HUMAN SUBJECTS RESEARCH APPLICATION

Brenau University
Institutional Review Board
School of Health and Science

One Centennial Circle
Gainesville, Georgia 30501
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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** ☐

Francine Bride
Name of Principal Investigator

Soc. Sec. No. (if project is grant affiliated)

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Brenau Department AND Brenau e-mail address

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

**Signature of Principal Investigator

Dr. ☐ **Mr.** ☐ **Ms.** ☐

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

Jamie Empert
Name of Co-investigator(s)

Soc. Sec. No. (if project is grant affiliated)

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

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

Signature of Co-investigator (s)

Brenau Faculty Advisor: Dr. Mary Shotwell (**Name**) Occupational Therapy (**Dept.**) (**Building**) 770 543-6182 (**Phone No.**)

Soc. Sec. No.: (if grant affiliated)

****Signature:** **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: Validation of a Bone Safety Evaluation for Persons with Osteoporosis

Start Date: _____ ***(Must be 4-6 weeks after date of submission to IRB)***

End Date: _____ ***(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?).*

It is estimated that 10 million Americans have osteoporosis and 44 million are at risk to develop osteoporosis because they have low bone density (National Osteoporosis Foundation, 2004). Typically, doctors prescribe drug therapy for individuals with osteoporosis; however, statistics indicate that although drug therapy is becoming more widely used by physicians, many individuals with osteoporosis continue to remain untreated (Bailey & Majeed, 2002). The number of individuals receiving therapy for symptoms of osteoporosis, such as vertebral fractures or pain, is even smaller than those who are receiving drug therapy. According to the National Institute on Health (2000) Consensus Statement, "less than 5 percent of patients with osteoporotic fractures are referred for medical evaluation and treatment. Further, this consensus statement recommends that more aggressive diagnostic and therapeutic interventions with this population will prevent subsequent fractures"

The impact of osteoporosis on an individual's life can be far-reaching and may include physical, psychosocial, and financial declines. Lyles et al. (1993) have shown that individuals with osteoporosis report more difficulties performing activities of daily living than do individuals without osteoporosis. Hip fractures, which are common sequelae to osteoporosis, result in a 24% mortality rate within the first year after the fracture for individuals over age 50 (National Ostoeporosis Foundation, 2004). In addition to the physical declines experienced by individuals with osteoporotic fractures, research has shown that patients also report fear, anxiety, and depression as a result of their condition (National Institute on Health, 2000). Finally, it is estimated that hospitals and nursing homes expended $17 billion in 2001 to care for patients with osteoporotic fractures (National Osteoporosis Foundation, 2004).

Traditional osteoporosis therapy consists of providing individuals with drug therapy and general osteoporosis information. In addition to drugs, many rehabilitative programs treat the symptoms and risk factors of osteoporosis. These rehabilitation interventions include exercise, posture correction techniques, pain management, and education regarding body mechanics and fall prevention (Pfeifer et al., 2004). Therapy referrals for pain are more prevalent than prevention related therapy referrals despite the fact that "regular activity and muscle strengthening exercises have been shown to decrease vertebral fractures and back pain" (Old & Calvert, 2004). Despite evidence, many individuals with osteoporosis do not receive therapy to address risk for falls or fractures in order to prevent injury.

It is believed that many individuals with osteoporosis are often unaware of the negative effects that natural motions have upon bone safety. Several body functions, such as twisting and spine flexion, are required of an individual for performance of common daily activities; however, twisting and spine flexion may increase risk for fracture in individuals with osteoporosis because they have low bone density.

Based on a literature review, no evidence was found of any existing evaluation that addresses the relationship between physical functional performance and valued daily life activities for the osteoporosis population. Furthermore, no standardized tool has been developed to assess and subsequently individualize therapy needs relative to bone safety issues in the osteoporosis population. To meet this need, the Bone Safety Evaluation (BSE) was developed (S. Grant, personal communication, month, date, year). The purpose of this study is to determine the validity of the BSE Balance Domain as a tool to

assess functional motion in the osteoporosis population. The BSE will more accurately identify patients, whose functional movements put them at risk for falls and fractures, thereby allowing early intervention to prevent the sequelae of osteoporosis and potentially other disabling conditions. Providing this tool will support clinicians in their quest for evidence-based practice.

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*.

In order to establish validity of this new tool, participants' performance on the balance and coordination domain of the BSE will be compared with their performance on the Computerized Dynamic Posturography (CDP) and the Clinical Test of Sensory Integration and Balance (CTSIB), two well-known standardized balance measures. A Pearson Product-Moment Correlation Coefficient will be derived using SPSS.

This validation study is non-experimental because each participant will serve as his/her own control by completing all three assessments; therefore, there will be no random assignment to a control and experimental group. Participants will perform the three balance tests in random order.

3. **RESEARCH SUBJECTS:**

a. *List maximum number of subjects* 75-100*, targeted age range* >50 *(specified in years); targeted gender* 80% Women, 20% Men; *targeted ethnicity/ race* No specific ethnicity is targeted for this study; however, it is expected that the greatest percentage of participants will be caucasian due to the ethnicity of the population in North Georgia.

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

Participants will be recruited through use of radio advertising, flyers, and existing personal contacts. Flyers will be distributed at senior centers, churches, the United Osteoporosis Centers and other places that seniors frequent in the community. Interested participants will contact the representative at the United Osteoporosis Centers and will be screened to determine if they meet the eligibility criteria. If they meet the criteria for inclusion, they will be placed on the schedule for completing the BSE, CTSIB and CDP.

Inclusion Criteria

Over age 50

Diagnoses of osteoporosis (for ½ of the participants), other medical diagnoses will be allowed as long as they do not interfere with participation in the performance measures. Gender not critical, though it is anticipated that we will get more women to volunteer because osteoporosis affects more women than men.

Willing and able to participate in a one hour session where participants must stand, bend, and have their balance challenged.

Exclusion Criteria

Acute medical conditions that would prohibit a participant from standing, walking, bending, reaching, lifting, or having one's balance challenged will be excluded from this study.
Clients with moderate to severe cognitive impairment would likely not be able to follow directions and therefore would not be appropriate for this study

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: United Osteoporosis Centers
2*)* County and state: Hall County, GA
3) Country: USA
4) *Written letter of authorization (<u>on official letterhead only</u>)*/ IRB approval:
Attached: ☒
Pending: ☐

d. *Is there any working relationship between the researcher and the subjects*?
Yes☒ No☐, *If yes, explain*.
Some participants may be patients at the United Osteoporosis Centers and have an existing relationship with the creator of the BSE.

e. *Describe any incentives (payment, gifts, extra credit).*
<u>Extra credit cannot be offered unless there are equal non-research options available for research using students</u>
Performance results will be summarized and mailed to each participant free of charge. This will provide the individual with information regarding their fall risk and performance during functional activities.

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.*

Prior to initiation of balance testing, participants will complete a 7 item questionnaire that records if the individual is experiencing dizziness, vision or hearing problems, or has fallen recently. Participants will also complete a form collecting demographic and biographical information. Participants will then complete the BSE, the CTSIB and CDP. Tasks included in the BSE are as follows: Pour Task, Footwear Task, Newspaper Task, Reach-Lift Task, Sweep Task, Washer Task, Dryer Task, Sit to Floor Task, Carry-Climb Task, and Night Walk.

All participants will complete these three evaluations on the same day but in random order. The BSE and CTSIB are both standardized tests, therefore the researcher will administer specific instructions for each test following a standard protocol. During CDP testing, the individual stands on a moveable, dual forceplate support surface within a moveable surround (enclosure). Under control of a computer, the force platform can either move in a horizontal plane or rotate out of the horizontal plane. The researchers will administer the CDP tests following a standard protocol.

Duration of participation in the study: Each subject will only be required to participate in one 60 minute session. With participant approval, testing results will be summarized and mailed at a later date.

No. of testing/training sessions:__1__ Length of each session:_60 minutes

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*?
   All evaluations will be taking place in the controlled environment of a medical office. Individuals will be closely monitored and wearing a gait belt for safety during participation in this study. Individuals may experience physical discomfort when performing some of the functional tasks, but may decline to participate or continue at any time. Participants may also take rest breaks at any time they request. If evaluation results indicate that a participant is a fall risk, he or she may experience psychological distress upon learning this information. These participants will receive appropriate referral information. Evaluation results for individuals at risk for falling will be sent to their primary care physician for appropriate follow-up.
   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.*
   Participation in this study is voluntary. All data will be recorded and coded such that there is no identifying information. Any documents with participants' names and demographic information will be kept in a secure location. All information collected in this study will be kept strictly confidential and participants' names will not be published with the findings.

   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.
   With permission, some photographs of participants may be taken and used for inclusion in professional presentations and publications.
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*:
   Performance results will be summarized and mailed to each participant free of charge. This will provide the individual with information regarding their fall risk and performance during functional activities. If the individual is identified as a fall risk, this information may be beneficial for undertaking preventive measures.

   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.
Establishing the BSE as a valid tool will more accurately identify patients whose functional movements put them at risk for falls and fractures, thereby allowing early intervention to prevent the sequelae of osteoporosis. Providing this tool will support clinicians in their quest for evidence-based practice.

8. **CONSENT PROCESS:**

a. *Detail how informed consent will be obtained from all research participants and, when applicable, from parent(s) or guardian(s).*
Individuals will sign the informed consent document prior to participation in this study.
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.
Despite the fact that there will be elderly participants in this study, they will not be frail, medically fragile, or incompetent to authorize consent. All participants will sign the informed consent document prior to participation.

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 ☒