**Approval for Human Subjects Research**

Office of Sponsored Programs and Research

Towson University

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Contents

[IRB POLICY 1](#_Toc394322641)

[IRB POLICY STATEMENT 2](#_Toc394322642)

[CATEGORIES OF IRB REVIEW: EXEMPT or EXPEDITED 2](#_Toc394322643)

[EXEMPT RESEARCH APPLICATION REVIEW 3](#_Toc394322644)

[EXPEDITED APPLICATION REVIEW 5](#_Toc394322645)

[INFORMED CONSENT 6](#_Toc394322646)

[INFORMED CONSENT FORM SAMPLE 1 7](#_Toc394322647)

[INFORMED CONSENT FORM SAMPLE 2: Minimal Risk Potential 7](#_Toc394322648)

[INFORMED CONSENT FORM SAMPLE 3: Parental Consent Letter 8](#_Toc394322649)

[INFORMED CONSENT FORM SAMPLE 4 9](#_Toc394322650)

[INFORMED CONSENT FORM CHECKLIST 11](#_Toc394322651)

[INSTRUCTIONS FOR FILLING OUT IRB APPLICATION FORM 12](#_Toc394322652)

[APPLICATION FOR APPROVAL OF HUMAN SUBJECTS RESEARCH 13](#_Toc394322653)

[Faculty Research Sponsor Agreement 17](#_Toc394322654)

[IRB APPLICATION CHECKLIST 18](#_Toc394322655)

# IRB POLICY

**Any research proposals from Towson University students, faculty or staff that involve human participants MUST BE REVIEWED AND APPROVED BY TOWSON UNIVERSITY'S INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS (IRB) BEFORE THE RESEARCH MAY BE INITIATED.** The request for approval should be submitted at least six weeks before the research is to begin or, if the Principal Investigator (PI)/Researcher is applying for external funding, before the agency's application deadline. The IRB will determine the classification of the research (exempt, expedited, or convened review). If the research is not considered "exempt" or eligible for "expedited review," it will be reviewed by the entire board and you will be asked to provide an additional eight (8) copies of the application. However, the IRB may request full review of any application. A research project may be disapproved only after review by the full IRB.

The application form should be completed and signed by the PI/researcher. If the PI is a student, the application must also be signed by the student's faculty sponsor to indicate approval of the project.

**If your research is to be performed at an institution other than Towson University, you should receive approval from that institution as well as from Towson University's IRB. Be sure to attach the approval from the off-campus institution to your TU application.**

Safeguarding the rights and welfare of persons participating as subjects in any research project involving Towson University personnel or students is considered an institutional obligation. Therefore, all research involving human participants, regardless of funding source or status of investigator (i.e., faculty, student or staff), must receive an approval or an exemption prior to initiation of the research. Approval will be based upon the determination that the rights and welfare of the participants will be adequately protected, that potential benefits outweigh any hazards, and that, when required, the informed consent of participants or their legally authorized representatives will be obtained.

**If you have any questions about the application, please contact the IRB office at (410) 704-2236 or irb@towson.edu.**

## IRB POLICY STATEMENT

The policies and procedures of the Institutional Review Board for the Protection of Human Participants are guided by the Federal Policy for the Protection of Human Participants, Notices and Rules, June 18, 1991, 56 FR 28001; the USM Policy on Human Participants in Research; and Towson University's Human Participant Assurance. Copies of these documents are available through the Office of Research Administration. In accordance with these regulations, the IRB defines "research" as any systematic investigation designed to develop or contribute to generalizable knowledge. Under this definition some research-like activity will not be subject to the review process, i.e., if it does not meet the definition of "research." For example, evaluation of a teaching or clinical method, if intended only as a means for the practitioner to make a personal decision about which methods to use, would not qualify as research. However, if the information is to be used for publication, presentation, or other research purposes, it would qualify as research. Also, some projects which are primarily for demonstration, service and training purposes may be considered to include research activities. Additionally, the University System of Maryland’s Policy on Human Participants in Research applies to all research activities and to development, training, and improvement or other related activities containing a research and development component.

# CATEGORIES OF IRB REVIEW: EXEMPT or EXPEDITED

The IRB will determine the classification of the research (exempt, expedited, or convened review). If the research is not considered "EXEMPT" or eligible for "EXPEDITED review," it will be reviewed by the entire board. Note, the IRB may request full review of any application.

**In your IRB application, you must indicate if you believe your research qualifies for exempt or expedited review by the IRB, and note the corresponding category that describes your research.** Please see below for a full description of EXEMPT and EXPEDITED Research Classifications.

### EXEMPT RESEARCH APPLICATION REVIEW

The regulations listed below are the exemption categories specified in 56 FR 28001 for research which involves little or no risk to research participants (see listing below). Responsibility for granting exemptions rests solely with the IRB. If the Principal Investigator believes the research qualifies for exempt status, he or she should so indicate on the application form. The application form must be completed in its entirety for a determination to be made concerning the "exempt" status. Research that is exempted under these categories does not require annual re-review unless new risks are discovered or the procedure changes.

#### Exemption categories (45 CFR 46.101(b))

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

 (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (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.

All research involving survey or interview procedures is exempt when the respondents are elected or appointed public officials or candidates for public office. Confidentiality must be maintained when required by federal statute.

 (3) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

 (4) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

 (5) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

 (6) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human participants may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

#### EXEMPT RESEARCH COVER LETTER CHECKLIST

**If you believe your research should have exempt status, you must include the following in a cover letter in lieu of the informed consent form. The cover letter must be printed ON TU DEPARTMENTAL LETTERHEAD and accompany the survey or questionnaire:**

1. A statement that participation is voluntary
2. A statement that what you are doing is research and the reason for such (i.e., classroom exercise, masters thesis, etc.)
3. A statement explaining the purpose of study--what you are investigating and why
4. A statement that the participants' responses will be kept confidential or anonymous; explain if a participant's name is to be reported or disclosed
5. A statement that participants do not have to answer every question
6. **If students**, a statement that their class standing will not be affected if they participate or choose not to participate, and if they are on a sports team, a statement that their status will not be affected and the coach will not receive individual scores/responses. **If employees** (of a school system, teachers, for example; of a clinic, of a business, etc.), a statement that their employment status will not be affected by their decision to participate or not to participate.
7. The names and telephone numbers of the PI, faculty sponsor (if PI is a student), and Chairperson of the IRB (Dr. Elizabeth Katz, 704-2236). These names will serve contact sources should a participant have any questions or concerns about the research.
8. Statement that the research was reviewed by the TU IRB.

#### EXEMPT RESEARCH COVER LETTER TEMPLATE

Sample cover letter for EXEMPT research - **TO BE PRINTED ON DEPARTMENTAL LETTERHEAD**.

January 1, 2010

Dear Participant,

My name is April M. Joon and I am a graduate student in the Department of Health Sciences at Towson University. As part of the research for my master’s thesis, I will be conducting a survey to determine whether or not educational health materials affect behavior. Participation in this study is voluntary. If you choose to participate in my project, you will be asked to complete a short survey. It is not necessary to answer every question, and you may discontinue your participation in the project at any time. Your decision whether or not to participate in the project or to withdraw from the project at any time will in no way affect your employment status. Your supervisor has given me permission to conduct my study at your workplace; she will not know whether or not you have participated, or, if you did, how you responded.

If you do choose to participate in the study, your participation will be completely anonymous. Neither anyone reading the results of the survey nor I will be able to identify you. Please do not put your name or any other identifying marks on the survey form.

If you have any questions about the project, you may contact me at (410) 555-8686, my faculty advisor, Dr. Helth E. Habitz at (410) 704-1111, or the Chairperson of Towson University’s Institutional Review Board for the Protection of Human Participants, Dr. Elizabeth Katz, at (410) 704-2236. A copy of the results of the survey, reported in aggregate form, will be available to you upon completion of my project, if you would like to see it. Copies will be forwarded to your employee lounge, where you may pick them up.

Thank you for your time.

Sincerely,

April M. Joon

Graduate Student

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY.

### EXPEDITED APPLICATION REVIEW

Certain research activities involving no more than minimal risk and in which human participants are involved in special ways are approved by Federal guidelines (46 FR 8392 and 56 FR 28001) for "expedited review." In such cases, only the IRB chairperson or one or more reviewers designated by the chairperson from among members of the IRB need evaluate the proposal which, if approved, is then forwarded to the entire Board for information and records-keeping. The individual reviewer may not disapprove a project, but must refer it to the entire Board if questions exist. If the Principal Investigator believes that the research qualifies for "expedited review," this should be noted on the application form. In such instances, the entire application form must be completed, and requirements for annual review, informed consent, and 36-month retention of records apply. The categories acceptable for expedited review are listed below.

**Research categories acceptable for expedited review:**

1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicated a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from participants 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body at a distance and do not involve input of matter or significant amount of energy into the participant or an invasion of the participant's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from participants 18 years of age or older and who are in good health and not pregnant.
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate\* participants' behavior and the research will not involve stress to participants.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

*\*"Manipulate" as interpreted by the IRB is any intervention.*

# INFORMED CONSENT

All PIs conducting research projects that involve Towson University staff, faculty and/or students and that are not given "exempt" status (see definition of exempt, page 4 of the policies document and page 8 of this document) must obtain and document the informed consent of each person who is participating in the research. PIs doing research that involves children must obtain and document the assent (affirmative agreement) of the child as well as the consent of one parent if there is minimal risk and both parents if there is more than minimal risk to the child. Assent and consent must be documented on an "Informed Consent Form" even if the research is determined to have "exempt" status. An "Informed Consent Form" (see sample informed consent forms ) should be developed/prepared by the Principal Investigator for his/her research project, submitted to the IRB with the application for approval form, and approved by the IRB before the research is initiated.

**The informed consent form consists of three major parts:**

1) a description of the research project;

2) a description of the methodology - what is expected of the participant and what the

participant can expect from the research experience; and

3) assurances.

**Under part 3 above (assurances) the applicant should include:**

1) a statement that the data is confidential and a description of the procedures to be

employed in maintaining that confidentiality;

2) a statement that participation is voluntary;

3) a statement that the participant is free to withdraw his/her consent at any time prior to

or during the experiment and that the decision whether or not to participate or to

withdraw will in no way affect the participant's status (as an employee, student,

patient, member of a team, etc.);

4) an offer to answer any questions;

5) the name and telephone number of the PI, the name and phone number of the faculty

sponsor (if applicable), and the name and the phone number of the Chairperson of the IRB should any questions arise later; and

6) lines for the date of signing and for the signature of the participant..

The PI should sign two copies of the consent form and keep one copy, with the other remaining with the participant. This form should be read out loud to the participant(s) or the participant's(s') legally authorized representative(s) at the same time as the participant(s) or representative(s) reads the form silently. The participant(s) or representative(s) should have adequate time to read and understand the entire form, and an opportunity to ask questions about the form and the study before signing.

An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence (i.e., there should be no extra credit for participation by students, and there should not be any mention of sanctions). No exculpatory\*\* language may be used anywhere in the form.

If the validity of the research will be compromised by a complete explanation of the research, incomplete disclosure is permissible only if in the IRB's judgment: 1) incomplete disclosure is truly necessary to accomplish the goals of the research; 2) there are no undisclosed risks to participants that are more than minimal risk; and 3) there is an adequate plan for debriefing participants, when appropriate, and a dissemination of research results to them. Information /about risks should never be withheld for the purpose of soliciting the cooperation of participants, and truthful answers should always be given to direct questions about the research.

Sample Informed Consent Forms are attached for the PI's/researcher's reference and use but they should only be used as a guide. The IRB Chairperson's name and telephone number should be included on the informed consent form as a contact point.

\*\*"*Exculpatory language" is defined as language that would imply that the investigator is being released from responsibility for any adverse effects caused by the study.*

## INFORMED CONSENT FORM SAMPLE 1

INFORMED CONSENT FORM

The Counseling Center is carrying out research on the various ways of controlling anxiety. We are attempting to determine whether a new biofeedback procedure will work in relieving test anxiety in college freshmen. While we know this procedure is effective with underachieving high school students, it has never been tried on college age students. Your role in this project will consist of attending six one-hour experimental sessions spaced approximately one week apart. Eventually this data will be used to improve the counseling program at Towson University.

At these experimental sessions, you will be introduced to a biofeedback relaxation procedure by a staff member who is experienced in this technique. The session itself consists of learning to relax by using a device that tells you how tense or relaxed your muscles are. When this device is connected, it will make clicking sounds. Your job is to sit back, relax, and by relaxing try to make the clicking sounds decrease in frequency. There are no known risks or discomforts associated with this procedure. We have reason to believe that this method may be of significant value in treating test anxiety. However, should you decide not to participate in this project, you will still be eligible for all the regular counseling services.

Participation in this study is voluntary. All information will remain strictly confidential. Although the descriptions and findings may be published, at no time will your name be used. You are at liberty to withdraw your consent to the experiment and discontinue participation at any time without prejudice. If you have any questions after today, please feel free to call 704-1234 and ask for Dr. Smith, or contact Dr. Elizabeth Katz, Chairperson of the Institutional Review Board for the Protection of Human Participants at Towson University at (410) 704-2236.

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I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,affirm that I have read and understood the above statement and have had all of my questions answered.

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

Witness: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY.

\*\*If investigator is not the person who will witness participant's signature, then the person administering the informed consent should write his/her name and title on the "witness" line.

## INFORMED CONSENT FORM SAMPLE 2: Minimal Risk Potential

INFORMED CONSENT FORM

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to participate in a study entitled "Occupational Skills Therapy," which is being conducted by Prof. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ of the Occupational Therapy Department, Towson University. This research project is a six-week live-in program designed to help severely physically disabled persons acquire adaptive skills. The purpose of this study is to evaluate the effectiveness of this program. The project directors hope to use the information obtained from this study to modify this program so that it will better serve physically disabled persons.

As a participant, I understand that my involvement in the GBMC Physically Disabled Program will be coincident with my participation in this research project.

I understand that periodically (2-4 times) I will be expected to participate in a number of experimental tasks including the completion of forms, checklists, and questionnaires relating to my knowledge, attitudes, and behavior, and the occasional observation of my activities. These instruments may include behavioral logs or diaries, attitudinal surveys, activity checklists, and information quizzes. In addition, I have been told that I may be asked to participate further in this research several months after my involvement in the Physically Disabled Program is ended. If I am asked to continue participation, I will be told exactly what further participation will entail.

I have been informed that any information obtained in this study will be recorded with a code number that will allow Prof. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to determine my identity. At the conclusion of this study the key that relates my name with my assigned code number will be destroyed. Under this condition, I agree that any information obtained from this research may be used in any way thought best for publication or education, provided that I am in no way identified and my name is not used.

I understand that there is no personal risk or discomfort directly involved with this research, that my participation is voluntary, and that I am free to withdraw my consent and discontinue participation in this study at any time. A decision to withdraw from the study will not affect the services available to me from Towson or my participation in the GBMC Physically Disabled Program.

If I have any questions or problems that arise in connection with my participation in this study, I should contact Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, the project director at 323-1010, extension \_\_\_\_\_\_\_\_ (work) or \_\_\_\_\_\_\_\_\_\_ (home) or Dr. Elizabeth Katz, Chairperson of the Institutional Review Board for the Protection of Human Participants at Towson University at (410) 704-2236.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Date) (Signature of Participant)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Date) (Investigator)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Date) (Witness)\*\*

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY.

\*\*If investigator is not the person who will witness participant's signature, then the person administering the informed consent should write his/her name and title on the "witness" line.

## INFORMED CONSENT FORM SAMPLE 3: Parental Consent Letter

 INFORMED CONSENT FORM:

Dear Parents:

I will be conducting a research project designed to study how children think and develop strategies in games. I request permission for your child to participate. The study consists of two twenty-minute sessions in which children will play tic-tac-toe on one day and a guessing game on another. The goals of the study are to detail the strategies of game-playing used by children of different ages, and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity, and will accompany me only if he or she is willing to do so. Children usually enjoy games, so I expect that they will be interested and enthusiastic about participating; however, any child who expresses a desire to return to the classroom will be escorted back immediately. Interviews will be conducted by me and videotaped by my research assistant. Children's responses will be reported as group results only. Individual taped responses will be used as examples of scoring procedures; however, the children will not be identified by name. Videotapes will be retained by me at the study's conclusion. These tapes may be viewed by the child's teachers, and some may be shown to groups when the study is presented to students, teachers and at professional conferences. To preserve confidentiality, only first names will be used to identify children. In addition to game participation, I will need to look at the school's records in order to obtain your child's birth date and mathematics scores on the Iowa Tests of Basic Skills.

Your decision whether or not to allow your child to participate will in no way affect your child's standing in his or her class/school. At the conclusion of the study, a summary of group results will be made available to all interested parents and teachers. Should you have any questions or desire further information, please call me at 410 704-1234, or you may contact Dr. Elizabeth Katz, Chairperson of the Institutional Review Board for the Protection of Human Participants, at (410) 704-2236. Thank you in advance for your cooperation and support.

Sincerely,

John Doe, Assistant Professor

Department of Education

Towson University

Please indicate whether or not you wish to have your child participate in this project, by checking a statement below and returning this letter to your child's teacher as quickly as possible.

\_\_\_\_\_ I grant permission for my child, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to participate in this project.

\_\_\_\_\_ I do not grant permission for my child,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to participate in this project.

\_\_\_\_\_ Affirmative agreement of child\*\*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Parent/Guardian's signature Date

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY (PHONE: 410-704-2236).

## INFORMED CONSENT FORM SAMPLE 4-With Headings

INFORMED CONSENT FORM

PRINCIPAL INVESTIGATOR:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PHONE: \_\_\_\_\_\_\_\_\_\_\_\_

Purpose of the Study:

This study is designed to evaluate the level of stress, burden, and depression of a caregiver for patients presenting for Comprehensive Geriatric Assessment at the Geriatric Team Service. The physical and emotional effects of caregiving for frail elderly on the participants will be assessed prior to and one month following the Comprehensive Geriatric Assessment of the patient.

Procedures:

Participants will be given a questionnaire twice by a trained interviewer. The interview will take place in the Hoffer Clinic at the same time as the patient is given the Comprehensive Geriatric Assessment. The interview will take no more than 45 minutes. The verbal questionnaire contains items on marital, educational, and living status, current physical and emotional health status, ability to perform usual activities as well as some additional questions regarding caregiving: specific caregiving activities performed, who helped perform these activities, time spent on caregiving, and the effect of your level of stress, burden, and depression.

Risks/Discomfort:

There are no known risks associated with participation in the study. Should the interview become distressing to you, it will be terminated immediately.

Benefits:

It is hoped that the results of this study will have beneficial effects to identify whether the information gathered and the recommendations provided to you at the time the patient receiving a Comprehensive Geriatric Assessment reduces your burden, stress, and depression.

Alternatives to Participation:

Participation in this study is voluntary. You are free to withdraw or discontinue participation at any time. Refusal to participate in this study will in no way affect the Comprehensive Geriatric Assessment or the treatment or services received by the patient.

Cost Compensation:

Participation in this study will involve no costs or payments to you.

Confidentiality:

All information collected during the study period will be kept strictly confidential. You will be identified through identification numbers. No publications or reports from this project will include identifying information on any participant. If you agree to join this study, please sign your name below.

\_\_\_\_\_ I have read and understood the information on this form.

\_\_\_\_\_ I have had the information on this form explained to me.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject's Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness to Consent Procedures Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

If you have any questions regarding this study please contact Dr. Smyth of the Hoffer Clinic at (301) 468-5924 or the Institutional Review Board Chairperson, Dr. Elizabeth Katz, Office of University Research Services, 8000 York Road, Towson University, Towson, Maryland 21252; phone (410) 704-2236.

THIS PROJECT HAS BEEN REVIEWED BY THE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS AT TOWSON UNIVERSITY.

\*\*If investigator is not the person who will witness participant's signature, then the person administering the informed consent should write his/her name and title on the "witness" line.

**INFORMED CONSENT FORM CHECKLIST**

(**Does not need to be submitted)**

Does the consent form include the 8 required elements of informed consent? (45 CFR 46.116)

1. Research

\_\_\_ Statement that the study is research

\_\_\_ Who is doing the research

\_\_\_ The purpose of the study

\_\_\_ List and describe the procedures to be followed

\_\_\_ Anticipated duration of the participant’s participation

\_\_\_ If appropriate, state the condition(s) of participation, if any

1. Risk, discomforts

\_\_\_ State the possible hazards, inconveniences, and risks the participant will undergo

\_\_\_ If appropriate, state the procedure may involve unforeseeable risks

\_\_\_ If appropriate, state that any significant new findings affecting risk will be reported to the participants

\_\_\_ If appropriate, state circumstances under which the participant’s participation may be terminated

\_\_\_ If appropriate, state any additional costs to the subject that may result from participation

1. Benefits

\_\_\_ State the benefits to the participant or to others that might be expected from the research

1. Alternatives to participation

\_\_\_ If the experiment is therapeutically related, disclose the alternate procedures the participant may choose

1. Confidentiality

\_\_\_ Contain a statement of the extent to which the confidentiality of the data will be maintained

\_\_\_ If appropriate, describe the procedures to be employed in maintaining confidentiality

1. Compensation for injury (If appropriate)

\_\_\_ For research involving more than minimal risk, an explanation as to whether any compensation, 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

1. Whom to contact

\_\_\_ Include the name, address and telephone number of the investigator, the investigator's faculty sponsor (for student applicants), and the chairperson of the IRB

\_\_\_ Instructions as to who and how to contact someone if questions or problems should arise later on

1. Right to refuse, or withdraw without penalty

\_\_\_ Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

\_\_\_ If appropriate, specify the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

\_\_\_ Is the consent form absent any exculpatory language?

\*\*"Exculpatory language" is defined as language that would imply that the investigator is being released from responsibility for any adverse effects caused by the study.

\_\_\_ Include appropriate signature and date lines (participant, investigator, witness (if required))

\_\_\_ Include a statement that research was reviewed and approved by the Towson University IRB.

# INSTRUCTIONS FOR FILLING OUT IRB APPLICATION FORM

**PLEASE SUBMIT THE APPLICATION FORM AND ALL ACCOMPANYING MATERIALS TO:**

Office of Sponsored Programs and Research

Towson University

8000 York Road; Towson, MD 21252

Phone: (410) 704-2236; Fax: (410) 704-449; Email: irb@towson.edu

Question/Item Number:

1. Principal Investigator Signature: All applications must be signed by the person completing this form. This will verify that all information is true and correct to the best of the PI's knowledge.

2. Faculty Sponsor Signature: No student application will be considered unless the student's faculty sponsor has signed the attached Faculty Research Sponsor Agreement form, indicating approval.

Purpose: Please indicate if this is a class requirement. If this is a master's thesis, not being done through a class, please indicate.

3. If this research has previously been considered by the IRB, please indicate the name of the original PI so the previous application can be located.

6. You must indicate the research classification and category that describes your research, exempt or expedited and indicate the corresponding category (see research classifications on page 3 and 5 of this packet). **The PI may not select both exempt and expedited categories of review.**

8. Outline what will be expected of the participant.

9. Please indicate if the participants will be solicited from classes. If they are, how will you ensure that there is no coercion for them to participate? If they are a protected population (i.e. nursing home residents, children, etc.), also indicate what role the staff will play in selection.  **If participants are solicited from another institution, the director of that institution should write a letter giving approval for your study. You should attach this letter to your application. In the case of schools, you generally need approval from the principal(s), the teacher(s) involved, and the superintendent(s) of the school system(s) or the authorizing system official.** If the study is to be conducted by someone other than the PI, you should also attach written permission from that person to your application.

10. Consider whether your research may cause discomfort to the participants in any way and indicate such. Risk may include boredom from completing questionnaires, and loss of confidentiality.

11. Any study that could uncover illegal acts, affect a prospective participant's employability or financial standing, or that asks sensitive questions of an embarrassing nature should be conducted anonymously. **At no point should anyone be able to identify the participant by his/her data**. How will this be ensured? If there is an anonymous pre/post-test, the participant should select a code number which is unknown to the PI.

13. Only in unusual circumstances should individual results or scores be given to participants. Each participant should be able to get a copy of the overall results of the study. If any information was not disclosed to the participant before participation, it must be disclosed at the debriefing with an explanation as to why he/she was not informed previously.

15. Do not destroy original data for at least three years.

# APPLICATION FOR APPROVAL OF HUMAN SUBJECTS RESEARCH

**Please type, hand written applications are not accepted.**

This form must be completed by the Principal Investigator/Researcher for any research project that involves human participants. Submit the following items with your completed application:

* Informed consent form(s) or Exempt Research Cover Letter **(please refer to pages 4-10 for instructions)**
* All materials, including any survey questionnaires, or instruments, to be used;
* And copies of any fliers, advertisements, or announcements that will be used to solicit participants.

1. Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Investigator’s Affiliation with Towson University (Please check one):

Faculty \_\_\_ Staff \_\_\_ Student \_\_\_ Outside Principle Investigator \_\_\_

Principal Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Research:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Period of Research (start and end dates) Start \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_End \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**NOTE: NO CONTACT WITH HUMAN PARTICIPANTS MAY OCCUR UNTIL THIS APPLICATION HAS BEEN APPROVED BY THE TU IRB. YOU WILL RECEIVE A NOTICE OF APPROVAL FROM THE IRB WHEN THIS OCCURS.**

Institution & Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address to which approval should be sent:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Applicant’s Day Time Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Applicant’s E-mail Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-Investigator(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. If you are a student please provide the following:

Faculty Sponsor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Purpose (i.e., classroom requirement, Master’s thesis): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 **SUBMIT FACULTY SPONSOR RESEARCH AGREEMENT FORM WITH YOUR APPLICATION.**

3. Has this research project been previously considered by the IRB?

Yes \_\_\_ No \_\_\_ Last approval date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Original PI’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(If this is a renewal application and there are no substantive changes in the project complete only through # 5.)

4. If the research is funded, indicate the source:

External Agency Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Development and Research Committee: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Check if the following is true: (Be sure that you check all appropriate responses)

Does the research include:

 \_\_\_ minors \_\_\_ prisoners \_\_\_ pregnant women

\_\_\_use of audio, video, digital recordings, or participant photos to collect subject data

\_\_\_use of protected health information

\_\_\_ information that could affect the participant's employability, financial standing or reputation

\_\_\_ information which deals with sensitive aspects of the participant's own behavior, such as illegal

conduct, drug use, sexual behavior, or use of alcohol.

\_\_\_ information which would place the participant at risk of criminal or civil liability if it became

known outside the research

\_\_\_ the use of educational tests (cognitive, diagnostic, aptitude, or achievement)

\_\_\_ survey or interview instrument

\_\_\_ the participants being fully informed of the research project

\_\_\_ voluntary participation by all participants

\_\_\_ interviewing or surveying only elected or appointed public officials or candidates for public office

\_\_\_ observation of public behavior

\_\_\_ the collection or study of existing data, documents, records or specimens

\_\_\_ procedures in which the anonymity\*\* of the participant will be insured

\*\*"Anonymous" refers to a study designed so as not to allow the investigator or anyone else to determine the identity of individual participants from the collected data. "Confidential" refers to a study designed so that, even if participants are identifiable to the investigator, their identity will not be revealed to anyone else.

6. Designate the category you believe describes your research:

 **(Refer to pages 3, and 5 for a detailed description of research classifications)**

 Exempt \_\_\_ (If yes, indicate category \_\_\_)

 Expedited review \_\_\_ (If yes, indicate category \_\_\_)

7. What is the objective of the study? (Be clear and concise. Do not use jargon)

8. What is the research design and what will be required of each participant? (Attach extra page if needed)

9. How will the participants be selected? If you intend to recruit volunteers, please attach all advertisements and flyers. (Be specific. If students, will they be solicited from classes?)

10. What are the risks to the human participant (physiological, psychological)\*\*

\*\*A participant is considered to be at risk if the possibility of physical, psychological, sociological, or other types of harm may be the consequence of an activity which goes beyond the application of established and accepted methods necessary to meet the needs of the participant, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

11. How will confidentiality of the participants be maintained? (Is the study anonymous? Who will know the identity of the participants? If pre- and post-test, how will participants be identified?)

12. Is there any information with regard to protocol or intention that will not be disclosed to the participant on the informed consent form? If so, what is it, and why will it not be disclosed?

13. What debriefing information will be given to the participants following their participation? If any information was withheld from the participants, it must be disclosed at the debriefing.

14. Specify the participant characteristics required (age, gender, etc.) and the number of participants. (Be specific)

15. How will the data be recorded and stored? (Be specific). PLEASE NOTE: All original data must be kept for a minimum of three years. Data of student researchers must be kept in a secure place in the faculty sponsors office.

# Faculty Research Sponsor Agreement

**Review of Research Validity, Design, and Oversight**

**(Required for student led Human Subjects Research)**

**Name Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title of Research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Purpose of research (i.e., classroom requirement, Master’s thesis):**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**The IRB will rely on your careful consideration and review of the following 4 questions:**

* Is the research likely to achieve its aim? Yes \_\_\_ No \_\_\_
* Is the proposed research of sufficient scientific importance to justify the risks entailed? Yes \_\_\_ No \_\_\_
* Are there adequate resources to complete the study? Yes \_\_\_ No \_\_\_
* Are the research procedures designed to minimize risk to subjects? Yes \_\_\_ No \_\_\_

**As the faculty sponsor of this project, I agree to do the following:**

1. Oversee the design and conduct of the study
2. Ensure that the student researchers assuming duties are well-trained and competent
3. Review the protocol application prior to submission to the IRB
4. Provide guidance in the protection of human research subjects
5. Assure proper application and reporting to the IRB
6. Work with the student researcher to identify modifications warranted by unanticipated problems or circumstances involving risks to participants.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Sponsor Signature Date

***My signature certifies that I have read the application referenced above and found it complete and appropriate for submission to the IRB for consideration.***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print Name of Faculty Sponsor/Department

**Please ensure this form is signed and submitted with the student’s IRB application.**

**For electronic IRB submissions, students must cc the faculty sponsor in the email correspondence.**

## IRB APPLICATION CHECKLIST

This form is for the PI’s use and does not need to be submitted

1. Have you completed the entire application form, including appropriate signatures?
2. If you are a student, has your faculty sponsor completed the Faculty Research Sponsor Agreement form?
3. Have you attached a copy of the informed consent form to be used?
4. If you believe your research is exempt, have you attached a copy of the exempt research cover letter to your questionnaire? (see page 18 of the application form)
5. Have you attached copies of the survey, questionnaires, or other instruments to be used?
6. Have you attached copies of any fliers, advertisements, or announcements that you intend to use to solicit participants?
7. If your project involves participants viewing videotapes or listening to audio recordings, have you included one copy of such with your application?
8. Have you attached copies of other IRB approvals (if applicable) or letters of support from collaborating institutions?