



NEW YORK INSTITUTE OF TECHNOLOGY  
 Institutional Review Board for the Protection of Human Participants  
 Northern Blvd, Old Westbury, NY 11568  
 516-686-7738 ♦ <http://iris.nyit.edu/sponsoredprograms/>

### Application Checklist for Expedited or Full Review

The following checklist must be completed by the Principal Investigator with the submission of any expedited or full review protocol to the Institutional Review Board for the Protection of Human Participants.

Principal Investigator: Joanne Donoghue

Department: OMM

Protocol Title: Can a 6-minute walking or resting break improve executive function and gaming performance in competitive men and women gamers: A virtual protocol

|   | Attached                            | N/A                                 |
|---|-------------------------------------|-------------------------------------|
| Application Form (with <u>all</u> required signatures) .....                            | <input checked="" type="checkbox"/> |                                     |
| Attachment A .....  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Attachment B .....  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Attachment C .....  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Attachment D .....  | <input checked="" type="checkbox"/> |                                     |
| Abstract (limit 400 words) .....  | <input checked="" type="checkbox"/> |                                     |
| Protocol Description .....  | <input type="checkbox"/>            |                                     |
| Purpose .....   | <input checked="" type="checkbox"/> |                                     |
| Source(s) of Subjects and the Selection Criteria .....                                  | <input checked="" type="checkbox"/> |                                     |
| Procedures .....  | <input checked="" type="checkbox"/> |                                     |
| Assessment of Risks & Benefits .....  | <input checked="" type="checkbox"/> |                                     |
| Protection of Data/Privacy .....  | <input checked="" type="checkbox"/> |                                     |
| Debriefing Process .....  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Consent Procedures .....  | <input checked="" type="checkbox"/> |                                     |
| Investigator Background and other Relevant Information .....                            | <input checked="" type="checkbox"/> |                                     |
| Draft Consent Form .....  | <input checked="" type="checkbox"/> |                                     |
| Draft Assent Form .....   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Fliers/Advertisements/Announcements .....   | <input type="checkbox"/>            | <input type="checkbox"/>            |
| Surveys/Questionnaires .....  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Interview Questions .....   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Vitas of all Investigators .....  | <input checked="" type="checkbox"/> |                                     |
| Copy of Certificate of Completion of Online Training Module for all key personnel ..... | <input checked="" type="checkbox"/> |                                     |
| Authorization from Performance Sites .....  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |

**The application checklist, application form and protocol description, and additional materials should be submitted to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at the Office of Sponsored Programs and Research, North House, Second Floor.**

**NYIT Institutional Review Board for the Protection of Human Participants****APPLICATION FOR EXPEDITED OR FULL REVIEW**

- This form must be completed for all protocols that do not qualify for exemption. (To request an exemption, review the exempt categories carefully and submit the Request for Exemption form.)
- The Principal Investigator (PI) assumes responsibility for the conduct of the study. Students and non-NYIT personnel may not serve as principal investigators. The PI should complete sections I through IV of this form and attachments A, B, C or D as applicable.
- Submit the application checklist, application form and attachments and other materials as needed to the Education, Social Science and Behavioral Research (ESB) IRB or the Biomedical and Health Sciences (BHS) IRB at North House, Second Floor.

**Protocol title:** Can a 6-minute walking or resting break improve executive function and gaming performance in competitive men and women gamers: A virtual protocol

**I. PERSONNEL**

Principal Investigator: (Last) Donoghue (First) Joanne

Check one:  Faculty  Staff  Other \_\_\_\_\_

Department: OMM

Address (where you want notification sent): AHCC Riland Building

Telephone (Home): 516--686-3759 Campus: Old Westbury

E-mail: jdonoghu@nyit.edu

*If the project has additional investigators, including students, complete **ATTACHMENT A**.*

**II. PROTOCOL****1. Assessment of Risk**

Minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Moderate risk (minor increase over minimal risk)

Considerable risk (greater than minor increase over minimal risk)

Comments Regarding Risks: \_\_\_\_\_

**2. Type of Review**

*Indicate the type of review you are requesting. If you select expedited, check the number of the review category that best fits your research. **Final decisions about the appropriate level of review rest with the IRB.***

I am requesting an EXPEDITED REVIEW under category:  1  2  3  4  5  6  7  8  9

*Submit the original and three (3) copies of your application to the IRB.*

I am requesting a FULL REVIEW because my research does not fit precisely into any of the expedited review categories.

*Submit the original and fifteen (15) copies of your application to the IRB.*

*PLEASE NOTE: Applications that qualify for Expedited Review are reviewed on a rolling basis. Check the IRB web site for a listing of IRB meeting dates and application receipt deadlines for full review protocols.*

**3. Participant Information:** Will data be collected from any of the following populations?

Minors (Under 18 yrs of age; Specify age range) \_\_\_\_\_

Prisoners

Fetuses

Pregnant women

Cognitively impaired (including comatose)

Staff/Employees

Students

Non-English speakers

Poor/Uninsured

**4. Research Support:** Do you plan to or have you applied for funding for this project? Please review the sponsor's guidelines carefully and allow sufficient time for IRB review.

Yes Please provide the funding source: \_\_\_\_\_

Program/Grant Number (if Known): \_\_\_\_\_

*Please provide one (1) copy of the complete grant proposal or contract.*

No

Please check the following as appropriate:

The above-referenced sponsor intends to fund 100% of the costs associated with participant participation in the research protocol.

The above-referenced sponsor intends to fund 100% of the costs associated with participant care that is beyond regularly required care. Regular care will be billed to the participant or the participant's insurance.

The above-referenced sponsor intends to fund only a portion of the total costs associated with participant care. Explain fully in the protocol description.

**5. Financial Conflict of Interest:** Does the principal investigator, any co-investigator or study coordinator involved in the study (or in aggregate with his/her spouse, dependents or members of his/her household):

A. Have an equity interest in the entity that sponsors this research or the technology being evaluated that exceeds 5% ownership interest or a current value of \$10,000?

Yes

No

B. Receive salary, royalty, licensing fees, or other payments from the entity that sponsors this research or the technology being evaluated that is expected to exceed \$10,000 per year?

Yes

No

C. Have a license agreement with the University or an external entity that would entitle sharing the current or future commercial proceeds of the technology being evaluated?

Yes

No

*If yes to any of the above, please submit detailed information on a separate sheet.*

**6. Study site(s):**  NYIT-Central Islip

NYIT-Manhattan

NYIT-Old Westbury

NYITCOM

Other (Please specify): This study will be conducted virtually from the investigators private locations and the participant's private location.

Please provide letters of agreement and/or complete **ATTACHMENT B**.

7. If this proposal has been submitted to another Institutional Review Board, give the name of the institution and date of review. Supply copies of approval letters and recommendations of that committee.

Institution: None Date of review:          /          /         

8. **Timetable:** What is the estimated duration of the entire study?

Begin: 06 / 15 /2020 End: 6 / 1 /2021

9. **Participant time commitment.** What is the time commitment for each participant participating in the study? Indicate the number of visits/sessions and the time involved per visit/session.

Visits/Sessions: 4 Time per visit/session: 1<sup>st</sup> session- 20 min- sessions  
2,3,4- 2:30-3 hours

10. **Compensation.** If compensation to participants is intended, indicate how much and in what form (cash, taxi fare, meals, etc). The amount of compensation is subject to IRB approval.

Is any form of compensation being provided?

Yes Describe: We will be offering a drawing for one participant to win a Fitbit Versa Smart watch when they complete the study.

No

### III. PROTOCOL DESCRIPTION

Please respond to the following requests on a separate sheet.

1. State the purpose of the research. Include major hypotheses and research design. If the study is part of a larger study, briefly describe that larger study. Briefly discuss the background and rationale for the study. Is the study design appropriate to prove the hypothesis? Provide references for the background information. Please keep in mind that the IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts.

ESports is electronic gaming and is also referred to as pro-gaming or competitive video gaming. Guidelines for maintenance of health of eSports players and the cognitive changes that accompany competitive gaming are understudied. Additionally, the difference between genders in terms of these factors has not been examined in any paper found, to date. Executive functioning is an important cognitive skill for an eSports player. In our most recently submitted publication, we found that executive functions were changed after a session of eSports gaming, with increased reaction time, but decreased accuracy for inhibitory tasks and problem-solving tasks.<sup>1</sup> Previous findings from other researchers suggest a relationship between eSports players and executive function abilities.<sup>2</sup> Similar to our findings, in comparisons of certain aspects of executive function

(reaction time and inhibitory control) in First Person Shooter (FPS) vs. Multiple Online Battle Arenas' (MOBAs), one other study found that gamers who played FPS presented faster reaction times, but a lower control over inhibition than gamers who favored MOBAs.<sup>3</sup>

The relationship between executive functions and physical exercise has been well established.<sup>4,5</sup> However, the effects of prolonged sitting regardless of physical activity level has not been established. For example, prolonged uninterrupted sitting reduces cerebral blood flow.<sup>6,7</sup> Reduced cerebral blood flow is associated with lower cognitive function and fatigue.<sup>6-8</sup> This decrease in cerebral blood flow has been shown to be offset by frequent and short walking breaks anywhere between 30 minutes and 60 minutes. These short breaks can be as little as 2 minutes at 30 minutes, and 6 minutes following 60 minutes of prolonged sitting. The rationale is the increase in blood flow and the positive effects this has on metabolic responses.<sup>8</sup> The primary purpose of this study is to evaluate executive function changes following a 6-minute walking break to a 6 minute resting break in competitive esports players following 60-75 minutes of prolonged play. Additionally, sex differences between these changes will be examined.

2. Describe the source(s) of participants, the selection criteria and the recruitment methods. Selection of participants must be equitable and, in the case of protected populations such as children, prisoners, pregnant women, the mentally disabled, etc. should address their special needs. Provide a detailed description of the participant population including criteria for inclusion/exclusion, number of participants involved in the study, age, sex and health status. The text of any advertisement, letter, flier, oral script or brochure used to solicit potential participants **must be attached**.

### *Design*

The study is a randomized repeated measures design.

### *Setting*

The study will take place remotely on four separate days. This allows participants to utilize their computers while maintaining social distancing measures due to the COVID-19 pandemic. Research participants will be connected with researchers via Zoom, Google Hangouts, or other modalities of internet based video chatting.

### Sample

Subjects will be recruited online via groups and servers on Facebook, Twitter, Slack, Twitch, and Discord. Participants will be incentivized to partake in the study through an opportunity to be randomly selected to win a Fitbit™ Versa smart watch for participating.

**Inclusion criteria:** 1. Women or men 18-25 years of age 2. Play first-person shooter games with a ranking of “gold” or higher (self reported).

**Exclusion Criteria:** 1. Any participants that do not have a competitive ranking 2. Any participants that are colorblind (self reported) 3. Any participants that have sustained previous hand injuries within the last year, or suffer from chronic wrist pain.

3. Provide a detailed description of the procedures to be followed. If applicable, include a detailed description of all drugs to be used including dosages, dosage changes varying from manufacturers' recommendations, frequency of use, FDA status of a formerly approved drug being used for new therapies, IND# of all new drugs and all other drug information necessary. Include copies of questionnaires and/or interview protocols, or a sufficiently detailed description of the measures to allow the IRB to understand the nature of participants' involvement. Include a time line for the study.

Thirty participants (15 men and 15 women) will be recruited via social media websites.

From this pilot data a power analysis will be calculated.

### **Data Collection will be done over 4 separate days.**

Subjects will have one day of completing the consent form and conduct a practice test of the outcome measures to familiarize themselves. This will be followed by each participant completing three days of gaming that will entail one day of continuous play, one day a 6- minute walking break between minutes 60-75 of game play, and one day of a 6- minute resting break between minutes 60-75 of game play. The window for game play is to allow for the participants to complete any started video game during the gaming session. Dunstan et al.<sup>9</sup> demonstrated that breaking up

prolonged sitting with 2 minute light walking breaks every 20 minutes for 5 hours reduced glycemic and insulin responses. Carter et al.<sup>7</sup> demonstrated that light walking for 2 minutes following 30 minutes of prolonged sitting prevented a decline in cerebral blood flow. Breaking up an esports game every 20-30 minutes is not feasible nor reasonable, therefore we chose to break at 60- 75 minutes of play using the cumulative time of 6 minutes rather than the more frequent 2 minute breaks. Both studies demonstrated light walking to be just as effective as moderate walking.

Each session will be within one week of the prior testing day with a minimum of 72 hours between testing days. All participants will be required to play on the same PC device and not change any equipment they used in the previous session

### **Day 1**

An online consent form will be executed through REDcap a secure HIPPA compliant web application. Interested participants will be asked to fill out a demographic form and will be administered the International Physical Activity Questionnaire Long Version (PAQ-L). Instructions for a baseline completion of executive functions measures will be administered and completed prior within 2 days of testing for familiarization.

The order of the arms will be randomized using an online program, Research Randomizer <https://www.randomizer.org/>.

### **Days 2, 3, and 4**

Subjects will be asked to connect to a researcher before each study day via Google Hangouts, Zoom, Facetime or Duo. They will be asked to complete the executive functioning measures

before playing (administered through redcap via email). After completion of each testing day they will be asked to play games for 120 to 150 minutes. Upon completion of the last gaming session, all participants will complete a final short open-ended questionnaire focused on how the participants' perceived the 6- minute walk break, the resting break, and whether they feel it did or did not impact their gaming performance.

### **The Three Arms:**

**The walking intervention group:** The 6-minute walk will be conducted indoors at the location where the participant is playing. They will be asked to find a place that they are able to walk for 6 minutes on a flat surface back and forth or in a circle while holding the timer on their smart phone in their hand. Between 60-75 minutes of game play, they will be instructed to “get up and walk for 6 uninterrupted minutes”. Before this walk the participants will be shown the 6-20 BORG Rating of Perceived Exertion Scale (RPE) that will be held up by the investigators. This RPE is a validated scale to measure how hard a person feels they are working during physical activity and has been validated to correlate heart rate and perceived effort during active videogame play.<sup>10</sup>

**The silent rest intervention group:** Between 60-75 minutes of game play, they will be instructed to lie down in a pre-determined area that can be seen by the investigators and lie supine with their eyes open for 6 minutes. The eyes will remain open to stay consistent with the 6 minute walking intervention and to avoid the closed eyes as a confounding variable. Before this rest the participants will be shown the 6-20 BORG RPE scale that will be held up by the investigators. Following the 6-minute rest, participants will return to their gaming console to resume play. Investigators will collect RPE before game play continues.

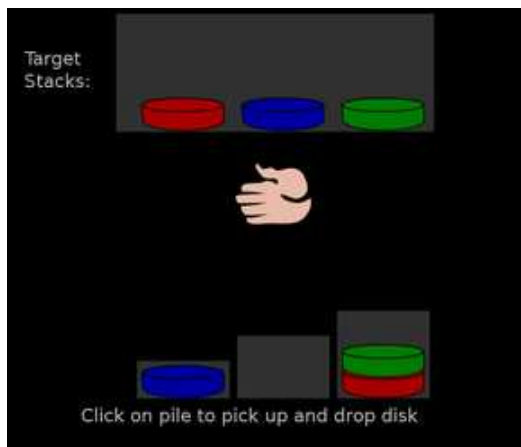


**The control session:** Subjects will be asked to complete the executive functioning measures before playing. After completion of the test, they will be asked to play games for 120 to 150 minutes.

Following the 120 to 150 hours of gameplay on all three testing days, the participants will be prompted to repeat the Stroop and Tower of London tests again. Number of FPS video game wins and losses will also be recorded.

### Outcome Measurements:

1. The Tower of London is a neuropsychological test to assess executive functioning and planning. The computer uses image of colored objects and relates them to classic problem solving puzzles.



2. Color Word Stroop with Keyboard (Stroop): The Stroop is based on the observation that individuals can read words much faster than they can identify and name colors. The cognitive dimension tapped by the Stroop is associated with cognitive flexibility, resistance to interference from outside stimuli, creativity, and psychopathology—all of which influence the individual's

ability to cope with cognitive stress and process complex input.<sup>11</sup> It measures cognitive processing and provides valuable diagnostic information on brain dysfunction and cognition. The test assesses the ability to inhibit cognitive interference by processing a stimulus feature at the same time as processing another attribute of the same stimulus. In the the most common version of the Stroop test, subjects are required to read three different tables as fast as they could. Two of the tables represented “congruous conditions,” where patients would be required to read names of colors printed in black ink and name different color patches, In the third table, the words were printed in different colors of ink (i.e. the word blue was in yellow ink), forcing participants to name the color of the ink instead of reading the word. This mechanism forces participants to engage in a less automated task (naming ink color), while also inhibiting the interference that comes from a more automated task (reading the word) therefore known as the Stroop effect. In present day, the Stroop test can be administered online through various softwares. The specific program we are using for the purposes of the study is Inquisit Lab, developed by Millisecond (Figure 2).

In the following trials you will see words presented in different colors. Your task is to indicate the **COLOR** in which each word is printed in while ignoring what the words actually say.

Indicate the color of the word by pressing either of the following keys:

- - d for **red** words
- - f for **green** words
- - j for **blue** words
- - k for **black** words

Example: if you see the word **RED** printed in the color GREEN press 'f' for green words regardless of the meaning of the word.

Try to respond as quickly and accurately as you can, because you will be timed. If an incorrect response is made, a red **X** will be flashed onto the screen.

Press [space] to continue

### Figure 2. Colored Stroop Test with Keyboard Responding by Inquisit Lab

The software mimics the paper version of the Stroop test, but also measures the time to reaction in milliseconds. This facilitates data collection because time to reaction is recorded, essentially distinguishing the automated task time. The test should take an estimated 3-5 minutes to complete

### 3. Borg Rating of Perceived Exertion

## Borg's Rating of Perceived Exertion (RPE) Scale

| Perceived Exertion Rating | Description of Exertion        |
|---------------------------|--------------------------------|
| 6                         | No exertion. Sitting & resting |
| 7                         | Extremely light                |
| 8                         |                                |
| 9                         | Very light                     |
| 10                        |                                |
| 11                        | Light                          |
| 12                        |                                |
| 13                        | Somewhat hard                  |
| 14                        |                                |
| 15                        | Hard                           |
| 16                        |                                |
| 17                        | Very hard                      |
| 18                        |                                |
| 19                        | Extremely hard                 |
| 20                        | Maximal exertion               |

4. Describe any potential harms or benefits to be derived by participants, with a discussion of the risk/benefit ratio. For approval of any study with more than minimal risk, the benefits must clearly be shown to outweigh the risk. Describe how the study may expose participants to stress, physical, psychological or interpersonal hazard, including the possibility of pain, injury, disease, discomfort, embarrassment, worry or anxiety. Discuss how risks will be minimized and additional safeguards for vulnerable subjects.

This study has no risk involved. The tests being administered can be terminated at any time if the subject wants to stop.

5. Describe the specific methods by which confidentiality or anonymity will be protected, including the use of data coding systems, how and where data will be stored and who will have access to it, and what will happen to data after the study has been completed.

Subject data will be coded on a master list in REDcap. When viewing, analyzing, discussing data, it will be done only in reference coded numbers, never using subject names.. Only

the principle investigator and co-investigators have access to this project in REDcap. We plan on submitting this study for publication.

6. If applicable, provide the following: 1) a description of the debriefing procedures to be used in cases where deception has occurred; 2) a statement describing what actions you will take should the research reveal the possibility of a medical or other potentially troubling condition.

No deception is included in the study.

7. Before submitting this application, all investigators should familiarize themselves with the discussion of informed consent. Describe the oral and written consent processes and attach all consent documents, including scripts for oral consent and assent forms. When the consent form to be used will be in a language other than English, an English translation must be provided. Use the Informed Consent Checklist (**ATTACHMENT D**) as a guide in drafting your consent form.

8. Please provide information about your background. You may attach a CV or resume for all investigators. CV's have been attached for all investigators.

#### IV. CERTIFICATION AND APPROVAL

By signing this document, I certify that in my opinion the protocol and safeguards described in this application meet the standards of the New York Institute of Technology (NYIT) and all Federal regulatory requirements concerning experiments that use human participants. I accept responsibility for assuring adherence to Federal and NYIT policies relative to the protection of the rights and welfare of participants in this study. I certify that my participation and the participation of any co-investigators does not violate the NYIT policy on conflicts of interest.

By signing below, I certify that I have undergone training in basic human participants protections and will ensure that all key personnel complete this training before working on this protocol.

**PI Signature** \_\_\_\_\_ / / \_\_\_\_\_  
**Department Chair** \_\_\_\_\_ / / \_\_\_\_\_

*If students will be involved in the project, complete **ATTACHMENT C**.*

**ATTACHMENT A:****ADDITIONAL INVESTIGATORS AND KEY PERSONNEL**

Fill out this section if additional investigators will work on this project. Attach additional pages as necessary.

**1. ADDITIONAL INVESTIGATOR/KEY PERSONNEL**

Check one:

Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) Ahmad \_\_\_\_\_ (First) \_\_\_\_\_ Sophia \_\_\_\_\_

Department: \_\_\_\_\_ OMS III \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: <sahmad11@nyit.edu> \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**2. ADDITIONAL INVESTIGATOR/KEY PERSONNEL**

Check one:

Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_ Yuen \_\_\_\_\_ (First) \_\_\_\_\_ Kyle \_\_\_\_\_

Department: \_\_\_\_\_ OMS III \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_\_\_ kyuen02@nyit.edu \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## 3. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_Hassan \_\_\_\_\_ (First) \_\_\_ Tamzid \_\_\_\_\_

Department: \_OMS III \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_ thassa03@nyit.edu \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

## 4. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_Bedell \_\_\_\_\_ (First) \_\_\_ Mariel \_\_\_\_\_

Department: \_OMS III \_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_ mbedell@nyit.edu \_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

## 5. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_Sousa\_\_\_\_\_ (First) \_\_\_Amber\_\_\_\_\_

Department: \_OMM\_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_asousa@nyit.edu\_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## 6. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_Douris\_\_\_\_\_ (First) \_\_\_Peter\_\_\_\_\_

Department: \_Physical Therapy\_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_pdouris@nyit.edu\_\_\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## 7. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

 Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_Jenny\_\_\_\_\_ (First) \_\_\_Seth\_\_\_\_\_



Department: \_ Department of Exercise and Rehabilitative Sciences, Slippery Rock University of Pennsylvania

Telephone #: \_\_\_\_\_ E-mail: \_\_\_seth.jenny@sru.edu\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

#### 8. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_ Gan \_\_\_\_\_ (First) \_\_\_Hillary\_\_\_\_\_

Department: \_OMS II\_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_hgan@nyit.edu\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

#### 9. ADDITIONAL INVESTIGATOR/KEY PERSONNEL

Check one:

Student  Faculty Staff  Other \_\_\_\_\_

Name: (Last) \_ Abraham \_\_\_\_\_ (First) \_\_\_Kenney\_\_\_\_\_

Department: \_OMS II\_\_\_\_\_

Telephone #: \_\_\_\_\_ E-mail: \_\_\_kabrah06@nyit.edu\_\_\_

By signing below, I certify that I have undergone training in basic human participants' protections and will conduct my work on this project according to established ethical principals and the protocol contained in this application.

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Department Chair: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**ATTACHMENT B:****RESOURCES**

The following consultants and service departments (e.g. Radiology, NYIT/NYCOM Academic Health Care Center [AHCC], Hospital Department, Medical Records, School Principal or Superintendent, Counseling Center Supervisor, etc), affected by elements of this protocol, have been consulted and agree to participate to the extent required by the protocol. Any protocol involving the NYIT/NYCOM Academic Health Care Center (AHCC), Old Westbury, and/or the NYIT/NYCOM Family Health Care Center (FHCC), Central Islip, must be reviewed by the Medical Director of the AHCC/FHCC. The investigator is responsible for submitting the protocol to the AHCC/FHCC Medical Director for his/her signature.

This project  does  does not involve the NYITCOM Academic Health Care Center (AHCC).

This project  does  does not involve the NYITCOM Family Health Care Center (FHCC).

**Service or Consultant** (Please print)

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Department/Organization: \_\_\_\_\_ Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

*Letters of agreement may be substituted for signatures here.*

**HIPAA Certification**

On April 14th, 2003, privacy regulations went into effect that regulate the access and handling of medical information. The investigator, not the IRB, is responsible for understanding and ensuring that the regulations are followed. If the protocol involves any unit of the Academic Health Care Center at NYIT/NYCOM, you must discuss the protocol with the compliance officer of NYIT/NYCOM, currently Nancy Bono, DO, in the Old Westbury Academic Health Care Center. If there is any doubt whether this applies, please discuss it with the HIPAA compliance officer. If the project involves medical records at any other institution, you must discuss your proposal with the compliance officer of that institution.

I certify that I have discussed my proposal involving medical records of any kind with the appropriate compliance officer, and understand and will comply with the requirements of HIPAA regulations.

PI Signature: \_\_\_\_\_ / \_\_\_\_ / \_\_\_\_

**ATTACHMENT C:****STUDENT PARTICIPATION IN RESEARCH****Principal Investigator**

I certify that I have instructed the student(s) listed below in research techniques and human protections standards; I have reviewed the entire research proposal, including any components composed by the student(s); any student role will be consistent with the description I provide in this proposal and in compliance with NYIT Human Protections Policies, to the best of my knowledge.

PI Signature: \_\_\_\_\_ Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Students**

I certify I am at least 18 years of age and that to the best of my understanding I will comply with the NYIT policies regarding Human Research Protections and will participate in research consistent with the descriptions in the submitted protocol

| Student Name (print/type) | Signature | Date               |
|---------------------------|-----------|--------------------|
| Sophia Ahmad              |           | ____ / ____ / ____ |
| Kyle Yuen                 |           | ____ / ____ / ____ |
| Tamzid Hassan             |           | ____ / ____ / ____ |
| Maribel Bedell            |           | ____ / ____ / ____ |
| Hillary Gan               |           | ____ / ____ / ____ |
| Abraham Kenney            |           | ____ / ____ / ____ |

**ATTACHMENT D:****INFORMED CONSENT CHECKLIST**

Please use this checklist to develop your informed consent form(s). Sample consent forms are available at <http://iris.nyit.edu/sponsoredprograms>. Submit **ONE** copy with your copies of the proposal and other forms.

Unless waived by the IRB, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant's legally authorized representative.

The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by Federal regulations (45CFR46.116). This form may be read to the participant or the participant's legally authorized representative. The investigator should give either the participant or the representative adequate opportunity to read it and ask questions before it is signed. Copies of the consent form should be given to the participant(s).
2. A short form written consent document, stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there should be a witness to the oral presentation. The IRB must approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness should sign both the short form and a copy of the summary, and the person obtaining consent should sign a copy of the summary. A copy of the summary should be given to the participant or the representative, in addition to a copy of the short form.

Please check one:

- I am requesting a waiver for documentation of informed consent.**  
*Complete Section 1 below*
- I have enclosed a draft informed consent form and assent form (if applicable).**  
*Complete Section 2 below.*

**Section 1:**

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

- 1). That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or
- 2). That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

- A. Does the research present more than minimal risk to the participants?
- Yes
- No
- B. Will a waiver adversely affect the rights and welfare of the participants?
- Yes
- No

- C. Can this research be practicably carried out without the waiver?  
 Yes  
 No
- D. Will participants be provided with additional pertinent information after participation?  
 Yes  
 No

**Section 2:**

Consent documents must be written in lay language at the 6<sup>th</sup> grade reading level and include the following required elements:

**Included**

- A statement that the study involves research and an explanation of the purposes of the research, the expected duration of the participant's participation, and a description of the procedures to be followed and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the participant
- A description of any benefits to the participant or to others, which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
- NA For research involving more than minimal risk, an explanation as to whether any compensation will be offered, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits, to which the participant is otherwise entitled
- Additional elements, as appropriate:

**Included    N/A**

- |                                     |                                     |  |
|-------------------------------------|-------------------------------------|--|
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent  |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | Any additional costs to the participant that may result from participation in the research   |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant  |
| <input checked="" type="checkbox"/> | <input type="checkbox"/>            | A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant  |
| <input type="checkbox"/>            | <input checked="" type="checkbox"/> | If minors are involved, an <b>assent</b> form  |

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