IRB FORM B shall be used if there is more than minimal risk associated with the research (i.e. none of the categories on page 2 of IRB FORM A apply) or if the research utilizes a special population (children, prisoners, institutionalized individuals, etc.).

**Basic Protocol Information**

**Project Title:** Effect of Wii Fit Plus Intervention on Fall Risk in Well-Elderly

**Principal Investigator**

Name: [redacted]
Title: Occupational Therapy Student
Department: College of Nursing and Health Profession: Occupational Therapy Program
Email: [redacted]
Phone: [redacted]

Role at USI:
☐ Faculty  ☐ Staff  ☑ Undergraduate Student  ☑ Graduate Student  ☐ Other - specify:

If there are additional Investigators, please fill out the USI IRB Protocol Co-Investigator Information form found in the IRBNet Library.

**Students only -- Name of Faculty Sponsor:** [redacted]

**EXPECTED DATES OF RESEARCH**

Start (month/date/year): August 28, 2013
End (month/date/year): December 1, 2013

**HUMAN SUBJECTS RESEARCH TRAINING**

**CITI Training**

Reference number: #10105950
Date completed: April 3, 2013

*Collaborative Institution Training Initiative (CITI) training must be completed prior to requesting a review of your IRB protocol. CITI (Collaborative Institution Training Initiative) training certification is good for 3 years. To complete the CITI training – go to [www.usi.edu/ospra](http://www.usi.edu/ospra)*

**DISSEMINATION OF RESULTS**

How are you intending to disseminate the results of the research? (Check all that apply)

☐ Journal article  ☒ Conference presentation  ☐ Academic white paper  ☐ Thesis / Dissertation

☐ USI course paper or presentation  ☐ Other - specify:

**FUNDING OF RESEARCH**

Is your research part of an external grant or contract?

☐ Yes → Attach copy of the grant application or contract  ☑ No
SECTION 1

REVIEW CATEGORY AND JUSTIFICATION

1a. Please read carefully the following categories and indicate which category or categories best describe your research by checking the appropriate box.

☐ Category 1 - Drugs or devices not needing investigational new drug or device exemptions

☐ Category 2 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

☐ Category 3 - Collection of biological specimens by noninvasive means (hair, saliva, sweat, nail clippings, etc.)

☒ Category 4 - Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples include weight, height, eye-color) and moderate exercise by healthy volunteers.

☐ Category 5 - Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ Category 6 – collection of data from voice, video, digital or image recordings made for research purposes (e.g. Investigation of speech defects)

☐ Category 7 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, that includes:
  i) Information obtained is recording in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
  ii) Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability or reputation;
  iii) The human subjects are elected or appointed public officials or candidates for public office; or
  iv) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1b. Please explain in layman terms why you believe your research protocol meet(s) the categories you selected:

It is a non-invasive procedure in which the researchers will obtain personal data such as age, gender, weight, height, and observed data. Researchers will also implement use of an assessment tool called the Berg Balance Scale in pre-test to establish a base-line in all participants. The researchers will implement a procedure using the Wii Fit balance board and Wii Fit Plus game for the Nintendo Wii console to work on standing balance in participants. Wii interventions have been used in clinical practice before. The games involved in the study will serve as a means for moderate exercise or activity to affect the Berg Balance Scale results. The Berg Balance Scale will also be used as a post-test to check for any changes in the participants’ performance.
SECTION 2

RESEARCH QUESTION AND DESIGN

2a. RESEARCH QUESTION

In layman terms, state the research question to be answered by this project.

What effect does a Wii Fit Plus intervention have on fall risk according to Berg Balance Scale scores in the well-elderly living in an assisted living facility?

2b. RESEARCH DESIGN

Provide a brief summary of the research design.

This study is a mixed method approach (combining both quantitative and qualitative data), quasi-experimental, pre/post test non-comparative pilot study implementing the use of Wii Fit Plus games focused on dynamic balance as an intervention. The study will examine the effects of the intervention on balance scoring according to the Berg Balance Scale in well elderly individuals (elderly individuals in good health with balance deficits). Qualitative questions will also be answered by the participants at the end of the interventions to acquire participants’ views of the Wii Fit Plus games and the study. The results of this study will be analyzed to check for improvement or decline in dynamic balance.

2c. USE OF SECONDARY DATA

Will you be using secondary data (i.e. data collected by someone else as part of medical or school records, information gathered from an existing database, or data that someone else has already collected via a survey, test, etc.)

☒ No
☐ Yes → Describe how the data was collected, the source of the data, and how you plan to use the data

**IF YOU ARE ONLY USING SECONDARY DATA FOR THE RESEARCH - SKIP TO PAGE 17:**

SECTION 7

CONFIDENTIALITY AND DATA SECURITY
SECTION 3
RESEARCH PROCEDURES

3. Describe in detail the research procedure below the following inclusion criteria.

If you are...
- Just observing participants, describe the setting.
- Asking participants to complete a survey, describe how you will distribute the survey. (Please attach the survey to this form)
- Interviewing participants, describe how you plan to interview the participants and the setting of the interviews. (Please attach the interview questions to this form).
- Audio or video recording participants, describe how the audio/video tapes will be used and how confidentiality will be maintained

Also include:
- Approximate dates and duration of research
- Approximate number of participants
- Total number of observations, surveys, interviews, visits, etc.
- Time commitment required per participant (ex. 10 minute interview x 3 interviews per participant)
- Location of research / data collection
- Explain participant withdrawal procedures (i.e. how a participant will allowed to stop out of the study)

Research Procedure:

During the fall 2013 semester, the participants will be assessed using the Berg Balance Scale for a pre-test score. Following this step, the researchers will implement an intervention using the Wii Fit balance board and Wii Fit Plus games that relate to balance. The participants will have a selection of Wii Fit Plus games that are focused on dynamic standing balance. Identifying or personal information will not be recorded in the Wii system and participants will use pre-made male or female characters to protect the contributor’s identity. Following the 6 week intervention, the participants will be reassessed for the Berg Balance Scale for a post-test.

The anticipated date for this study is to begin on August 28\textsuperscript{th}, 2013 and to conclude on December 1\textsuperscript{st}, 2013. There will be approximately 20 participants included in the study. The data will be collected from participants at West River Health Campus in Evansville, Indiana. Participants will be seen 2 times a week for a six week period starting August 28\textsuperscript{th}, 2013. The first and last session will include the pre-test and post-test for the Berg Balance Scale. The remaining 10 sessions will consist of Wii Fit Plus intervention. Each session will include 25-35 minutes of Wii Fit Plus intervention. Participants are able to withdraw from the study at any time.

To relate the study to occupational therapy, the researchers intend to provide further evidence of the Wii’s use in therapeutic activities. The goal of this research is to determine the effect of a Wii Fit Plus intervention of balance related to fall-risk. The primary focus in using the Wii Fit Plus games is to affect balance skills used in dynamic balance activities. Dynamic balance is a key factor in many areas of daily activities. With improved dynamic balance, the participant will become more independent in performing many areas of daily activities, such as self-care activities. Qualitative questions will be included after the post-test to determine the participants’ views of the intervention and the use of the Wii Fit Plus games.
SECTION 4
PARTICIPANTS

4a. TARGET POPULATION

Describe the participant group to be studied below the following inclusion criteria.

<table>
<thead>
<tr>
<th>Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Description of the group to be studied and why</td>
</tr>
<tr>
<td>• Description of the inclusion / exclusion criteria for participants.</td>
</tr>
<tr>
<td>o Include the rationale for the involvement of any special groups including children, prisoners, pregnant women, or subjects with cognitive impairments.</td>
</tr>
<tr>
<td>o Describe the characteristics of the targeted participants, including gender, age ranges, ethnic background, and health/treatment status.</td>
</tr>
<tr>
<td>o If women or minorities are excluded, provide justification.</td>
</tr>
<tr>
<td>o Give the number of participants you anticipate including from each targeted group listed above.</td>
</tr>
</tbody>
</table>

Participant Group:

The target population will consist of well-elderly adults living in the assisted living facility in West River Health Campus of Evansville, IN. The well-elderly population consists of individuals who are in generally good health and are able to perform basic activities of daily living. Basic activities of daily living include tasks related to self-care, such as self-feeding, bathing, dressing, and grooming. Individuals in the assisted living facility require help with instrumental activities of daily living, such as medication management, laundry, cooking, cleaning, and money management. There will be approximately 30 participants invited to the study and we anticipate at least 20 to accept and participate. The population is a sample of convenience. Inclusion criteria includes individuals who are considered well-elderly, must be English speaking, must be a resident of West River Health Campus assisted living facility, must complete the pre-test and post-test of the Berg Balance Scale, must complete 8 of the 10 intervention sessions, and must be cognitively competent to understand and sign the consent form. Exclusion criteria consists of individuals who require the use of a wheelchair for at least 80% of the day, have contradicting diagnoses that produce more than minimal risk in order to participate in the study, and/or primarily ambulate with the use of a wheelchair. Exclusion criteria regarding contradicting diagnoses will be left at the discretion of the West River Health Campus nursing staff and therapy department.

4b. RECRUITMENT PROCEDURES

Describe how you will recruit participants for the study below the following inclusion criteria.

<table>
<thead>
<tr>
<th>Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Describe participants will be recruited</td>
</tr>
<tr>
<td>• Describe how participants will be informed that their participation is voluntary</td>
</tr>
<tr>
<td>• Describe how participants can withdraw from the study</td>
</tr>
</tbody>
</table>

Recruitment:

For convenience, the participants will be recruited from the assisted living facility in West River Health Campus of Evansville, IN. The recruitment process will follow the attached recruitment script to assure consistency in the recruitment process between researchers, which can be referred to by both the participants and family members. The participants will also be informed that their participation is completely voluntary and that they
can drop out at any time. Participants will also be required to sign consent forms in order to participate. The participants can withdraw verbally from the study at any time by simply indicating their intent to a researcher.

4b.1 Will email, flyers, brochures, posters, letters, etc. be used to recruit participants?

☒ No
☐ Yes  ➔ Upload the email language, brochures, posters, letters, etc. on the Project Designer page on IRBNet that will be used to recruit participants.

4b.2 Will you give the participants any type of compensation (i.e. money, t-shirt, extra credit, etc.) for participation.

☒ No
☐ Yes  ➔ describe compensation

4c. RESEARCH SITE

Describe all sites where this research will take place.

The study will take place at West River Health Campus of Evansville, IN. West River Health Campus is a branch of the health care company; Trilogy, LLC. The building offers three separate sections which consist of the assisted living facility, the skilled nursing facility, and a memory care facility known as The Legacy. The facility offers adult day services, assisted living, memory care, long-term care, respite care, skilled nursing, short-term rehabilitation, and transitional care. The staffing for the facility offers physical, occupational, speech, and respiratory therapies; nursing staff; certified, registered, and qualified nursing assistants; dietary services; recreational staff; and environmental service assistants. The building has been open since 2009 and offers 133 beds throughout its three sections. The facility is also built around a central courtyard which offers a small miniature put-put green.

Upload documentation of permission from the appropriate source if the study involves participants from places other than common public spaces or at USI. (Must be on the study site letterhead)
SECTION 5
INFORMED CONSENT / ASSENT

5a. INFORMED CONSENT PROCEDURE

Describe how (oral or written) and when voluntary consent will be obtained from participants below the following inclusion criteria.

Include:
- Who will be responsible for obtaining consent from participants
- Who will be providing consent? (ex. The participant, a parent, guardian, etc.)

NOTE: If individually identifiable information such as images (video or photos), audio recordings, names or notable descriptions of participants will be published, shared or otherwise disseminated, the consent form must make this explicit to the participant.

Informed Consent Procedure:

The researchers are responsible for obtaining any and all forms related to informed consent from the participants. The consent form will be a typed document that will be issued to participants to notify them what the study entails, potential risks related to the study, and possible benefits. The participant must understand and sign the consent form prior to beginning the study.

5b. INFORMED CONSENT DOCUMENTS

Upload copies of all written consent forms and/or the script language for oral consent on IRBNet on the Project Designer page.

- Please use the consent templates available in the IRBNet Library or at http://www.usi.edu/ospra under Institutional Review Board

The informed consent document (written forms or script language for oral consent) must include:

- Title of study (Title should match the title listed on this form – if not, explain why)
- The purpose of the research
- A description of the research procedure
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Whether identifying information will be collected, and if so, how it will be kept confidential
- Benefits of the research to society and/or to the individual
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions about the study, their rights as research subjects or in the event of a research-related injury or emergency (PI, Faculty Sponsor (if applicable) or USI Office of Sponsored Projects & Research Administration 812-465-1630 rcr@usi.edu)
5c. Are the participants between the ages of 7 and 17?
☒ No → Skip to Section 6.
☐ Yes → Assent is required. Complete 5d. and 5e.

5d. INFORMED ASSENT PROCEDURE

Describe how (oral or written) and when voluntary assent will be obtained from participants who are between the ages of 7 and 17.

5d. INFORMED ASSENT DOCUMENTS

Upload copies of all written assent forms and/or the script language for oral assent on IRBNet on the Project Designer page.

- Please use the assent templates available in the IRBNet Library or at [http://www.usi.edu/ospra](http://www.usi.edu/ospra) under Institutional Review Board

The assent document (written forms or script language for oral consent) must include:

- Title of study (Title should match the title listed on this form – if not, explain why)
- The purpose of the research
- A description of the research procedure
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Whether identifying information will be collected, and if so, how it will be kept confidential
- Benefits of the research to society and/or to the individual
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions about the study, their rights as research subjects or in the event of a research-related injury or emergency (PI, Faculty Sponsor if applicable, or USI Office of Sponsored Projects & Research Administration 812-465-1630 rcr@usi.edu)
SECTION 6
POTENTIAL RISKS AND BENEFITS

6a. Describe any potential risks to participants (physical, psychological, social, legal, etc.) below the following inclusion criteria.

<table>
<thead>
<tr>
<th>Include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Description of risk</td>
</tr>
<tr>
<td>- Likelihood of risk</td>
</tr>
<tr>
<td>- Level of seriousness of risk</td>
</tr>
<tr>
<td>- Efforts / safeguards to minimize risk</td>
</tr>
<tr>
<td>- Justification for why risk is necessary for the research design</td>
</tr>
<tr>
<td>- Provision of medical or psychological resources for participants exposed to risks</td>
</tr>
</tbody>
</table>

Potential Risks:

Physical risk factors can include falling, dizziness, joint pain, and fatigue. Psychological risk factors can include fear of falling, anxiety, and frustration due to technology and/or inability to perform task well. The likelihood of risk is dependent on the individual. The risk is minimal, but safeguards such as the use of a secured gait belt to provide assistance and confidence. In addition to the gait belt, researchers will provide standby assistance as well as hands-on support as needed. In addition to the assistance level provided by the researchers, any adaptive equipment such as a walker or cane will be allowed to be used by the participant during the intervention to increase the level of safety for the participant. The facility also has a nursing staff. Resting and water breaks and the opportunity to decrease the difficulty of the Wii Fit Plus games will be offered as well. These risks are justified due to the nature of the study. These are all factors associated with balance deficits.

6b. Does the study design involve deception of participants?

☒ No
☐ Yes → Explain why deception is necessary and how participants will be debriefed about the deception after the completion of their participation in the study

6c. Describe how the results of this study will benefit society and/or the individual participant.

Benefits of this study are that it may provide further evidence of the benefits of Nintendo Wii Fit Plus games for intervention to improve balance. For the participants, the benefits may include improving balance, increasing social participation, decreasing fear of falling, and decreasing fall risk. The results could provide evidence for occupational therapists and other professions for future research.

6d What, if any, benefits will the participants receive from participating?

For the participants, the benefits may include improving balance, increasing social participation, decreasing fear of falling, and decreasing fall risk.
SECTION 7
CONFIDENTIALITY AND DATA SECURITY

7a. **Outline the specific steps that will be taken (i.e. during study participation, after study participation and with the publication of study results) to ensure the subject’s participation will be confidential.**

The names of the participants will be coded for confidentiality, and the data will be kept in a locked filing cabinet at the West River Health Campus. Data will be properly disposed after the content is no longer needed. There will be no identifying data that will be discussed about the participants in reporting the results. Any digital data recorded on the Wii will be deleted following the study.

7b. **Describe how and where the data will be kept so that the data remain confidential and secure.**

The data will be kept in a locked filing cabinet at the West River Health Campus. There will not be any identifying information included on the Wii gaming system nor documents.

7c. **List who will have access to the data.**

Only the researchers and the faculty sponsor will have access to the data.

**Attachments Included Check List (as appropriate):**
- ☒ List of additional investigators include name and contact information
- ☒ Data collection instruments (surveys, focus group guides, tests, observation guides, etc.)
- ☐ Research external funding proposal
- ☒ Informed consent and/or assent documents
- ☐ Recruitment flyers ads, letters, emails, etc.
- ☒ Approval / verification letters from sites where research will be conducted (if not on USI property)
- ☒ CITI Certification

**NOTE:** If you are a student, you are required to have your faculty adviser review and sign off on your IRB proposal package in IRBNet prior to submitting it for review. To do this, your faculty adviser must have an account on IRBNet (they may need to create one – just like you did). You will then need to share your IRBNet proposal package by granting your faculty advisor Read access to it in IRBNet. This will allow your faculty advisor to review documents and electronically sign the proposal package prior to submission.
Additional Investigators:

Co-Investigator
Name: [redacted]
Title: Occupational Therapy Student
Department: College of Nursing and Health Profession: Occupational Therapy Program
Email: [redacted]
Phone: [redacted]
Role at USI: Student

HUMAN SUBJECTS RESEARCH TRAINING
CITI Training
Reference number: 9782885 (See attached certificate)
Date completed: 02/19/13

Co-Investigator
Name: [redacted]
Title: Occupational Therapy Student
Department: College of Nursing and Health Profession: Occupational Therapy Program
Email: [redacted]
Phone: [redacted]
Role at USI: Student

HUMAN SUBJECTS RESEARCH TRAINING
CITI Training
Reference number: 9644164 (See attached certificate)
Date completed: 02/26/13

Co-Investigator
Name: [redacted]
Title: Occupational Therapy Student
Department: College of Nursing and Health Profession: Occupational Therapy Program
Email: [redacted]
Phone: [redacted]
Role at USI: Student

HUMAN SUBJECTS RESEARCH TRAINING
CITI Training
Reference number: 9844192 (See attached certificate)
Date completed: 02/26/13