TOURO COLLEGE
HEALTH SCIENCES

Institutional Review Board for the Protection of Human Subjects (IRB)

Every application must be accompanied by proof of completion of the Collaborative Institutional Training Initiative course on working with human subjects. The course is free. Instructions for this mandatory instructional training can also be accessed at this link:
http://www1.touro.edu/shs/home/docs/MANDATORY_TRAINING_NEW.pdf

It is also requested that all researchers inform the committee when their research has been completed, and submit a copy of any paper or article which results from the study.

IRB applications should be sent to the IRB committee via email, to the current chair of the committee, Dr. Joseph Indelicato – HSIRB@touro.edu

If email is impractical, the forms should be mailed, in triplicate, to:

Touro College Health Sciences IRB
1700 Union Blvd.
Bay Shore, NY 11701

For questions and additional information, please call 631- 665-1600 ext. 6219.

Allow a minimum of THREE weeks for processing the forms (projects identified for expedited or exempt status may be faster). You may be asked to elaborate on or revise some portions of your submitted forms. When approval is granted, you, your advisor and your supervisor will get a letter to that effect.

You may NOT begin your project unless you have IRB approval.

If your project changes substantially after you receive IRB approval, you must resubmit it to the committee.

INSTRUCTIONS FOR FILLING OUT IRB PROPOSAL FORM

Items that are explained are in BOLD type.
Explanations are in italic type.

P.1:

Put your name next to the space for **Principal Investigator.**
Put the name of your advisor next to the space for **Research Advisor.**
Write the title of your research project next to the space for **Project Title.**

P.2 – Part A:
Application status:
The Federal government recognizes three levels of ethical reviews:

1. Full review – for studies involving invasive procedures or other medical or therapeutic interventions. The full committee has to review these projects, and annual recertifications are required.
2. Expedited review – for studies that do not involve invasive procedures or other medical or therapeutic interventions. These studies are reviewed by two members of the committee and require annual recertifications.
3. Exempt status – for surveys or studies that meet the Federal requirements listed below under Supplements.

While the committee would like researchers to identify their project's status, ONLY the committee can make the final determination. The committee will inform the researcher of the project status in a letter.

Concise Statement:
The description of the study should be **short and concise**, and should focus on the purpose and how human subjects will be used. More details will be provided later in the application.

Remember that most of the committee members are not members of your profession. Do not use professional jargon! Do not assume that others on the committee "should understand what you say." (For example, do not assume that an OT should understand PT terminology, since the professions are closely related). When in doubt, use simpler language or provide a list of terms with their definitions.

You are a professional – make sure to edit your application for spelling and grammar!!!

Pgs.3 to 7 - Part B: is self-explanatory.

P. 8 - Part C:
Please provide a typewritten response to these eight questions. **Please answer the questions using full sentences.**

Please address the following questions regarding your project. Answer as briefly as possible, but **provide sufficient detail**. Remember that some reviewers are not specialists in your field. Word your answer so that an educated layperson will be able to understand your study. Use a separate page(s) for each question.

Question 1. Who will the subjects be and how will they be selected?

You will need to address the following points:

- *a.* *Specify the pool from which the subjects will be selected and <u>how</u> they will be selected.*
  Whenever possible, avoid direct recruitment. The use of flyers is strongly recommended (For example, it is better to give a potential participant a flyer about the study that includes your contact information, than asking him/her directly)
- *b.* *If pertinent, include specifics regarding the person who will provide the pool.*
- *c.* *Detail the mechanism for access to the pool.*
- *d.* *Obtain the signed permission letter of the institution from which the subject pool is obtained.*
- *e.* *Identify criteria for selection.*
  e.g. age, sex, handedness
  If you will not have direct contact with potential participants (e.g., if you use a recruitment flyer), how will interested individuals let you know that they are interested in participation?
- *f.* *Identify criteria for exclusion.*
  a. *Who will make sure that potential participants meet the inclusion criteria?*
- *g.* *If the study involves more than one group of participants, how will the subjects be assigned to groups?*
- *h.* *Describe how you will communicate with the subject and obtain the consent form. Specifically, how will you ensure voluntary participation?*
- ***i.*** *Attach a copy of all the recruitment material, including flyers, inclusion criteria checklists, protocol of phone conversations, etc.* ***All recruitment material must include the College's name, the purpose of the study, and contact information for research advisor and the IRB office. For example, you may include the following statement at the bottom of your recruitment flyer:***

  If you have any questions about the study, you can also contact [enter advisor's name here], my/our research advisor, at [enter research advisor's phone number and email address here]. For questions about your rights as

a research participant, you may contact the Health Sciences Institutional Review Board for the Protection of Human Subjects (IRB), Touro College, Phone: 631-665-1600 ext. 6219 or HSIRB@touro.edu

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Question 2. Where will the research be performed? Who will be your <u>approved</u> supervisor?

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a. The location of the study has to be given.
b. Describe how the subjects will get to and from this location.
c. The exact environment should be specified.
e.g. private room or gym, time of day
Detail whether the subjects will be alone or in the presence of others.
d. If the project will be done in a Touro facility, such as a Research Lab, you must have a Touro faculty supervisor.
e. If the project will be done elsewhere, you must have authorization from the Director of your Department to use a supervisor in that facility. Attach a copy of the authorization.

Question 3. What precisely will be done with the subjects? Describe in reasonable detail. If a questionnaire will be used, please enclose a copy.

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a. If equipment is to be used, it must be described.
Use a picture, which may be from a catalog or a photograph, if necessary. This should include all identifying label details. The mode of application of the equipment and of any restraints must be given. Photographs are helpful here as well.
b. All time variables, frequency and number of sessions, the total duration of individual sessions and of the project have to be specified.
c. For example, if the project involves exercise, you must state the number of repetitions, sets, and weights used.
d. Are subjects going to be tested individually or simultaneously?
e. If a separate control group will be used, under what conditions will they participate?
f. Remember that if treatment is proved successful, it must be offered to the members of the control group once the study is completed. Address how you will ensure that this happens.

Question 4. How will subject anonymity and confidentiality be guaranteed?

No personal data should be shared with anyone without their consent.
In addition to specifying procedures for ensuring the privacy of the participants, you also must specify how and where you will store material related to the study, who will have access to this material, and how do you plan to protect information saved on a computer.
Please note that all study materials (e.g., filled out surveys, signed consent forms, etc.) must be kept for at least 3 years after the completion of the study. Please specify were will you keep this material and who will have access to it. Also specify how you plan to discard this material (for example, use a shredder).

Question 5. Will the project require subjects to be uninformed, misled or misinformed in any way? (e.g. sham treatment, placebo effects)

If yes, discuss the rationale for this approach and what measures are being taken to remove the deception at the earliest possible moment.

Question 6. In your judgment, will the project involve discomfort, stress or risk to the subject?

If yes, describe all risks. Discuss the rationale for the approach selected and what measures are being taken to minimize or remove the discomfort, stress or other risk. Remember discomfort also includes both physical and emotional stress your study might cause.

a. In a study where discomfort is expected, the subject must be warned to avoid any activity that would aggravate discomfort.
b. Include a copy of the list of specific precautions or instructions you will give to the subject.
c. What specific precautions will you be taking?

Question 7. If a written consent form will be obtained from the subjects, please attach a copy. If your project is a survey, please attach the cover letter and questionnaire. Generally, surveys will not require a separate consent form.

The following information must be included in the consent form or cover letter:

a. Full disclosure of who is doing the research and why.

e.g. Jane Doe, a physical therapy student at the Touro College, in partial fulfillment of the requirements for a Doctor of Physical Therapy degree.

b. *Location of the study.*

c. *Supervised by (on-site supervisor's name).*

d. *Rationale for the study.*

e. *Description of procedure, including number of sessions and duration of each session.*

f. *Statement of risks.*

g. *Liability disclosure.*

h. *Assurance of confidentiality.*

i. *Questions are to be addressed to: Give the name and phone number (and when available, email address) for the principal investigator, the faculty advisor. You must include* ***Touro College Health Sciences IRB, 1700 Union Blvd. Bay Shore, NY 11706, phone – 631-665-1600 x6219, and email: HSIRB@touro.edu***

j. *Assurance that the subject may withdraw at any time without any negative consequences.*

k. *Make sure the consent letter adequately addresses all items previously covered.*

l. *The consent form/cover letter should be written in language that can be understood by a layperson with an 8th grade education. Avoid using technical terms.*

m. *The consent form must be printed on your department's letterhead*

n. *Sample consent form is enclosed below, under Supplements.*

o. *Children ages 2-12 must provide a verbal assent. Explain how you intend to obtain this assent.*

p. *Children ages 12-17yrs.11mo. must provide a written assent. Attach a written assent form written in child-friendly language.*

q. *Parents to children 0-17yrs.11mo. must sign a permission letter. Remember that parents may give their children permission to participate in the study, but children still have a legal and ethical right to decline participation. The parental permission form and verbal and/or written assents must inform the participants of this. For example, the written assent should include the following statement:*
"Your parents gave their permission for you to be in the study, but you can choose not to be in it. It is OK to say no."

r. *The Committee recognizes that it may be difficult to obtain verbal consent from babies and toddlers. Researchers must identify strategies to ensure that the children are willing to participate in the study. For example, the researcher will stop all activities if the child cries.*

Question 8. What benefits may there be to the subject(s) and/or society?

It is not sufficient to say that you will receive a degree.

Refer to the hypothesis, the theoretical issue, the social dilemma and what part of society will benefit.
This is your opportunity to convince the committee that your study is needed, that it has the potential to make meaningful contribution to your field, and that the benefits outweigh the risks. Support your argument with literature and previous research findings.

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SUPPLEMENTS

(I) Federal Criteria for Expedited Review and Exempt Status:

Expedite review and exempt status can be requested for non-experimental projects and for projects which meet the following criteria:

Expedited Review requiring review of only two members of the committee will be allowed under the following circumstances as voted by the committee on February 1, 2008 based upon 45 CFR 46.110 and 21 CFR 56.110. The decision as to whether the study meets these criteria will be made by the SHS IRB chairperson or the vice chairperson.

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review - expedited or full - utilized by the IRB.

(F) Categories one (1) through seven (7) below pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric

solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(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. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

II. Sample Consent Form:

The Consent Form must be printed on your department's stationary

Title of Study
Name of researcher and contact information

You have been invited to take part in a study to learn more about [enter the purpose of study here]. This study will be conducted by [researchers' names and role, such as OT students], as part of [e.g., is this a part of degree requirements?]. The faculty sponsor is [enter the name of research advisor and department here, such as Dr. John X from the PT Dept.]

Participation in this study will include:

[Specify in detail what the participant will be required to do]

[If the study includes audiotaping and/or video taping add the following statement:] The study will involve audio recording and/or video recording. You may review the audiotapes and/or videotapes and request that information that includes your participation be modified or omitted.

Your participation will last [enter the exact time of the study. For example – one hour a week for 3 weeks].

Participation in this study may involve the following risks [list the risks. If there are no risks involved, include the following statement: There are no risks or hazards associated with participation in this study beyond those of everyday life.].

This research may result in [list the benefits of this study for the participant and in general].

Information obtained during this research is confidential, and will be used for the purpose of this study only. [If the study involves a group of participants that may be aware of each other's participation, for example a study that involves a focus group, include the following statement: Your information will be kept confidential by the researcher, but the researcher cannot guarantee that others in the group will do the same.] Your name or other identifying information will not be disclosed to anyone but the researcher. All

records will be kept locked and available only to the researcher, and will be destroyed 3 years after the study is completed.

Your participation in this study is voluntary and you can withdraw your consent to participate at any time without any negative consequences. Participation or non-participation in no way impacts your current employment or any services that you receive. [If the study includes interviews or surveys add the following statement: During interviews you can refuse to answer any question presented to you. You may also ask to stop the interview at any point.]

You can request a summary of the research findings from the researchers named above. If there is anything about the study or your participation that is unclear or that you do not understand, if you have any questions or concerns, or if you wish to report a research-related problem, you can call the researcher, [enter your name and contact information here]. You can also call the faculty sponsor, [enter your research advisor's name and contact information here]. For questions about your rights as a research participant, you can contact Touro College Health Sciences Institutional Review Board for the Protection of Human Subjects (IRB) at 1700 Union Blvd, Bay Shore, NY 11706. Tel: 631- 665-1600 ext 6219, or email: HSIRB@touro.edu.

You will receive a copy of this consent form to keep.

Participant Consent

Name of Participant _____

Signature of Participant _____ Date _____