only be approved after the following requirements have been met:

a. Risks to subjects are minimized by using procedures with sound research design that do not expose subjects to undue risks.
b. Risks to subjects are reasonable relative to anticipated benefits, and the importance of the expected knowledge that may result from the research.
c. Subject selection should take into account the purposes of the research and the setting in which it is conducted. It is particularly sensitive to vulnerable populations such as: children, economically and educationally disadvantaged persons, mentally disabled persons, pregnant women, prisoners, students, unborn children or other institutionalized individuals. If subjects are likely to be susceptible to undue influence or coercion, the IRB may require additional safeguards to protect the subjects.
d. Informed consent will be obtained from each subject or from the subject's legally authorized representative. This must be in the form of a written document.
e. The research plan has adequate provisions for ensuring the safety of participants.
f. There are adequate provisions to protect the privacy of participants and maintain confidentiality of the data obtained. Each principal investigator (PI) must provide the IRB with written assurance of compliance in protecting human subjects by describing the procedures used.

Decisions available to the IRB:

a. Full Approval
b. *Disapproval* which requires written documentation to the PI of reasons for disapproval and opportunity to resubmit the proposal after concerns are addressed.
c. *Approval with stipulation*. Stipulations must be addressed in writing by the PI and submitted to the Chair prior to beginning the implementation of research. The Chair may approve such documentation or may submit tit to the full IRB for review.
d. *Approval with non-binding recommendations*. Recommendations must be addressed in writing by the PI and submitted to the Chair prior to beginning the implementation of research. The Chair may approve such documentation or may submit it to the full IRB for review.

e. *Table a proposal* which requires written documentation to the PI of the rationale for such action and plans for further review.

Categories of Review done by the IRB

Expedited Review

An investigator may request an exempt review from the IRB if the research proposal involving human subjects will be in one or more of the following categories:

1. Research involving normal educational practices conducted in commonly accepted educational settings such as:
    a. research on special and regular education instructional strategies
    b. research on the comparison among or effectiveness of curricula, classroom management, and instructional strategies
2. Research involving the use of cognitive, diagnostic, aptitude, or achievement educational tests, if the information taken is recorded in a manner that subjects cannot be identified, directly or through identifiers linked to the subject.
3. Research involving surveys or interviews except in the following cases:
    a. the responses are recorded in a way that can identify the human subject directly or through identifiers linked to the subject
    b. Responses, that if they became known outside the research could place the subject at risk for criminal or civil liability or be damaging to the subject's financial standing or employment.
    c. Research deals with sensitive aspects of the subject's behavior such as illegal conduct, substance abuse, or sexual behavior.

All research using surveys and interviews in considered exempt when subjects are elected or appointed public officials or candidates for public office.

4. Research involving observation by either the PI or the subject of public behavior, except where conditions listed in item C (above) exist.
5. Research involving records, pathological specimens, diagnostic specimens or the study of existing data, if the sources are publicly available and the information is recorded by the PI so that the subjects will not be identifiable directly or through identifiers linked to the subjects.

6. Any other category added to this list by the Department of Health and Human Serviced and published in the Federal Register.

Exempt Review

Expedited review of research proposals may occur in the following cases, research which involves only:

1. Collection of hair and nail clipping done in a nondisfiguring way.
2. collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor
3. Recording of data from adult subjects using noninvasive procedures routinely employed in clinical practice, including the use of physical sensors applied to the body which do not involve input of matter or significant amounts of energy into the subject, or the invasion of the subject's privacy.
4. collection of blood samples by venipuncture in amounts not exceeding 450 milliliters in an 8 week period and no more often than 2 times per week, from adult, non-pregnant subjects in good health.
5. voice recording made for research purposes
6. moderate exercise by healthy, non-pregnant adults
7. study of existing data, documents, records, or specimens
8. research on individual or group behavior or characteristics in which the researcher does not manipulate the behavior and the research will involve no stress to subjects
9. previously approved research which undergoes minor changes in protocol during implementation

These categories of research appropriate for expedited review are taken from The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, published by the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research, United States Government, Department of Health, Education, and Welfare. Expedited Review will consist of the following procedures:

1. The PI will submit all documentation required for full review to the IRB chair

2. The IRB Chair will determine whether or not the protocol qualifies for expedited review according to the previously definitions
3. When it is determined that a proposal meets the criteria for expedited review, the IRB or a designee of the chair may review the proposal and make any decision except denial of approval. Denial of approval requires full IRB review and vote.

Full review

All research not meeting the criteria for exempt or expedited review full under the category of full review. Generally these studies involve an intervention, manipulation, or some invasive procedure that is of higher risk that the proposals that are expedited. Full Review means that the application and associated paperwork will be reviewed by all committee members at their monthly meeting.

Application and notification process for submitting an IRB

(See Appendix A)

In order to facilitate the review process the IRB must receive:

- Seven (9) copies of the application with appropriate attachments (i.e. consent forms, survey materials, assessment tools, etc) ten (10) working days prior to the IRB meeting.
- In the case of exempt or expedited review, the PI can submit two (3) copies of the materials as these will only be reviewed by two committee members.
- It is **important** to note that before submitting to the IRB, faculty and/or grants personnel should review the IRB **prior to submitting the application.**
- **As a general timeline for completing a project during one academic school year the following is a suggested schedule of events:**
    - August-September- meet with advisor to discuss topic and proposal
    - Sept- Oct- Draft proposal for research and draft IRB for advisor approval
    - Oct-Nov – Submit IRB application (Jan-Feb submission for Summer completion of project) **IRB notification can take up to 6 weeks depending on volume of proposals, timeliness of submission, etc**
    - Dec-March- Data collection
    - March-April- Data analysis, **notify IRB of completion of project** (see Appendix E)

Application for Approval of Research should attend to:

a. Description of the research project should clearly explain: objectives of the study, study population, research design, and outcome parameters written for a general audience.
b. Goals – A statement of the hypothesis and goals of the study.
c. Study design and methods - Description of the involvement of human subjects in the study design and methods of implementation of the design. Provide credentials of investigators, and identify the relationships between investigators if research is collaborative or cooperative.
d. Monitoring for withdrawal of subjects from the study – Description of monitoring of study and criteria for withdrawing a subject form the study.
e. Analysis of study – Delineate how the outcomes will be measured and analyzed. Describe the statistical procedures to be used, and the method used to determine the number of subjects needed.
f. **Human subject protection is of utmost importance to the IRB**. Application should clearly describe procedures for:
    i. Selection: Describe the characteristics of the population including; (1) anticipated number of participants, (2) age, (3) sex, (4) ethnic background, and (5) health status. Include criteria for including or excluding a subject.
    ii. Explain the rational for involving vulnerable populations (children, economically and educationally disadvantaged persons, mentally disabled persons, pregnant women, prisoners, students, unborn children or other institutionalized individuals). Discuss procedures and practices (if applicable) that will be used to minimize susceptibility to undue influences and unnecessary physical/psychological risks for research participants.
    iii. Evaluation of benefits: Describe potential benefits to participants and others. Clearly state whether or not compensation will be provided.

iv. Evaluation of risks: Describe potential risks and explain how you will minimize any risks. Consent forms must also attend to the benefits and risk of participation in your study

Informed Consent

(See Appendix B and C for samples)

The basis for informed consent is the ethical principles of respect for persons, beneficence and justice. The principle of respect requires that researchers recognize the autonomy and dignity of individuals. The subjects should have the opportunity to choose what will and will not happen to the. This occurs when the following aspects of informed consent are met:

1. Disclosure of information-participants should be given enough information to make an informed decision.
2. comprehension-individuals must have the intellectual capacity to understand the information; it should be presented in terms understandable to the subjects
3. Volunteer- consent should be free of undue influence and coercion.
4. Informed consent should be:
    a. Obtained in writing from the participant or legally authorized representative.
    b. Understandable to the subject or representative
    c. Obtained in a situation that allows the participant sufficient opportunity to consider participation and which minimizes coercion or undue influences. It shall include no language that suggests that the participant waives any legal rights or releases the investigators from any liability

Consent and assent processes and documents:

1. Describe plan for recruitment of participants and consent procedures to followed, including who will seek the consent, the nature of information provided to prospective participants, and methods of documenting consent.
2. A copy of the consent document must be attached. The language should be simple and easy to understand.
3. Children cannot legally give their consent. Depending on their age they may have the ability to give assent ("assent" means a child's affirmative agreement to participate in research). Protocols involving children should include a discussion of how assent will be attained. If an assent document is used it should be attached

APPENDIX A- IRB APPLICATION
HUMAN SUBJECTS RESEARCH APPLICATION

Brenau University
Institutional Review Board
School of Health and Science

500 Washington St. SE
Gainesville, Georgia 30501
(770) 718-5304

Check One

New Application: ☐

Resubmission: ☐ **Revision** ☐ (*All changes must be highlighted*)

☐ **Applying for Exempt review** (see guidelines)

☐ **Applying for Expedited review** (see guidelines)

NOTE: *Application must have a Brenau e-mail address. All communication will occur via e-mail.*

MAIL 7 COPIES (2 copies for expedited review) OF APPLICATION TO ABOVE ADDRESS 4-6 weeks prior to start date

Dr. ☐ **Mr.** ☐ **Ms.** ☐

Faculty ☐ **Undergraduate** ☐ **Graduate** ☐

Name of Principal Investigator **Soc. Sec. No. (if project is grant affiliated)**

Brenau Department AND Brenau e-mail address

Mailing Address (if you prefer not to receive mail in dept.)

Phone Number (s) **E-Mail (REQUIRED)**

Dr. ☐ **Mr.** ☐ **Ms.** ☐

Faculty ☐ **Undergraduate** ☐ **Graduate** ☐

Name of Co-investigator(s) **Soc. Sec. No. (if project is grant affiliated)**

Brenau Department AND Brenau e-mail address

8:00 a.m. - 5:00 p.m. Phone Number (s)

Phone Number (s) **E-Mail**

**Signature of Principal Investigator

Signature of Co-investigator (s)

Brenau Faculty Advisor:

Name **Dept.** **Building** **Phone No.**

Signature: **Soc. Sec. No.: (if grant affiliated)** **Date:**

*Your Signature indicates that you accept responsibility for the research described in this application.

If funded:

***Sponsored Programs Proposal#** **Name of Funding Agency**

By listing a proposal number, you agree that this application matches the grant application and that you have disclosed all financial conflicts of interest (see Q6a)

TITLE OF RESEARCH:

Start Date: _____ **End Date:** _____

(Must be 4-6 weeks after date of submission to IRB) ***(Approval is granted only for a year at a time)***

Check all that apply:

Deception ☐ **Illegal Activities** ☐ **Minors** ☐ **Pregnant Women/Prisoners** ☐

Data Sets ☐ **Bio Medical** ☐ **(describe)**_____

HUMAN SUBJECTS RESEARCH APPLICATION

1. **PROBLEM ABSTRACT:** *State rationale and research question or hypothesis (why is this study important and what do you expect to learn?).*

2. **RESEARCH DESIGN:** *Identify specific factors or variables, conditions or groups and any control conditions in your study. Indicate the number of research participants assigned to each condition or group, and describe plans for data analysis.*

3. **RESEARCH SUBJECTS:**

   a. *List maximum number of subjects , targeted age group/ range (specified in years); targeted gender ; targeted ethnicity/ race*

   b. *Method of selection and recruitment - list inclusion and exclusion criteria. Describe the recruitment procedures (including all follow-ups).*

   c. *The activity described in this application involves another institution (e.g. school, university, hospital etc.) and/or another country.* Yes☐ No☐
   If yes, provide the following details:
   1) Name of institution:
   2) County and state:
   3) Country:
   4) *Written letter of authorization (on official letterhead only)*/ IRB approval:
      Attached: ☐
      Pending: ☐

   d. *Is there any working relationship between the researcher and the subjects*?
   Yes☐ No☐, *If yes, explain.*

   e. *Describe any incentives (payment, gifts, extra credit).*
   Extra credit cannot be offered unless there are equal non-research options available for research using students

4. **PROCEDURES**: *State in chronological order what a subject is expected to do and what the researcher will do during the interaction. Indicate time commitment for each research activity. And detail any follow-up.*

   Duration of participation in the study: ____ Months
   No. of testing/training sessions:____ Length of each session:_____

5. ***Check all other materials that apply and are attached***:
   Interview protocol ☐ Debriefing Statement ☐ Recruitment flyers or advertisements ☐
   Consent/Assent forms ☐ Photo/Video release on consent form ☐
   If no consent documents are attached, justify this omission under Q. 8
6. **RISK**: *Detail risks to a subject as a result of data collection and as a direct result of the research and your plans to minimize them and the availability and limits of treatment for sustained physical or emotional injuries.*
   NOTE: REPORT INCIDENTS CAUSING DISCOMFORT, STRESS OR HARM TO THE IRB IMMEDIATELY!
   a. **CURRENT RISK**: *Describe any psychological, social, legal, economic or physical discomfort, stress or harm that might occur as a result of participation in research. How will these be held to the absolute minimum*?

   b**. FUTURE RISK**: *How are research participants to be protected from potentially harmful future use of the data collected in this project? Describe your plans to maintain confidentiality, including removing identifiers, and state who will have access to the data and in what role. Justify retention of identifying information on any data or forms*.
   DO NOT ANSWER THIS QUESTION WITH "NOT APPLICABLE"!
   Anonymous ☐ Confidential ☐ *Check one only and explain below.*

   Audio-taping ☐ Video-taping ☐ Pictures ☐
   If taping, how will tapes be securely stored, who will have access to the tapes, will they be publicly disseminated and when will they be erased or destroyed? Justify retention.

7. **BENEFIT**: *State the benefits to individuals and humankind. Potential benefits of the research should outweigh risks associated with research participation*.
   a. *Identify benefits of the research for participants, e.g. course credit, educational benefits*:

   b. *Identify any potential benefits of this research for humankind in general, e.g. advance our knowledge of some phenomenon or help solve a practical problem*.

8. **CONSENT PROCESS:**
   a. *Detail how informed consent will be obtained from all research participants and, when applicable, from parent(s) or guardian(s).*

   Request for waiver of signed consent using data sets Yes☐ No☐
   If yes, a full explanation must be submitted for approval, including assurance that risk to the participant will be minimal. Also submit a consent script that will be used in lieu of a form.
   b. **Deception** Yes☐ No☐
   If yes, describe the deception, why it is necessary, and how you will debrief them. The consent form should include the following statement: "In order to make this study a valid one, some information about my participation will be withheld until completion of the study."

9. **VULNERABLE PARTICIPANTS**: Yes☐ No☐
Minors ☐ Prisoners ☐ Pregnant women/fetuses ☐ Elderly ☐
Immigrants/non-English speakers ☐ Mentally/Physically incapacitated ☐ Others ☐ *List below*.
Outline procedures to obtain their consent/assent to participate. Describe the procedures to be used to minimize risk to these vulnerable subjects.

10. **ILLEGAL ACTIVITIES:** (illegal drug use, prostitution, undocumented immigrants, etc)
NOTE: Some ILLEGAL ACTIVITIES must be reported, e.g. child abuse.
Does the data collection relate to illegal activities? Yes☐ No☐
If yes, explain how subjects will be protected.

11. ***STUDENTS*** *(check all that apply to this application*)

This application is being submitted for :
Class assignment ☐ Pilot study ☐
Applied Project, Thesis or Exit Exam Research ☐

APPENDIX B- SAMPLE CONSENT FORM

Brenau University
Department of Occupational Therapy
Bradykinetic Therapy Consent Form

Purpose of the Study:

The purpose of this study is to perform preliminary testing on the development of Bradykinetic Therapy as a recognizable strategy for facilitating motor learning. Bradykinetic Therapy is the practice of prescribed slow movement to enhance accuracy of motor performance.

Procedure:

The prescribed movement in this study will be the golf swing (wedge shot). The research study will last approximately six consecutive weeks and will take place on the Brenau University soccer field. Once informed consent is obtained, all participants will meet for pre-testing of the mechanics of the golf swing, balance, accuracy, and an interview. All participants will be trained on the principles of Bradykinetic Therapy; they will be instructed to swing the golf club in a slow manner. A daily routine will last one minute per swing, ten swings per routine, which will include the motor performance as well as the mental imagery of the swing. Each participant will be given a personal log book to report his or her practice regimen. The study will last six weeks and every two weeks, thirty-minute meetings will be held to review the routine and his or her log entries.

Potential Benefits:

Receiving Bradykinetic Therapy may improve motor learning. Other benefits may include an increase in accuracy, golf score, swing mechanics, balance, strength, and an overall satisfaction of performance. Incentives will include refreshments, and snacks during each session and new golf balls at the completion of the study. Compensation other than instruction in golf is not included in this study.

Potential Risks:

Potential risks to participants may include a decreased satisfaction of his or her golf performance. Other unlikely risks may include muscle strains, fatigue, and loss of personal time. These risks are not anticipated and in order to prevent injury, proper warm up and body mechanics will be reviewed during each meeting. You may remove yourself from this study at any time without penalty.

Confidentiality:

All videos, data collected and personal information will be stored in a locked filing cabinet in the Occupational Therapy department. Only the researchers of this study will have access to this data. At the conclusion of the study, all materials will remain in the locked cabinet for two years, after which, they will be shredded. All participants have the right to discontinue this study with no consequences or penalties.

Supervision of research:

This research is being conducted to fulfill graduate thesis requirements for Brenau Univeristy Department of Occupational Therapy under the supervision of Dr. H.Keith Brown, PhD. He can be reached @ 770-534-6296

Contact Person:

If you have any questions or concerns about this project, please contact the IRB Office of Brenau University @ 770-718-5304

Printed Name _____

Signature _____ Date _____
Witness _____ Researcher(s)_____

APPENDIX C- SAMPLE PARENT LETTER/CONSENT FORM (EDUCATION)

Consent Form

December 15, 2003

Dear Parent(s) of _____,

As you may be aware, I am currently pursuing my Educational Specialist degree from Brenau University. One requirement of this objective is to complete an Applied Research Project.

I am asking parents and students for permission to use data gathered from Saxon ™ Math2 scores and Accelerated Math ™ scores. I am also asking permission for students to complete an attitudinal survey regarding use of the computer software. Data will be stored in a locked filing cabinet within the classroom. Each student will be assigned a number and their data will be listed by that number. This list will be kept separate from the data. Some data will be maintained in the grade book and some will be retrieved from the Accelerated Math ™ software. Data from the Iowa Test of Basic Skills used is from the grade level as a whole, no individual scores will be used. Only data from students who are present for the entire length of the study and who, along with their parents, give consent will be eligible for evaluation. There will be no negative consequences for children whose parents choose not to allow the data to be included or for their child to complete the survey.

Please discuss this with your child and check the appropriate line below. Please sign and date the bottom of the form. Thank you for your consideration of this matter.

Sincerely,

Allison W

____ My child and I give permission for his/her data to be used in Ms. Allison W's Applied Research Project and for my child to complete an attitudinal survey regarding the computer software. My child and I understand that their data will remain confidential.

____ My child and I prefer not to give permission for his/her data to be used in Ms. Allison W's Applied Research Project nor for my child to complete an attitudinal survey regarding the computer software. My child and I understand that he/she will not be penalized in any way because of this choice.

_____ _____

Parent Signature Date

_____ _____

Student Signature Date

If you have any questions or concerns about this project, please contact my project advisor @ 770-xxx-xxxx or you may contact the IRB Office of Brenau University @ 770-718-5304

APPENDIX D- APPLICATION FOR INSTRUCTOR DIRECTED ACTIVITIES (see pg.7)

Human Subjects Office
Brenau University
c/o Dean of the School of Health and Science
One Centennial Circle
Gainesville, GA 30501
770-718-5304

INSTRUCTOR NOTIFICATION FOR COURSE DIRECTED HUMAN SUBJECTS ACTIVITY

Instructor Title & Name:

Department: ***Campus Address:***
Course Title: ***Course Number:***
Email (REQUIRED): ***Telephone:***

1. NUMBER OF STUDENTS:
[Attach a list of the students involved with this class project]

2. DESCRIPTION OF CLASS ASSIGNMENT AS PRESENTED TO STUDENTS:
[Course syllabus and/or handouts may be attached]

3. DESCRIPTION OF PROCEDURES FOR MAINTAINING CONFIDENTIALITY:

Instructor's Signature: _____ Date: _____

Your Signature indicates that you have read the IRB Guidelines document and that you accept responsibility for the assigned research projects conducted by the students of this course. It further attests that you are fully aware of all the procedures to be followed, will monitor the research, and will notify the IRB of any significant PROBLEMS that arise.

APPENDIX E

Brenau University
Institutional Review Board
Notification of Completion of Study

Complete and submit to IRB Committee upon completion of the approved research project.

Date:_____

Principal Investigator:_____

Title of

Study_____

_____

Date of completion:_____

_____ _____

Principal Investigator Signature Date

APPENDIX F- CRITERIA FOR EVALUATING IRB APPLICATION

Brenau University
Institutional Review Board
Criteria for approval of a research proposal involving human subjects

Name of Project: _____ Principal Investigator: _____

	Elements of the IRB proposal contains:	Comments and concerns (What does PI need to do to fix problem?)
Cover Sheet	Title of Research	
	Name(s) addresses, phone number of researcher(s) or Principal Investigator (PI)	
	Name(s), addresses, phone number of faculty advisor	
	Advisor signature or IRB was received via e-mail from the advisor	
Summary of Proposed	Summary of research project written for "lay audience"	
	Objectives of the study	
	Hypothesis or research questions are clearly stated	
	Study population is clearly described	
	Design of the study is clearly articulated	
	Outcome of the study is described	
Human Subjects form	Characteristics of the study population (number of people, gender, ethnicity, age, health status of the participants)	
	Inclusion and exclusion criteria are clearly articulated	
	Procedures and practices for the study are clearly described. (How long? How many visits, etc…will participants have to make)	
	Procedures and practices account for all potential risks and actions are stated that prevent risks (You have emergency contact numbers in case something happens during your study)	
	Procedures to reduce any undue influence or unnecessary physical or psychological risk are described (describe all safety precautions to prevent physical or emotional harm)	
Appendices	Appendices are attached	
	Appendices are clearly labeled and referenced in the "Description of the Research Project"	
	Appendices provide overview of data collection tool or actual data collection instrument	

APPENDIX G- CRITERIA FOR EVALUATING CONSENT FORM

Criteria for evaluation of Consent form

Elements of the consent form contains:	**Comments and concerns (What does PI need to do to fix problem?)**
Consent form is attached	
Consent form is written in "*lay terms*"	
Consent form explicitly states that *participation is voluntary* and that participants may withdraw without penalty	
Procedures for *maintaining confidentiality or anonymity* is clearly stated	
Disposition of data, including scores, any additional data (such as interview transcripts, surveys, etc…) tapes, and/or photos is clearly stated	
Compensation is addressed in the consent form (if none, must also state this)	
Consent form clearly states the *risks and benefits* for the participants in the study	
Statement that *participant is aware* that they were given the *opportunity to ask any questions* is clearly made on the consent form	
An explanation of the *circumstance that could lead to the subjects participation being terminated* by the investigator without regard to the subjects consent is written in if applicable (e.g. if participant is demonstrating unsafe behavior that would put themselves or the researcher at risk)	
Consent form has *signature line for participant*	
Consent form has *signature line for researcher*	
Consent form has a statement (usually near the end) that the participant has been made aware that they may *contact the project advisor (with a phone number on the form) or the Brenau University IRB* if any questions or concerns about the project arise	
Consent form includes an initial line giving expressed permission for researcher to: • Use data for professional presentation • Use photos or video's for professional or educational presentations	

APPENDIX H- DECISION LETTER

Brenau University
Institutional Review Board
Results of review

Dear _____

The IRB has reviewed your proposal and has made the following recommendations:

- **Full approval, no changes needed.**
  You may begin your research on the start date listed on your proposal
- **Approval with stipulations.**
  You need to make the following changes and resubmit this proposal and your changes to the IRB:
  _____
  _____
  _____
  _____
- **Approval with non-binding recommendations**
  The following recommendations are being made to enhance your study and further protect human subjects:
  _____
  _____
  _____
  _____
  _____
- **Disapproval**
  At this time, the committee does not see your research as sufficiently protecting human subjects. You need to meet with your advisor and revise your proposal taking into account the following reasons for disapproval:
  _____
  _____
  _____
  _____
- **Table your proposal**.
  We cannot make a decision on your proposal because information is missing. You must submit the following information:
  _____
  _____
  _____
  _____

Please feel free to contact me (or have your advisor contact me) if you have questions or concerns.

Rebecca Penwell, PhD.
Chair, Institutional Review Board
Brenau University

CC: Student's Advisor: _____

APPENDIX I: IRB COMMITTEE PROJECT LOG

Brenau University
Institutional Review Board
IRB Project Log for Academic Year _____

Principle Investigator	Advisor/ Department or program	Title of Project	Method of receipt (electronic, paper) Date Received	Comments/ Concerns	Date approved