# TOWSON UNIVERSITY

# IRB Application Instruction Manual

***Guidance for Principal Investigators and Faculty Advisors on how to prepare an IRB application that will require few revisions!***

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# WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

Federal regulations require that institutions conducting biomedical or behavioral research have an Institutional Review Board (IRB) and that IRB must follow Federal laws governing its operation. IRBs are administrative bodies established to protect from intentional or unintentional harm human subjects (participants) involved in research activities. Specifically, the IRB is responsible for determining whether the anticipated risks to human subjects of a research study are either outweighed or justified by the anticipated benefits. Therefore, the IRB is particularly concerned with:

- Making sure that participants fully understand and agree to participate in the research
- Protecting individuals' rights to confidentiality and/or anonymity as much as possible
- Ensuring that vulnerable populations are protected (e.g., children, prisoners, pregnant women)
- Determining that the level of risk in each project is acceptable and necessary
- Determining that protections and safeguards exist if the research should distress or harm the participants.

The Towson University (TU) IRB for the Protection of Human Participants reviews all proposals for human subjects' research ***before*** the research is conducted to determine whether the research plan adequately protects human subjects. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both federal regulations and local institutional policy. The IRB also has authority to suspend or terminate approval of ongoing research for the following reasons: (a) The study is not being conducted in accordance with the protocol that was approved; (b) new information changes the anticipated risks or the risk/benefit ratio of the study; or (c) the study involves unwarranted risk to participants. Researchers who do not comply with IRB policies or rulings will be reported to the researcher's department and to the funding agency, if appropriate. The IRB Chairperson will also file a formal, written allegation requesting a scholarly misconduct inquiry of the project.

Research that has been reviewed and approved by the IRB may be subject to review and approval/disapproval by officials of TU or other institutions. However, those officials may not approve research that has been disapproved by the IRB.

The policies and procedures of TU's IRB for the Protection of Human Participants are guided by the **Code of Federal Regulations, Tile 45 – Public Welfare, Part 46 Protection of Human Participants** (hereinafter referred to as 45CFR46 or the Common Rule) effective January 18th, 2018; Applicable Maryland Law, the University System of Maryland (USM) Policy on Human Participants in Research, and Towson University's Human Participant Assurance (FWA00003648). Copies of these documents are available through the Office of Sponsored Projects and Research (OSPR). This manual describes those policies and procedures and discusses critical areas of concern in reviewing the use of human subjects in research. It also includes instructions for completing the applications for IRB review: (a) *Application for Accelerated Review – Studies Involving Minors/Legal Minors*; (b) *Application for Accelerated Review – Studies involving Adults*; and *Application for Standard or Full Board Review*.

# WHAT ARE MY RESPONSIBILITIES AS A PRINCIPAL INVESTIGATOR (PI) OR FACULTY ADVISOR (FA) FOR A STUDENT CONDUCTING HUMAN SUBJECTS RESEARCH?

As noted above, it is the IRB's responsibility to determine whether the anticipated risks of a research study to human subjects are either outweighed, or justified, by the anticipated benefits. As such, when preparing your application for IRB approval, it is your responsibility to provide sufficient detail so that the IRB can determine (a) the extent of risk to human participants, (b) the protections in place to mitigate those risks, and (c) whether the anticipated benefits outweigh or justify those risks. In addition to reviewing the planned protections for mitigating risks to human subjects, *the IRB also has the right and responsibility to review the rationale for your study as well as the design*. The reason for this is because a study that lacks an appropriate rationale AND/OR that is poorly designed so that it will not meet its aims has only risks and no benefits for participants or society. As such, the PI may be asked to provide more detail about the rationale or may be asked to modify the design to ensure that it can meet its stated aims. *Failure to make these requested revisions could result in the study being disapproved*.

## What are my Responsibilities as a Principal Investigator (PI) Conducting Human Subjects' Research?

Given the preceding information, the PI has the following responsibilities:

1. *Complete required Human Subjects' Protections Trainings*
   Every PI must show evidence of having completed Human Subjects' Protections Training. See WHAT ARE TOWSON's REQUIREMENTS FOR HUMAN SUBJECTS PROTECTIONS TRAINING? for more information about the training requirements and a link to the training website. The training MUST be completed **BEFORE** the IRB will review the application.
2. *Ensure that the study has a strong rationale that supports the hypothesis/es to be tested*
   It is important to provide a brief rationale, supported by a literature review, for the research. This will help the IRB reviewer(s) to know whether the study rationale is appropriate.
3. *Ensure that the study is designed in such a way that it can meet its intended aims*
   As noted above, a poorly designed study that has a low chance of meeting its aims has ONLY risks and no benefits. Thus, it is important that the PI explain the study design in sufficient detail so that the reviewer knows what is planned and can decide about whether it has the potential meet its stated aims.
4. *Ensure that the study has the potential to benefit research participants and/or society*
   All research must have the potential to contribute (either indirectly or directly) to advancing knowledge of an issue/or area or to the betterment of the human condition or society. As such, it is the PI's responsibility to clearly outline the anticipated benefits of the research. It should be noted that it is not necessary for research subjects to directly benefit from the research; only that the research activity has the potential to benefit individuals in the future.
5. *Ensure that protections are in place to minimize risks to participants*
   Risks can include loss of confidentiality, social risks (such as loss of reputation or employment), physical risks (such as health complications, injuries or death), and emotional risks (such as anxiety or embarrassment). It is the PI's responsibility to determine if the risks are more than

what would be encountered in everyday life. If the risks are not more than what would be encountered in daily life, then the PI needs to make sure that this is explained in detail in the application (and supported by prior research, if available). If the risks are more than what would be encountered in daily life, then the PI must explain in detail how those anticipated risks will be managed or mitigated. If the study involves a sensitive population (i.e., children or legal minors; prisoners; pregnant women/fetuses; cognitively impaired individuals), the PI must be certain to explain what additional protections are in place to ensure that all potential risks are minimized to the extent possible.

6. *Ensure that the potential benefits either outweigh the anticipated risks or are sufficient to justify the risks to participants*
   The PI should ensure that there is a discussion of the balance of anticipated risks and benefits. This discussion should address either the extent to which the anticipated benefits outweigh any possible risks (typical of minimal risk studies) or the extent to which the anticipated benefits justify any possible risks (typical of more than minimal risk studies). If the study involves children (or legal minors), the PI must ensure that consent is obtained from parents/legal guardians and assent is obtained from the child/legal minor participants, as appropriate.
7. *Ensure that the consent form includes all the required elements*
   There are instances in which written informed consent is either not necessary or can be waived (See Are there Circumstances when the Informed Consent Process can be Waived or Altered?). However, for those studies that require written informed consent, it is the PI's responsibility to ensure that all required elements are included in the consent document. This manual includes a checklist as well as templates to assist with writing Consent Forms or Information Sheets (See Appendix A and B).
8. *Determine whether the research activities meet the criteria for Human Subjects Research*
   Not all research activities require IRB review. The PI should use this manual (or consult with an IRB member) to determine if the research they are planning requires IRB review. See Does My Study Require IRB Review? for more information on this.
9. *Submit a complete application to the IRB for review and approval before any research activities take place*
   If it is determined that the research you, or your student, qualifies as Human Subjects research, it is your responsibility to ensure that you, or your student, apply for IRB approval. Please note that **NO RESEARCH ACTIVITIES CAN BE UNDERTAKEN UNTIL IRB APPROVAL HAS BEEN GRANTED**. The IRB Applications are available at the following website: https://www.towson.edu/academics/research/sponsored/comply/irb/. Once the study has been approved, the PI will receive a Notice of Approval via e-mail. The PI may begin data collection only after the Notice of Approval has been received (i.e., verbal confirmation of approval is not sufficient).

## What are my Specific Responsibilities as a Faculty Advisor (FA) to a Student PI Conducting Human Subjects' Research?

As a FA to a Student PI conducting Human Subjects' Research, you have the following responsibilities:

1. *Ensure that the student PI has the knowledge and skills necessary to conduct ethically responsible Human Subjects' Research*

It is the IRB's expectation that you will ensure that your student has the research knowledge necessary to conduct Human Subjects' Research (e.g., has taking the necessary academic coursework). You should also ensure that your student completes the required Human Subjects' Protections trainings (see pg. 39, What are Towson's Requirements for Human Subjects Protections Training? for more information and for links to the training site). It is recommended that you have students provide you with a copy of the completion certificate for your records.

2. *Review the student PI's application to determine whether it meets the requirements noted above and described throughout this manual*
   As a FA, YOU (not the student) are responsible for the research that your advisee is conducting (and any adverse events or protocol deviations/violations that may occur). As such, it is your responsibility to ensure that the study has a strong rationale, is designed in such a way as to meet its stated aims and that it adheres to the ethical standards described within this manual. Before a student can apply for IRB review, you will be required to sign the *Investigator's Assurances* section on the application form indicating that you have reviewed the application and are giving your assurance that it meets all the stated criteria. It is also your responsibility to make sure that the students do not begin data collection before IRB approval has been obtained.
3. *Ensure that all research assistants who are involved in subject consenting and data collection have completed Human Subjects' Protections trainings and are adequately trained in the study protocol* It is expected that you will supervise the implementation of the study to ensure that it adheres to the strictest ethical standards. Specifically, you are expected to make sure that the student PI and all research assistants understand the necessity of strictly adhering to the IRB-approved protocol, of protecting the privacy and confidentiality of study participants (e.g., by not discussing participants or sharing data with anyone outside of the research team), and of recording AND reporting any adverse events (serious or otherwise) and protocol deviations/violations that may occur. It is also expected that the PI will observe the consent process, to ensure that it is does not involve coercion, as well as implementation of all other student procedures (e.g., at the beginning when new research assistants run the study for the first time and periodically thereafter if it seems appropriate such as after a protocol deviation or violation occurs).

# DOES MY STUDY REQUIRE IRB REVIEW?

The Institutional Review Board is responsible for review and oversight of activities that meet the definition of ***Human Subjects Research***.

## Definition of Human Subjects Research

*Definition of Human Subject*: A living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens (45CFR46.102.e.1).

- A human subject is an individual who is currently living; as such this policy does not apply to information collected about individuals who are deceased
- Intervention includes both physical procedures AND manipulations of the subject's environment (as in experimental studies where the investigator manipulates an independent variable)
- Interaction includes any communication or contact between the investigator/research team and the research subject; as such, this policy MAY NOT apply when the information involves unobtrusive observation of individuals in public places
- Private Information refers to information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and to information that has been provided for specific purposes that the individual can reasonably expect will not be made public. For example, private information includes behavior that occurs in the individual's home or information collected as part of a routine medical examination
- Identifiable means information or specimens for which the identity of the subject may be readily ascertained. Research suggests that a minimum of three pieces of data can be sufficient to re-identify an "anonymous" participant. For example, a researcher at Harvard University used zip code, date of birth and gender combined with information from publicly available records (such as voter rolls) and could re-identify 40% of the sample in a high-profile DNA study in which medical information was collected[1].

*Definition of Research*: A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

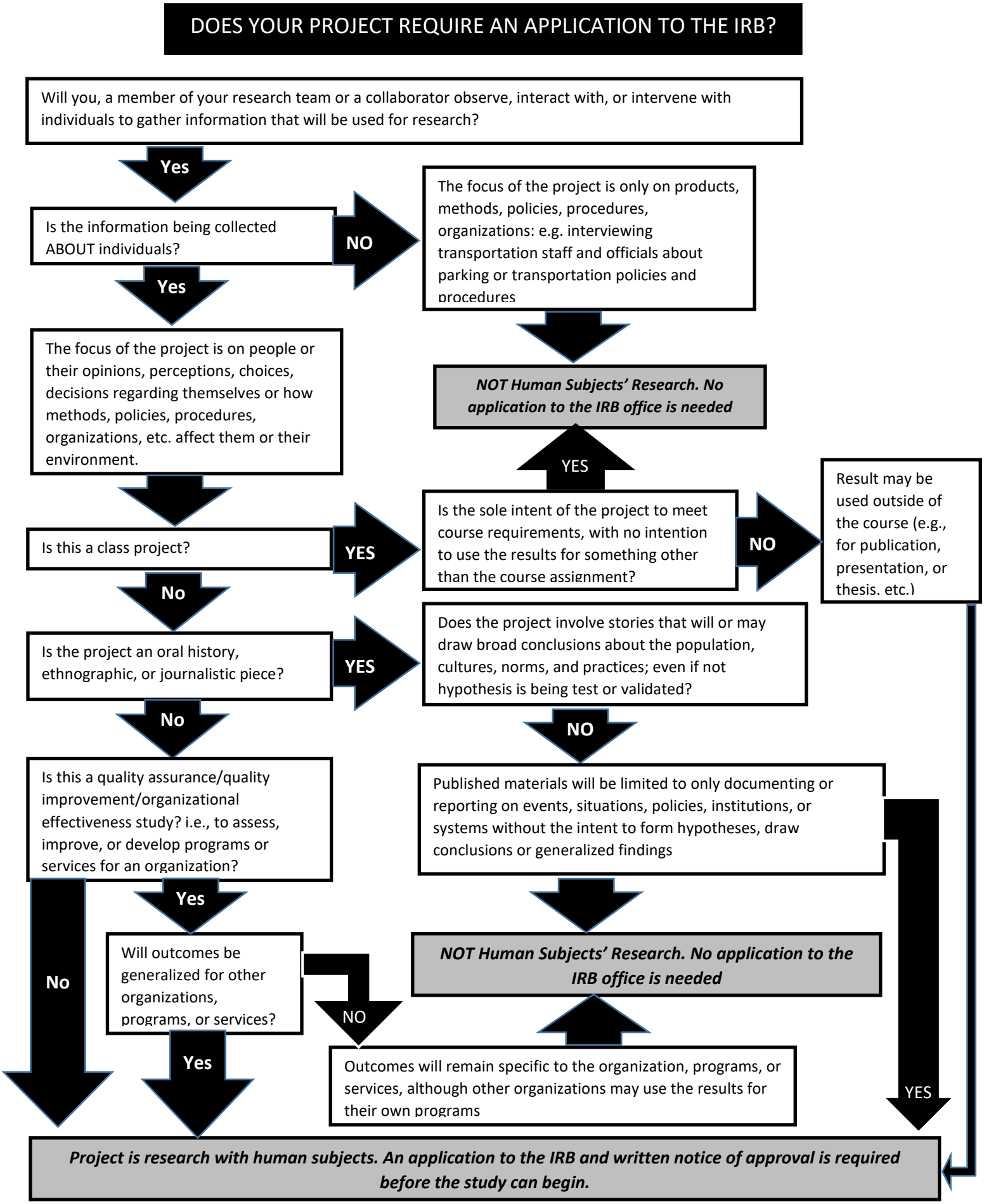
- Generalizable knowledge – this is inferred to mean that the researcher has the intention of disseminating the information in some form (either through presentations or publications). Research that is conducted for internal use only (e.g., quality improvement studies; pilot studies in which the data are used only for the purposes of planning a larger study) do not fit this definition.

Any research activity that meets these criteria must undergo some form of IRB review (See How Do I Determine the Review Category for My Study? for more information). If you are uncertain about

[1] Sweeney L, Abu A, and Winn J. Identifying Participants in the Personal Genome Project by Name. Harvard University. Data Privacy Lab. White Paper 1021-1. April 24, 2013. https://dataprivacylab.org/projects/pgp/

whether the research study you are planning requires IRB review, contact the IRB Chair or a representative of the IRB from your college for advice before you begin data collection. Research that does not meet these criteria are exempt from 45CFR46 and therefore do not require IRB review.

Figure 1. Flow Chart for Determining Whether Your Study Requires IRB Review



# HOW DO I DETERMINE THE REVIEW CATEGORY FOR MY STUDY?

The Office of Human Research Protections (OHRP) describes three main types of research: (1) Exempt, (2) Expedited, and (3) Full board. Because the language is somewhat misleading, and has caused some confusion for PI's about the anticipated nature and speed of the review, Towson University's IRB uses a different designation: Accelerated Review, Standard Review, and Full Board review.

## Types of Review

### Accelerated Review

Accelerated Review: Accelerated review is limited to minimal risk studies that meet very specific criteria (see Table 1. Accelerated Review Categories). All studies that meet criteria for accelerated review fall within OHRP's exempt category. Accelerated Review is conducted by the IRB Chair or Assistant Chair and should take no more than one week. If your study meets the criteria for Accelerated Review you will be required to complete and submit a Request for ***Application for Accelerated Review***, either the Adult or the Minor/Legal Minor versions. Studies undergoing accelerated review do not require continuing review by the IRB. However, it is the PI's responsibility to contact the IRB if (a) you intend to modify the study procedures or consent document, (b) a participant complains about the study (regardless of the reason) or there is an adverse event, (c) there is a protocol deviation/violation (e.g., anonymous participants become identifiable), and/or (d) new findings indicate that the study risks, or the risk/benefit ratio has changed.

### Standard Review

Standard Review: Standard review is also limited to minimal risk studies which either include the collection of sensitive information or may require collection of identifying information. Studies requiring standard review include both certain OHRP exempt category studies as well as studies meeting the criteria for expedited review. Standard review is conducted by a single IRB member and will take between 2 to 3 weeks. You will be required to complete the ***Request for Standard or Full Board Review*** application which will require more detail than the ***Request for Accelerated Review*** application. Studies undergoing standard review will require a progress report to be completed once every three years.

### Full Board Review

Full Board Review: Full board review is reserved for studies that are more than minimal risk (see What are the Criteria for Full Board Review? for factors that would indicate the need for a Full Board review) although some minimal risk studies may also require Full Board Review. Studies meeting criteria for Full Board review involves having the protocol discussed by a quorum of IRB members. Studies approved via full board review will need to undergo continuing review annually. You will be required to complete the ***Request for Standard or Full Board Review*** application. PI's can expect to receive initial comments on their application within one month.

To facilitate the review process, you must specify the category for review and provide a justification for why you believe your study fits that category. *Please note that the IRB has the right to change the category for review (including requiring Full Board Review) if they deem it is necessary to do so.*

## What is the Definition of Minimal Risk?

**Minimal Risk**, as defined in 45CFR46.102.j, "*…means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those risks ordinarily encountered in daily life or during the performance of routine physical or psychological tests*."

- Harm or Discomfort includes physical harm, such as injury or illness, and psychological harm, such as embarrassment, anxiety, depression. For example, the following indicate that a study is more than minimal risk:
    - Disclosure of the human subjects' responses outside of the research would place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation
- Encountered during Daily Life should be inferred to mean risks of the activity for the population to which the study findings will be generalized; e.g., if the study is looking at interventions for athletes, the determination of risk would be based on what an athlete is likely to encounter in their daily life.
- Routine Physical or Psychological Tests include routine blood draws or achievement tests; Tests involving radiation are not considered routine physical tests and therefore do not qualify as Minimal Risk

## Does my Study Qualify for Accelerated Review?

OHRP defines eight (8) categories that qualify as Exempt. Five out of the eight Exempt studies meet the criteria for Accelerated Review for Adults and four out of the eight Exempt studies meet the criteria for Accelerated Review for Minors/Legal Minors. They must also meet the specific criteria for those categories.

The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. In this case, the IRB must determine that there are adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data.

### If my Study Involves Deception, Can it Still Qualify for Exempt Status?

The answer to this question is maybe. If your study meets the criteria for Benign behavioral intervention (defined in Table 1. Accelerated Review Categories) and involves deceiving or misleading participants about the nature or purpose of the research, it can only qualify for exempt status if participants sign an agreement, prior to their participation, indicating their willingness to participate in studies in which they may be deceived about the nature and purpose of the research. The agreement that participants sign indicating their willingness to participate in research in which they may be deceived or misled about the nature or purpose of the study must be approved by the IRB. If prospective consent is not or cannot be obtained, then the study will require either Standard or Full Board review.

Table 1. Accelerated Review Categories

| No. | Category Description | Definition of Terms |
|---|---|---|
| 1 | Research conducted in established or commonly accepted educational settings, that specific involves normal educational practices that are not likely to adversely impact students' opportunity to learn required education content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. | |
| 2 | Research that ONLY includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)<br>**Note 1**: Must also meet condition (i) or (ii) below:<br>(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects? OR<br>(ii) Any disclosure of responses outside of the research would NOT reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement, or reputation<br>**Note 2**: For Minors/Legal Minors, the study may only include educational tests or observation of public behavior, must meet condition (i) or (ii) in Note 1, and the PI does not participate in the activities being observed. | |
| 3 | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. Research involving deception is only permissible under this exemption IF the individual signs a prospective agreement noting their willingness to participate in research in which they will be unaware of or misled regarding the nature or purpose of the study<br>**Note 1**: Must also meet condition (i) or (ii) below:<br>(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects? OR<br>(ii) Any disclosure of responses outside of the research would NOT reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement, or reputation | Benign behavioral intervention – brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, participants are not expected to find the intervention offensive or embarrassing (e.g., playing an online game; deciding how to allocate a nominal amount of cash between themselves and someone else) |

| No. | Category Description | Definition of Terms |
|---|---|---|
| 4 | Secondary research for which consent is not required: Secondary research uses of identifiable private information or biospecimens, if at least one of the following criteria is met:<br>(i) The data are publicly available<br>(ii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects?<br>(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45CFR Parts 160 AND 164, subparts A and E, for the purposes of "health care operations or "research" or for "Public health activities and purposes".<br>(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained according to specifically federal guidelines. | Definitions of Health Care Operations and Research for the purposes of this provision can be found at:<br>https://www.law.cornell.edu/cfr/text/45/164.501<br><br>The definition of Public Health Activities for the purposes of this provision can be found at:<br>https://www.law.cornell.edu/cfr/text/45/164.501 |
| 5 | Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, amended.<br><br>Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly available Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.<br>Section 1115 of the Social Security Act can be found here:<br>https://www.ssa.gov/OP_Home/ssact/title11/1115.htm<br>Section 1115A of the amended Social Security Act can be found here:<br>https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm | |

NOTE: Categories that are shaded qualify for exempt status for both Adults AND Minors/Legal Minors.

## What are the Criteria for Standard Review?

Studies meeting the OHRP criteria for Expedited review will be subject to Standard Review (by TU's definition). In addition, studies meeting the criteria for OHRP Exempt Categories (2) or (3) (i.e., Accelerated Review Categories (2) or (3) as noted in Table 1. Accelerated Review Categories) if they also meet condition, (iii) described below, and OHRP Exempt Categories (6), (7), or (8) will also require Standard review. For information on the specific criteria that your study must meet to qualify for Standard review, please see Table 2a. "Expedited" Research Requiring Standard Review and Table 2b. "Exempt" Research Requiring Standard Review.

## What are the Criteria for Full Board Review?

Any study that does not meet criteria for **Accelerated** or **Standard** review, and/or meets one of the criteria mentioned below, will require **Full Board** review. Full Board review means that a quorum of IRB members has reviewed and approved the study.

1. Studies which have been determined by the IRB Chairperson to be MORE THAN MINIMAL RISK (See How do I determine the Review Category for my Study?, for the definition of Minimal Risk)
2. Studies involving elements, procedures or interventions that require additional provisions or safeguards, as noted below:
    a. The study involves vulnerable or sensitive populations (e.g., prisoners)
    b. Studies taking place in foreign countries with few or no provisions for the protection of human subjects and in which the procedures pose more than minimal risk to subjects
    c. Studies where information may be disclosed that could require reporting, such as child or elder abuse; illegal activities, etc.
    d. Studies involving deception unless the individual signs a prospective agreement noting their willingness to participate in research in which they will be unaware of or misled about the nature or purpose of the study
    e. Studies involving behavioral interventions that do not meet the criteria for "Benign".
3. Studies requiring an Investigational New Drug or Investigational Device Exemption Application
4. Studies involving procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial or legal).
5. Studies assessing sensitive topics and data collected are not anonymous, such as the following:
    a. Sexual orientation, attitudes, preferences or practices
    b. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
    c. Information that could damage the individual's financial standing, employability, or reputation
    d. Information that could lead to social stigmatization or discrimination
    e. Psychological well-being or mental health
    f. Incest, rape, date rape, or sexual molestation
    g. Veteran or war-time experiences

For this category, when the risks to participants are due exclusively to consequences associated with loss of confidentiality (e.g., Categories 5.b; 5.c; or 5.d), collecting and storing the data in such a way as to ensure participant anonymity and securing a Certificate of Confidentiality from the Federal Government

may be sufficient to mitigate the risk and therefore could qualify the study for standard review. Studies involving potential physical or emotional harm will always require Full Board Review.

## Table 2a. "Expedited" Research Requiring Standard Review

| 45CFR46 No. | "Expedited" Research Description | Definition of Terms |
|---|---|---|
| 1 | Clinical studies of drugs and medical devices only when condition (i) or (ii) is met.<br>(i) Research on drugs for which an investigational new drug application is not required.<br>(ii) Research on medical devices for which (a) an investigational device exemption application is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.<br>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 Standard review. | |
| 2 | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture<br>(i) from healthy, non-pregnant 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<br>(ii) from other adults and children, 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. | **Adults** are anyone 18 years of age or older, who are legally allowed, and cognitively capable, of making medical decisions for themselves<br><br>**Other Adults** are **Adults** as defined above but are <u>not</u> considered healthy. |
| 3 | Prospective collection of biological specimens for research purposes by noninvasive means.<br>Examples of non-invasive procedures for this category, include:<br>(i) Hair and nail clippings in a non-disfiguring manner;<br>(ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;<br>(iii) permanent teeth if routine patient care indicates a need for extraction;<br>(iv) excreta and external secretions (including sweat);<br>(v) 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;<br>(vi) placenta removed at delivery;<br>(vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;<br>(viii) 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;<br>(ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;<br>(x) sputum collected after saline mist nebulization. | **Non-Invasive Procedures** are those procedures that are a routine part of medical practice and involve a minimal amount of physical or emotional discomfort or harm.<br><br>**Urine specimen collection that must be observed is not considered a non-invasive procedure** |

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## Table 2a. "Expedited" Research Requiring Standard Review (continued)

| 45CFR 46 No. | "Expedited" Research Description | Definition of Terms |
|---|---|---|
| 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 of non-invasive procedures for this category, include:<br>(i) 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;<br>(ii) weighing or testing sensory acuity;<br>(iii) magnetic resonance imaging;<br>(iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;<br>(v) 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). In addition, the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained either directly or through identifiers linked to the subjects. The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | |
| 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. In addition, the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained either directly or through identifiers linked to the subjects. The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | |

## Table 2a. "Expedited" Research Requiring Standard Review (continued)

| 45CFR 46 No. | "Expedited" Research Description | Definition of Terms |
|---|---|---|
| 8 | Continuing review of research previously approved by the convened IRB as follows:<br>(i) Where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or<br>(ii) where no subjects have been enrolled and no additional risks have been identified; or<br>(iii) 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. | |

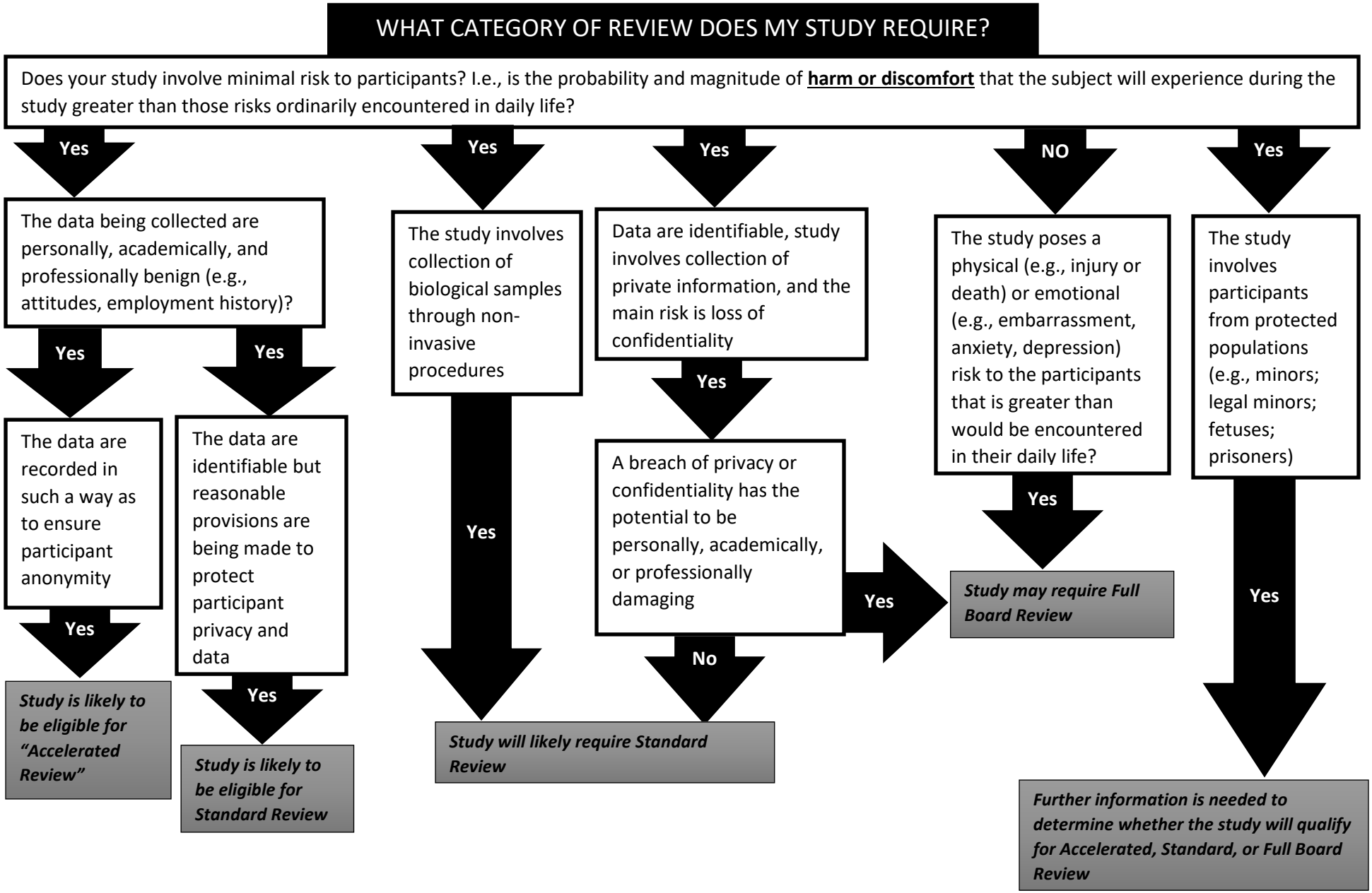
## Table 2b. "Exempt" Research Requiring Standard Review

| 45CFR 46 No. | "Éxempt" Research Description | Definition of Terms |
|---|---|---|
| 2 | Research that ONLY includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **AND** the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained either directly or through identifiers linked to the subjects. The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | |
| 3 | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. Research involving deception is only permissible under this exemption IF the individual signs a prospective agreement noting their willingness to participate in research in which they will be unaware of or misled regarding the nature or purpose of the study **AND** the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained either directly or through identifiers linked to the subjects. The PI must make appropriate provisions for ensuring the privacy of subjects and for maintaining the confidentiality of the data. | **Benign behavioral intervention** – brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, participants are not expected to find the intervention offensive or embarrassing (e.g., playing an online game; deciding how to allocate a nominal amount of cash between themselves and someone else) |

Table 2b. "Exempt" Research Requiring Standard Review (continued)

| 45CFR 46 No. | "Exempt" Research Description | Definition of Terms |
|---|---|---|
| 6 | Taste and food quality evaluation and consumer acceptance studies:<br>(i) If wholesome foods without additives are consumed, or<br>(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 and Inspection Service of the U.S. Department of Agriculture. | |
| 7 | Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited review and makes the determined discussed in **Notes**<br><br>In order to approve research covered by this policy, the IRB shall determine that the Broad consent for storage, maintenance, and secondary research or identifiable private information or identifiable biospecimens is obtained in accordance with the requirements for Broad consent (see **Definition of Terms**), Broad consent is appropriately documented or waiver of documentation is appropriate (See What are the Requirements for Informed Consent section), AND if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | **Broad Consent** involves consenting to storage or maintenance of identifiable private information or identifiable biospecimens for potential, unspecified secondary research use (See What are the Requirements for Informed Consent section for more information). |
| 8 | Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the procedures for obtaining Broad Consent conformed with those requirements discussed in What are the Requirements for Informed Consent section and an IRB determines that documentation, or waiver, of informed consent conforms with the requirements discussed in What are the Requirements for Informed Consent section and that the proposed research falls within the scope of the Broad Consent obtained. Furthermore, the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. | |

Figure 2. Flow Chart for Determining the Category of Review



# WHAT ARE THE REQUIREMENTS FOR INFORMED CONSENT?

Informed consent is the process by which potential research subjects are informed about critical elements of the research. The main reasons for obtaining informed consent from participants is to ensure that participants understand what they are expected to do as well as any potential risks so that they can make an informed decision about whether to volunteer for the research. ***It is important to note the following***:

1. ***Informed consent is a process that begins at the time of recruitment and continues throughout the entire duration of the study. In studies with long follow-up periods, the IRB may require that participants be reconsented to ensure that they remember what is required of them and the potential risks associated with the study.***
2. ***NO RESEARCH PROCEDURES MAY BE UNDERTAKEN WITH A STUDY PARTICIPANT until legally effective informed consent has been obtained, and documented, from the research subject or their legally authorized representative.***
3. ***Research participants and/or parents/legal guardians MUST BE GIVEN SUFFICIENT TIME to read the informed consent document and to ask any questions they may have.***
4. ***THE IRB RETAINS THE RIGHT TO PERIODICALLY (AND RANDOMLY) AUDIT INFORMED CONSENT PROCEDURES OF ANY TOWON UNIVERSITY IRB-APPROVED PROTOCOL.***
5. ***Consent forms may not include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence." (pp. 7265- 7266; emphasis added)***

## What are the Basic Elements of Informed Consent?

All informed consent forms MUST INCLUDE the following basic elements:

1. A statement that the study involves research;
2. An explanation of the purpose of the study;
3. If the PI is a student, they should also indicate that they are a student, under the supervision of <Faculty Advisor's name> and the research is being conducted as part of their undergraduate or Master's thesis, Doctoral dissertation, or as part of a class project.
4. The expected duration of the subject's participation;
5. A description of the study procedures. This should include the types of questions that will be asked.
6. If any study procedures are experimental, this should be specified;
7. A description of any reasonably foreseeable risks;
8. A description of how any anticipated risks will be mitigated;
9. A description of the anticipated benefits the research. *It is important to note the following*:
    a. *Participants in the research DO NOT have to benefit from their participation*;
    b. *Compensation for participation IS NOT considered a benefit of research*. A research benefit includes any positive impact the findings are expected to have on increasing understanding of a specific problem or in helping to treat a problem. Thus, the beneficiary of the research can be the research participants, future recipients of an experimental treatment, should it be found effective, or society.

10. A discussion of appropriate alternatives to participation in the study. If, for example, participants will earn extra credit in a course for participating in a study, the professor MUST offer alternative ways to earn extra credit that do not involve research participation. OR, if the study involves an investigational treatment, participants must be told what other forms of treatment are available.
11. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. In addition to addressing the way in which data will be collected and stored to ensure confidentiality, there should also be a statement indicating the procedures used to ensure participant confidentiality (or anonymity) when disseminating findings through presentations or publications.
12. A statement indicating the information below as well as contact information (phone number and e-mail) for the relevant individuals:
    a. that participants should contact the PI or the Faculty Advisor if the PI is a student if they have questions about the research.
    b. that participants should contact the Chair of the IRB if they have questions about their rights as research subjects
    c. whom participants should contact in the event of a research-related injury
13. A statement that
    a. involvement in the study is voluntary; i.e., that it is the participant's decision whether to participate in the study;
    b. refusal to participate will (i) involve no penalty, (ii) no loss of benefits to which they are already entitled, or (iii) not negatively impact their relationship with the university, the faculty teaching the course, etc.;
    c. they may discontinue their participation at any time without (i) penalty, (ii) loss of benefits to which they are already entitled, and (iii) negatively impacting their relationship with the university, the faculty teaching the course, etc.;
    d. They do not have to answer any questions they do not want to answer. This is an important. Consents SHOULD NOT STATE that participants can skip any questions that make them upset. Rather, it should be made clear that participants can skip ANY question they do not want to answer, regardless of the reason.
    e. If there are any questions or procedures that cannot be skipped, this must be indicated in a statement of exclusion criteria (i.e., You must agree to XXX if you want to participate in this study).

*If the research involves more than minimal risk*: the consent form must include statements about:

1. whether there is any compensation and/or medical treatment available if an injury occurs as well as what the compensation and/or medical treatment would consist of.
2. who will be responsible for any costs incurred because of a medical injury, i.e., will medical costs be covered by the university or PI or by the participant and their insurance?

*If the research involves collection of identifiable private information OR identifiable biospecimens*: the consent form must include a statement that:

1. identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for

future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
2. the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

## Are there Additional Elements of Informed Consent?

When appropriate (or if desired), the following additional information should (can) be provided to each subject or to their legally authorized representatives:

1. A statement that the treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent; for example, if the study involves a procedure that could be harmful to developing fetuses, the PI may terminate a participants' involvement in the study if she were to become pregnant.
3. Any additional costs to the subject that may result from participation in the research. For example, if the study involves sending text messages to participants, it will be important to inform them that they are responsible for covering the cost of any text messages sent or received as part of their study participation. See also, If the research involves more than minimal risk, above about participant's responsibility to cover the cost of medical care required because of an adverse reaction to the research.
4. The consequences of a subject's decision to withdraw from the research and procedures to ensure their safety. For example, if the study involves the administration of a medication, it may be necessary for the participant to be weaned off slowly to prevent any adverse reactions;
5. A statement that significant new findings developed during the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (please note that this would also NOT be considered a benefit of the research);
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. In particular, participants may be informed about how they can obtain a summary of the findings if they so desire; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

## What is Broad Consent?

Broad consent is intended to obtain permission from participants or their legal representatives to store, maintain, and use identifiable private information or identifiable biospecimens for the purposes of testing new research questions or for a non-research purpose. In other words, by providing broad consent, participants are permitting researchers to use their identifiable personal information or biospecimens for additional purposes that were not included in the study to which they originally consented. It is important to note that the way in which the information or biospecimens are to be used

will not necessarily be disclosed to the participant and any future uses may involve procedures that the individual may not have consented to had they known about it in advance.

### What information must be provided to participants or legal representatives who are being asked to provide Broad Consent?

At minimum, broad consent should include the following information:

1. Points (7), (9), (11), and (13) under What are the Basic Elements of Informed Consent? and, when appropriate, points (7) and (9) under Are there Additional Elements of Informed Consent?
2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. Any further use of the information or specimens should fall within the scope described in the broad consent document;
3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which also could be indefinite);
5. Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that participants will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
6. Unless it is known that findings (both aggregate and individual) WILL be disclosed to participants, the consent form should include a statement that findings from future studies may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

### Are there Circumstances when the Informed Consent Process can be Waived or Altered?

Under certain circumstances, the IRB may waive the requirement to obtain informed consent (i.e., permit the researcher to collect data without the need to obtain written informed consent from participants). The IRB may also approve an alteration of the consent procedure that omits some or all the required elements. It is important to note that an IRB may neither waive nor alter Broad Consent for the storage, maintenance, or secondary research use of identifiable personal information or biospecimens.

In order to be granted a waiver or alteration of informed consent *in research involving public benefit and service programs conducted by or subject to the approval of state or local official*, the PI must document that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in or alternatives to those programs or procedures; or
    d. Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

To be granted *a general waiver or alteration of informed consent*, the PI must make the case that:

1. The research involves no more than minimal risk to the subjects (as defined in What are the Minimal Conditions for Exempt or Expedited Review?);
2. The research could not reasonably be carried out without the requested waiver or alteration. It is important to note that just because it is difficult to obtain informed consent (e.g., as in obtaining parental consent for school children to participate in research) does not mean a study will be eligible for a waiver. By "could not reasonably be carried out" we mean that it is genuinely not be possible to obtain informed consent, such as when naturalistic observation is used or when accessing deidentified clinical data that have been collected for non-research purposes.
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not reasonably be carried out without using such information or biospecimens in an identifiable format. In this case, the data must be identifiable because it will be linked to other sources of data via those identifiers;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects. In other words, if sensitive data are being collected, then those data are completely anonymous OR disclosure of any information from the study will not negatively impact the subject's reputation, employability, etc.; and
5. Whenever appropriate, the subject or legally authorized representative will be provided with additional pertinent information after participation.

A PI may request permission to collect certain information or biospecimens prior to obtaining informed consent if that information or biospecimen is being used to screen, recruit, or determine the eligibility of prospective subjects for a study, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

## Must Informed Consent be Documented in Writing?

Except under certain circumstances, specified below, informed consent must be documented via an IRB-approved written informed consent form that is signed (either by hand or electronically) by the subject or the subject's legally authorized representative. Subjects should be offered a copy of the informed consent form for their records. Informed consent may be documented in one of the following ways:

1. A written informed consent form that includes all of the required elements specified above. The subject or legally authorized representative should be given sufficient time to read the document and ask any questions before being required to sign. Alternatively,
2. Alternatively, the PI may request approval from the IRB to describe the study orally and then have participants or their legally authorized representative sign an abbreviated written informed consent form. In this case, the following must occur:
    a. The summary to be provided to participants must be approved by the IRB
    b. The abbreviated consent form, which must also be approved by the IRB, must indicate that they were informed about the study and that this information was presented before any other study information.
    c. There must be a witness to the oral presentation of the study summary
    d. The abbreviated informed consent form must be signed by the subject or their legally authorized representative as well as the witness
    e. A hard copy of the summary must be signed by the witness and the individual obtaining informed consent
    f. A copy of the summary should be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

Under certain circumstance, a PI may request permission to waive the need for written informed consent. In order for the IRB to grant a waiver, the PI must document that:

1. The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm AND the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the IRB waives the requirement to document informed consent, the IRB may still require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research. The written statement, also known as an information sheet, must contain the same information as is required in a consent form.

## Are there any Additional Considerations for Obtaining Informed Consent when Conducting Research with Minors/Legal Minors?

See "What are the Requirements Regarding Informed Consent when Conducting Research with Children or Legal Minors?" in the section, "WHAT IF MY STUDY INVOLVES CHILDREN OR LEGAL MINORS?"

Are there guidelines I should Follow when Writing My Informed Consent/Study Information Forms?

All informed consent forms should be written at no higher than an eighth (8th) grade reading level. Readability statistics are available through the Grammar and Spell Check function of Microsoft Word.

To turn on the Readability Statistics in MS Word, go to the FILE tab, click on <options> and then <proofing>. Under, "When Correcting Spelling and Grammar in Word", click on "Show readability statistics". Once MS word has completed checking the grammar and spelling of your document, a window will pop up showing your readability statistics.

Informed Assent forms should be written at the appropriate level for the children who will be included in the study.

***The IRB has developed standard Consent form and Information Sheet templates that are to be used by all Towson University Investigators. You should take the template and fill in all of the requested information.***

## What Should I do if I need to Modify my Consent Form?

Minor revisions to consent forms, such as correcting typos or grammatical errors, can be made without consulting the IRB. If, however, you must make more substantive changes, such as when you are requesting an amendment to an approved protocol, then you should submit a copy of the revised consent form for approval. You should also be certain to indicate the revisions using either (a) track changes, (b) a different color font, or (c) highlighting.

# WHAT IF MY STUDY INVOLVES CHILDREN OR LEGAL MINORS?

## Definitions

### What is the Definition of Minor?

A minor (or child) is anyone under the age of 18 (although the age of majority does vary by state and country).

### What is an Emancipated Minor?

Under Maryland Law, a child as young as 15 can file for Emancipation which would allow him/her to legally make his or her own decisions regarding school, healthcare and other legal matters. Emancipation may be partial (in which the child has the legal right to make decisions about specific issues, e.g., what to do with personal income, or for a limited period) or complete (in which the parents have no legal responsibility for the child). Documentation of legal emancipation would be required before an individual under the age of 18 would be permitted to consent to participate in research.

### What is a "Legal Minor"?

A "Legal Minor" is an individual 18 years of age or older who has been found by a court to be incapable of making or communicating responsible decisions concerning personal and financial matters. Such individuals will have a parent or legal guardian who is appointed by a court to make decisions on their behalf.

### What is the Definition of a Parent?

A parent refers to the child's biological or adoptive parent who has the legal right to make medical and other decisions on the child's behalf.

### What is the Definition of Guardian?

A guardian is an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

## What are the Risk Categories that Pertain to Research with Children?

Table 3. Minor/Legal Minor Risk Categories and Consent Requirements

| CATEGORY OF RISK TO THE CHILD | CONSENT REQUIREMENTS |
|---|---|
| Pediatric Risk Category I: Minimal Risk | • One parent/guardian can provide permission for the child to participate in the research<br>• Assent is required if child is over the age of 7 and capable of providing assent<br>• If the population includes children over the age of 7 who lack the cognitive capacity to provide assent, the PI must indicate this in the application and request a waiver of child assent. |
| Pediatric Risk Category II: Greater than minimal risk, BUT the research has the potential to directly benefit individual participants | • One parent/guardian can provide permission for the child to participate in the research<br>• Assent is required if child is over the age of 7 and capable of providing assent<br>• If the population includes children over the age of 7 who lack the cognitive capacity to provide assent, the PI must indicate this in the application and request a waiver of child assent. |

Table 3. Minor/Legal Minor Risk Categories and Consent Requirements (continued)

| CATEGORY OF RISK TO THE CHILD | CONSENT REQUIREMENTS |
|---|---|
| Pediatric Risk Category III: Great than minimal risk and no prospect of direct benefit to individual participants BUT is likely to yield important generalizable knowledge about the participant's disorder or condition | • Both parents must grant permission for the child to participate in the research UNLESS one parent is not reasonably available (this does not mean difficult to contact), deceased, unknown, legally incompetent, or does not have legal responsibility for the care of the child<br>• Assent is required if child is over the age of 7 and capable of providing assent<br>• If the population includes children over the age of 7 who lack the cognitive capacity to provide assent, the PI must indicate this in the application and request a waiver of child assent. |
| Pediatric Risk Category IV: Otherwise not approvable BUT presents an opportunity to understand serious health or welfare problems of children | • Generally, not approvable; requires review by a panel of experts as well as an opportunity for public comment |

## How does the inclusion of Children or Legal Minors affect the Review Category for my Study?

### PEDIATRIC RISK CATEGORY I: No More than Minimal Risk

1. Research involving children or legal minors will qualify for Accelerated Review if they FULLY MEET the criteria for Accelerated Review categories 1, 3, 4, or 5 (See Table 1. Accelerated Review Categories).
2. Research that meets the following criterion IS NOT eligible for Accelerated Review:
    a. the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects but the IRB determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data
3. Research that does not qualify for Accelerated Review will require either Standard or Full Board review depending on the nature of the research and the extent to which it involves minimal or greater than minimal risk to participants (See below for additional information about requirements for conducting Research with children that involves greater than minimal risk).

### PEDIATRIC RISK CATEGORY II: More than Minimal Risk, Approvable by the IRB

1. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects is allowed if the IRB finds that:
    a. The risk is justified by the anticipated benefit to the subjects;
    b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
    c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

### PEDIATRIC RISK CATEGORY III: More than Minimal Risk, Approvable by the IRB

1. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition is allowed if the IRB finds that:
    a. The risk represents a minor increase over minimal risk;
    b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
    c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
    d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

### PEDIATRIC RISK CATEGORY IV: More than Minimal Risk, Generally Not Approvable

1. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children is allowable if the IRB finds that:
    a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children as well as meets other conditions outlined in Subpart D (See https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd)
    b. The secretary of HHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment has determined either:
        i. The research satisfies the requirements of Pediatric Risk Categories I, II, or III OR ii the following criteria:
            1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affective the health or welfare of children;
            2. The research will be conducted in accordance with sound ethical principles; AND
            3. Adequate provisions are made for soliciting the assent of children and the permission of their parents of guardians.

## What are the Requirements Regarding Informed Consent/Assent when Conducting Research with Children or Legal Minors?

Informed assent is a formal process in which children/adolescents and given the opportunity to express whether they are willing to participate in research. Prior to conducting research with children or legal minors, the PI must obtain informed consent from parents and assent from children. See Table 3. Minor/Legal Minor Risk Categories and Consent Requirements to determine whether permission of one or both parents or legal guardians is required.

## Under what Circumstances is Informed Assent Required from Children?

According to 45 CFR 46, Part D, child assent is required when, in the judgment of the IRB, the intended participants can provide assent. The factors that must be considered when determining whether a child or legal minor can provide assent include the following:

1. Age;
2. Maturity level; and
3. Psychological state of the children

The requirement to obtain child/legal minor assent may be made for all children involved in research or for each child individually. In other words, studies involving children who vary in age may require informed assent of some, but not all the participants depending on their ability to provide informed assent.

## Under What Circumstances Can Child Assent be Waived or Altered?

Child assent can be waived when the IRB determines that:

1. Some or all the children to be involved in the research are unable to grant their permission to participate in the research
2. The intervention or procedure involved in the research has the potential to directly benefit the health or well-being of the child/legal minor and is ONLY AVAILABLE within the context of the research
3. The research involves no more than minimal risk to the subjects; the waiver will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

## Can Children who are Wards of the State or other Agency, Institution, or Entity, be involved in Research?

Children who are wards of the state or any other agency, institution, or entity can be included in research if the research meets the following criteria:

1. The research is directly pertinent to their status as wards; OR
2. The research is conducted in schools, camps, hospitals, institutions, or other similar settings in which most of the child participants are NOT Wards.

If the research involving wards is approved by the IRB, the IRB will require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or “in loco parentis.” One individual may serve as the advocate for more than one child. The appointed advocate must have the background and experience to act in the best interests of the child for the duration of the child’s participation in the research. The advocate cannot be associated in any way (except in the role of advocate or IRB member) with the research, the investigator, or the guardian organization.

# WHAT IF I AM CONDUCTING RESEARCH AT (OR WITH) ANOTHER INSTITUTION?

## The Inter-Institutional Authorization Agreement

Research conducted at another institution is considered "cooperative research," where each institution is responsible for safeguarding the rights and welfare of human subjects. Federal regulations require approval by a "single IRB of record" for studies qualifying as cooperative research. An Inter-Institutional Authorization Agreement is a cooperative agreement between the IRB's of two or more institutions in which one IRB (i.e., the IRB of record) is assigned responsibility for review and oversight of a study. In order for Towson University to enter into an IIAA with another institution, the other institution must have a Federalwide Assurance (FWA) on file with the Office for Human Research Protections (OHRP). If the other participating institution(s) does not have an FWA, then Towson will have to be the IRB of record.

## When will Towson Serve as the IRB of Record?

TU Will serve as the IRB of Record on an IIAA with another institution when:

1. If the study Principal Investigator is a Towson University Faculty Member, Staff or Student,
2. data collection is occurring on site at TU, and
3. TU faculty, staff or students are serving as research subjects for the project

If the PI is a TU faculty member, staff, or student, and the study is being conducted at another institution, then the preference would be that TU serve as the IRB of record on the IIAA. However, if the study involves the other institution's faculty, staff, or students as research subjects, then TU will consider the possibility of permitting the institution to serve as the IRB of record.

## Are there Circumstances When Towson will Assign IRB Review and Oversight Responsibility to another IRB?

TU's IRB will assign responsibility for review and oversight of a student (and therefore enter into an IIAA where the other institution's IRB is the IRB of record) when:

1. The PI is from another institution, the study is not being conducted at TU, and the study does not involve TU faculty, staff, or students as research subjects. Investigators who must submit a project to another IRB should work closely with the IRB to develop an IIAA.
2. If the PI is from another institution, but the study is being conducted on site at TU and/or involves TU faculty, staff, or students as research subjects, then the TU IRB may assign responsibility for review and oversight for the study to the other institution's IRB ONLY AFTER it has been reviewed by the IRB Chair, Co-Chair or an IRB member designated by the Chari or Co-Chair. Before entering into an IIAA with the other institution as the IRB of record, the TU IRB will request to see the following:
    a. The full approved protocol
    b. The approved consent form
    c. A copy of the signed approval letter
    d. Any other relevant supporting documentation

# WHAT SHOULD I DO IF I WANT TO COMPENSATE SUBJECTS FOR THEIR PARTICIPATION?

Compensation or payment to research participants for participation in studies is not considered a benefit. Rather, it should be considered compensation for time and inconvenience. PI's are responsible for discussing how, and how much, they intend to compensate their participants in both their applications and the consent forms.

## Monetary Compensation

If you want to compensate participants using money or gift cards for their involvement in your research, you need to address the following points in your application:

1. The amount and schedule of all payments
2. Where the funding is coming from. If grant related, include the name of the grant and the grant number. If it is department funded, you will need the department's budget code.
   **Note that a grant or department fund may have restrictions on the types of incentives purchased for participant payments (e.g. gift card purchases). The PI will need to consult their appropriate department budget manager and/or grant administrator for terms and conditions.*
3. The number of participants you plan on compensating
4. If study participation is anonymous, articulate how the participant name and contact information will be separated from the data submission to assure anonymity

## Other Forms of Compensation

Sometimes PI's want to offer course or extra credit as compensation for participation in research. In such instances, the PI must ensure that:

1. Students do not feel any undue pressure to participate, such as when the study investigator is also the course instructor, AND
2. There are other methods for earning course or extra credit other than participating in research.

In preparing your application, you should address the following:

1. The amount of extra credit that participants can earn and how it will be awarded
2. Whether they must complete all research activities in order to earn full credit (or whether partial credit will be awarded)
3. Any alternatives to research participation that can be used to earn extra credit

### What Should I do if I Want to Conduct Research in one of my Classes?

If you want to use your students in your courses as research subjects, you must be particularly sensitive to the possibility that they may feel obligated to participate, especially when offering extra or course credit. There are several ways to minimize this risk.

1. You can ask someone else to collect informed consent and implement study procedures
2. You can conduct the research online

3. To the extent possible, it would be a good idea that you do not know who has agreed to participate in the research until such time as you are ready to calculate final grades and therefore need to know how many extra credit points each students has earned
4. You could ask students to participate but not compensate them so that their responses remain anonymous

# WHAT IF I WANT TO USE DATA PANELS IN MY RESEARCH?

## Issues to Consider when Using Data Panels

Research conducted using data panels cannot be considered anonymous because it is not always clear whether and how data panel providers use data collected by their customers. As such, the IRB recommends the following when a PI wants to use a data panel:

1. Do not state in your application nor in your consent form that you are using procedures where anonymity is assured; instead, you should discuss how you will protect the confidentiality of the data collected
2. You should provide a link to the Data Panel User Agreement in case participants want to familiarize themselves with the data panel provider's privacy policies
3. You should NOT use data panels to collect sensitive information (e.g., private health information; mental health history; criminal behavior; substance use; etc.)
4. Some data panels (e.g., Amazon Turk) allow PI's to "reject" surveys for random responding. However, rejection of surveys may lead participants to not get paid and/or to be given negative employment ratings. This latter issue actually increases risks to participants and therefore makes the risk/benefit ratio of the study unfavorable. As such, PI's are not permitted to reject surveys for random responding. Instead, you should be prepared to oversample in order to achieve your target sample.

## Compensating Participants through Data Panels

PI's should know that due to USM regulations, Towson University cannot agree to certain terms and conditions presented in user agreements for some data panel providers (e.g. Mturk). As such, PI's cannot use University or Departmental funds to pay participants through these data panels. It is strongly recommended that PI's consult their respective department, Procurement and/or the General Counsel to confirm if the user agreement for the planned data panel provider complies with USM regulations.

To determine whether you may use departmental or university funds to compensate participants through a specific data panel, you should contact the following after securing IRB approval and are seeking reimbursement:

- If department funded ⇨ Accounts Payable (ap@towson.edu)
- If grant funded ⇨ OSPR administrator

If requesting your funds for payment in advance, you will want to complete a Working Fund Advance form.

PI's will want to refer to the "Human Subjects' Incentives, Payment for Research Participation" policy document under the Forms page of the website for more information on how to gain access to funds.

# WHAT IF I NEED TO MAKE CHANGES TO AN APPROVED PROTOCOL?

During the course of a research project, the sponsor and/or PI may decide that the study procedures should be modified. The study PI should submit an amendment to the IRB whenever the PI or sponsor finds it necessary to change IRB approved eligibility requirements, study procedures or consent forms. The request to amend a previously approved application should be made in writing.

*Changes in the research may not occur until IRB approval of the amendment has received IRB approval unless there is an immediate threat to the health of a participant*. If such a situation were to occur, it would be the PI's responsibility to immediately report the event to the IRB as a protocol deviation and serve notice that an amendment to the project will be forthcoming.

Major changes to an existing project, such as a change in the aim of the study, or the degree of risk to participants may require that a new application be submitted (usually with a new title) and the old project be closed. If you are unsure of whether a new application must be submitted, consult the IRB office.

## How to Submit Amendments

To submit an amendment, the PI will send an e-mail to the IRB that summarizes the proposed changes to the protocol and the rationale for those changes. If the changes affect the risk/benefit ratio of the study, this should be addressed in detail in the e-mail. In addition, the PI must submit a modified protocol. To facilitate the review of the amendment, all changes to the protocol form should be clearly indicated using track changes, highlighting, or a different colored font. Any amendment that does not clearly illustrate in where the changes have been made will be returned to the PI for correction.

If a change affects the approved consent and/or assent form, or includes the addition or modification of existing elements on a survey or questionnaire, it will be necessary to submit these documents with the revisions clearly indicated.

## What Happens after I Submit an Amendment?

Amended applications will be reviewed as either accelerated, standard, or full board review (depending on the type of initial review and the nature of the changes requested). Applications that undergo standard review will be sent back to the original reviewer, when possible. Project amendments that are greater than minimal risk will undergo Full Board review. Applications for accelerated review must only include one or more of the following types of modifications:

1. Change in personnel (addition or removal of study personnel). CITI training certificates must be included for the addition of study personnel.
2. The addition or change in existing funding. The IRB must have record of all funding sources for a project. *Make sure to include WHERE the funding is coming from (department budget, grant funds, PI's start-up funds, etc.), the AMOUNT of funding for the project, and WHAT the funds will be used for.*

# WHAT ARE TOWSON's REQUIREMENTS FOR HUMAN SUBJECTS PROTECTIONS TRAINING?

## Human Subjects Protections Training

Human Subjects education and training is a federal requirement for all individuals engaged in research. To ensure compliance with this requirement, Towson University provides access to The University of Miami's Collaborative Institutional Training Initiative (CITI). This training, delivered completely online, is available to faculty, staff, students, and external investigators who are unaffiliated with another institution. ***ALL INDIVIDUALS*** conducting human subjects research must complete CITI training prior to IRB review. Applicants who fail to include the necessary training certifications for themselves and relevant study personnel will have their applications put on hold until these have been received by the IRB office.

Below are the instructions for registering for a free account and selecting the proper coursework to satisfy the Human Subjects Protections Training requirement.

- Go to the CITI Program Login page at: https://www.citiprogram.org/index.cfm?pageID=14&region=1&_ga=2.101396804.459768103.1512158777-1478011766.1512158777
- Click on *Register* to set up a free account
- Click on *Affiliate with Another Institution*; follow instructions
- Under Towson University Courses, Click on *Add a Course*
    - Question 1: Responsible Conduct of Research – optional
    - Question 2: *Skip*
    - Question 3: Faculty/Staff → Select *Social & Behavioral Research* OR *Biomedical Research* Students → *Students Conducting No More than Minimal Risk Research*
    - Question 4: *Not at this time, thank you*
- Hit *Submit*
- In order to enter the course, go back to the *Main Menu/My Courses Page* and click on the link to the course

The Training has 20+ modules and will take several hours to complete. Make sure to plan ahead to get the training done so that there is no delay in the review of your application. The PI must earn a score of at least 80% across all of the knowledge quizzes associated with the training.

## Are Other Collaborators in my Study Required to Complete CITI Training?

Individuals who are involved in the design or conduct of study procedures or who will have access to data with identifiers must complete the training. These individuals are considered to be "study personnel" on research involving human subjects. Study personnel who are not involved in the design and conduct of human subjects research do not need to comply with this requirement. For example, an individual simply distributing consent forms in the PI's personal classroom (to help the PI avoid coercion) or an individual involved solely in the analysis of de-identified data are not required to complete Human Subjects Protections training. Third party study personnel and consultants must comply with the education requirement if they are involved in the design and conduct of the research.

## What if I Have Completed Human Subjects Protections Training through a Different Program (i.e., Not CITI Training)?

Any Human Subjects Protections Training that will satisfy the Federal Government's training requirements will be acceptable to the Towson University IRB as evidence of compliance with this requirement. The PI will still need to submit evidence of completion of the training in the form of a completion certificate.

## How Many Times Will I need to Complete the Training?

Human Subjects Protections Training must be renewed every three years at Towson. This requirement of recertification is to ensure that PI's are maintaining their knowledge on human subjects protections for data collection, informed consent, etc., as well as remaining aware of any updates to federal regulations and policies. PI's will need to complete the renewal course prior to the expiration date of their previous training to maintain their approval status on existing protocols. Failure to do so will result in the suspension or termination of an active protocol.

# WHAT SHOULD I DO IF THERE IS AN UNANTICIPATED PROBLEM OR A DEVIATION FROM THE APPROVED PROTOCOL?

It is the responsibility of the PI, or Faculty Advisor if the PI is a student, to report to the IRB any adverse events, deviations from the approved protocol, or other unanticipated problems. There are two types of reports that need to be made to the IRB: protocol violations or incident reports.

## Definitions of Problems or Events that Must be Reported to the IRB

### What are Unanticipated Problems? [2]

An **Unanticipated Problem** is defined as any occurrence as part of the research that meets all the following criteria:

1. The event is unexpected (in terms of nature, severity, or frequency) given either the research procedures and/or the participant characteristics;
2. There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
3. The event suggests that the risk/benefit ratio has changed (i.e., there is greater risk to participants or others than originally anticipated).

For example, an unanticipated problem may involve an unexpected or unforeseen side effect of a medication or a more intense emotional reaction to study procedures than expected. In general, the unanticipated event will be of such a magnitude that it will require corrective actions or changes to the protocol to prevent its recurrence.

### What are Adverse Events?[3]

An **Adverse Event** is any "abnormal sign, symptom, or disease" (either physical or psychological) that is experienced by a participant during their involvement in a research study that may or may not be related to the individual's participation in the research. Adverse events can include the following: a participant is hospitalized for a medical or psychological event; a participant dies while involved in research; a participant develops a serious allergic reaction that may be related to a study medication; etc.

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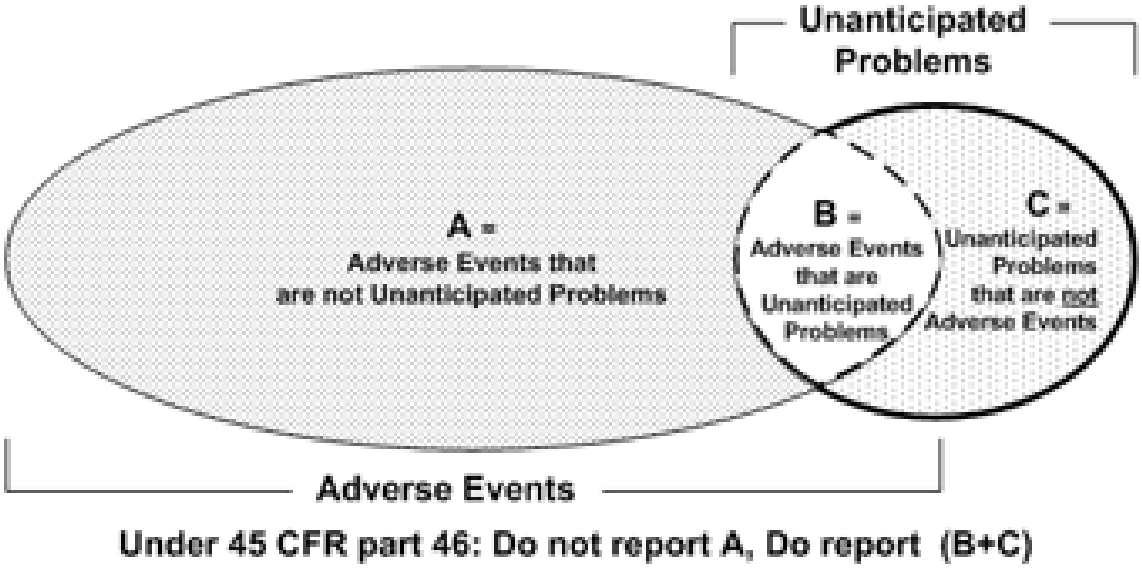
[2] Department of Health and Human Services (USDHHS) Office of Human Research protection (OHRP) (2007). *Unanticipated Problems Involving Risks & Adverse Events Guidance*. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1

[3] Department of Health and Human Services (USDHHS) Office of Human Research protection (OHRP) (2007). *Unanticipated Problems Involving Risks & Adverse Events Guidance*. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1

### *When are Adverse Events considered Unanticipated Problems?*

USDHHS OHRP offers the following Venn Diagram to illustrate when Adverse events are considered Unanticipated Problems as well as when Adverse Events and Unanticipated Problems should be reported to the IRB.



[4]

This diagram suggest that most adverse events are NOT unanticipated problems and therefore do not need to be reported to the IRB. If an adverse event is (a) unexpected, (b) related or possibly related to participation in the research and (c) suggests that the risks to participants or others is greater than known or expected, then it must be reported to the IRB. The IRB will determine if the adverse event must be reported to OHRP.

## What are Protocol Violations and Deviations?

A **Protocol Violation** (aka breach of protocol) is any procedure that occurs during the conduct of a study that is NOT part of the IRB approved protocol. Examples of protocol violations include the following: (a) having an individual undergo study procedures prior to providing written informed consent; (b) learning the identity of a participant when the study is supposed to be anonymous; (d) breaching confidentiality of study participants by revealing their identity outside of the research team; (e) etc. These protocol changes may affect the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

A **Protocol Deviation** is any incident that is not a protocol violation but may still has the potential to negatively impact participants. Examples of Protocol Deviations include problems during study recruitment or the informed consent process, such as a third-party software platform accidentally

[4] Department of Health and Human Services (USDHHS) Office of Human Research protection (OHRP) (2007). *Unanticipated Problems Involving Risks & Adverse Events Guidance*. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1

collecting IP addresses in an anonymous study or inadequate screening of participants for inclusion/exclusion in a study.

Protocol Violations/Deviations should be taken very seriously. The IRB has the authority to terminate the study if it is found that the study presents more harm to participants or others than originally expected, if a violation(s) has occurred more than once in the same protocol, or if a PI failed to notify the IRB of an existing violation. Once the IRB office receives a report on a protocol violation, the Towson University Institutional Official will be notified in writing, and a formal report will be submitted to the Office for Human Research Protections (OHRP). Protocol violations require a quorum of IRB members to conduct a full board review of the violation to determine its impact and severity, corrective actions to be taken, and the status of the study going forward. Protocol Deviations, however, do not require a full board review by the IRB, but will be referred to the IRB chair and/or vice-chair for review of corrective actions taken and for further guidance.

## How do I Report Unanticipated Problems, Adverse Events, or Protocol Violations to the IRB?

The PI must notify the IRB in writing as soon as an Unanticipated Problem, Adverse Event, or Protocol Violation has been discovered. The report should include the study title, IRB approval number, date of the event, a detailed description of what happened, personnel involved, and any corrective actions taken. The Protocol Incident Report or Violation Form (found on the IRB Forms Page) may be completed as a starting point for submitting a report to the IRB; however, additional documentation should be attached to provide more detail.

*NOTE: If a PI is unsure of whether something qualifies as a protocol “deviation” or a “violation,” an unanticipated problem, or an adverse, they should consult the IRB for guidance. No matter the type of event, PI’s are obligated to make a good faith effort to resolve any study-related concern or complaint they receive.

## What are Towson's Recommendations for Ensuring Data Security?

Personal information (data) collected for research purposes by a Towson PI is jointly owned by the researcher(s) and the University. All data should be stored and secured in an approved University location or device. PIs are at risk of data breaches and jeopardizing their research if the necessary steps are not taken to ensure data security.

The Office of Technology Services (OTS) has developed a document on Data Use Standards for information on the proper safeguarding and classifications of data. PIs should also refer to the OTS website for the TU policies on data storage and additional resources.

# APPENDIX A. STANDARD CONSENT FORM/INFORMATION SHEET TEMPLATE

**TITLE OF STUDY**

| | | | | | |
|---|---|---|---|---|---|
| Investigators: | Full Name | | Full Name | | Full Name |
| Phone: | Phone # | | Phone # | | Phone # |
| E-mail: | e- | mail | e | -mail | e-mail |

**Purpose of the Study**: *In this section please describe the specific purpose or aims of the study. Although you do not need to explicitly state your hypothesis, you should give a general sense of what you are investigating. It is in this section that you will indicate that the study involves research.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Procedures**: *In this section, you will inform participants about what they can expect to happen. Specifically, you should provide a step-by-step description of the specific study procedures including the method of recruitment, the informed consent process, as well as any study procedures they will be asked to complete. You should also give an overview of the types of questions that will be asked. Participants should also be informed about how long the procedures are expected to take.*

*If the study involves more than one data collection period, this needs to be specified. You should discuss how many sessions they will be expected to attend, how long each session will last as well as when and how they will be scheduled.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Inclusion/Exclusion Criteria**: *At minimum, this section should include the age range of participants. You may also include any procedures to which the subject must consent in order to participate in the study as well as any characteristics that must or must not be present for the participant to be eligible.* To participate in this study, you must be <*specify age range or minimum age*>years. <*Specify any other inclusion or exclusion criteria if applicable. Note also if there is any procedure that they must agree to do in order to participate; i.e., you must agree to … in order to participate.*>

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Risks/Discomfort**: *In this section, you will inform participants about any risks (e.g., physical injury; loss of confidentiality) or discomforts (e.g., becoming upset) associated with their participation. Each potential risk or harm should be described in its own paragraph followed by an explanation for how that risk will be minimized. If there are no foreseeable risks, you may indicate this here.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Benefits**: *In this section, you should inform participants about the anticipated benefits of the research. Research benefits are the potential impact the study findings will have on understanding or treating a societal problem. Participants may benefit directly from their participation but this is not a requirement.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Alternatives to Participation**: *In this section, you inform participants that their participation is voluntary and that they have the right to withdraw or discontinue their involvement in the study at any time. If you are offering treatment, you must tell participants other ways they can get treatment without participating in the study. If students are being offered extra credit for their participation, then they must be offered other opportunities to earn extra credit without participating in the study.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Cost Compensation**: *In this section, you will inform participants either that they will not be compensated for their participation or how, when, and how much they will be compensated*.

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Confidentiality**: *Data collection can be considered anonymous when there is no reasonable way to link the person's identity to their responses either directly or through identifiers. If you are collecting identifying information and maintaining a list of names and unique identifiers so the person can be linked to their responses, then your study is confidential but NOT anonymous. In this section, you must describe the measures you are taking to ensure that the participants' data and identities are either anonymous or confidential. This includes methods of data collection, transmission (if data are being shared among 2 or more sites), entry, storage, and dissemination.*

*For studies collecting sensitive information that, if released outside of the study, could place the person at risk for legal or civil liability or be damaging to their reputation or employability, PI's will be expected to obtain a certificate of confidentiality (COC) from the federal government. A COC protects the PI and their research team from being compelled by court order or subpoena to release any information about research participants. For information about COCs and how to apply for them, see XXX in the PI Instruction Manual. The federal government provides required language to include in consent forms that have COC's protecting the confidentiality of participant data.*

*If the study makes use of data panels, the PI should familiarize him/herself about the Data Privacy Policies and provide participants with a URL to those policies in case they want to become more informed about if/how the company managing the data panel makes use of any data collected.*

*See Consent Template Recommended Language for Suggested Stems, Examples and Required language (if appropriate).*

**Limits to Confidentiality (OPTIONAL)**: *If your study involves collection of reportable behavior or there is a risk of a medical injury, you will be required to include this section. See*

**Contact Information**: *Required language for this section is included below*.

If you have any questions regarding your rights as a research participant please contact 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. If you have questions about the study or if you wish to withdraw your consent, please contact the Investigators, <*include PI and Co-PI's names and contact information or if the PI is a student, the name and contact information for the Faculty Advisor*>.

***IF AN INFORMATION FORM IS BEING USED, INCLUDE THE FOLLOWING:***

Thank you in advance for your participation!

Signed:

_____ _____

*PI's Signature* *Faculty Advisor's Signature*

***IF A WRITTEN INFORMED CONSENT FORM IS BEING USED, INCLUDE THE FOLLOWING:***

**Disclosures**:

By signing this consent form, I am indicating my understanding that (a) I am participating in a research study; (b) my participation is completely voluntary and that I can withdraw my consent at any time without penalty; and (c) I do not have to answer any questions I do not want to answer.

_____ I have read and understood the information on this form and have had any questions answered to my satisfaction

_____ _____

Subject's Signature Date

_____ _____

Witness to Consent Procedures Date

***IF THE STUDY IS BEING CONDUCTED ONLINE, INCLUDE THE FOLLOWING***:

By clicking YES below, I am indicating my understanding that (a) I am participating in a research study; (b) my participation is completely voluntary and that I can withdraw my consent at any time without penalty; and (c) I do not have to answer any questions I do not want to answer. If you do not wish to participate, please click NO.

# APPENDIX B. CONSENT TEMPLATE RECOMMENDED/REQUIRED LANGUAGE

The recommended or required language for each section of the consent form is listed below. If specific language is not required, you are provided with some suggested stems to begin each sentence of the section. The standard consent form MUST INCLUDE all REQUIRED sections and may include OPTIONAL sections if appropriate.

**Purpose of the Study (REQUIRED)**

*Suggested Stems*

The purpose of this research study is to…
The current research study will investigate…

*Examples*

The purpose of this research study is to examine predictors and consequences of problematic substance use among college students.

The current research study is testing the effectiveness of two different approaches to enhancing the accuracy of eyewitness testimony

**Procedures (REQUIRED)**

*Suggested Stems*

If you decide to participate, you will be asked to… You will also be asked questions about… The entire study should take approximately…

*Examples*

If you decide to participate in this study, you will be asked to complete a number of paper and pencil, self-report measures. These questionnaires will ask about your personal characteristics, personality, drug and alcohol use, as well as sexual history. It should take you no more than 30 minutes from start to finish.

After providing informed consent, you will be assigned to either an experimental treatment group or a control group. You will not be told which group you have been assigned to.

If you agree to participate, you will expected to come to the lab three times over a period of 6 weeks (i.e., once every two weeks). The first session (today) will take about 2 hours. The remaining two sessions will take no more than an hour each. A research assistant will contact you via text, e-mail and/or telephone to schedule each of your appointments. OR At the end of this session, the research assistant will schedule each of the follow up sessions.

**Inclusion/Exclusion Criteria (REQUIRED)**

*Suggested Stems*

In order to participate in this study, you must… You may not participate in this study if…

*Examples*

To participate in this study, you must be between the ages of 18 and 25 years. You must also agree to have your heart-rate recorded. You may not participate in the study if you are a current

smoker, have a history of cardiovascular or neurological disease, have known cardiac arrhythmias, or have a pacemaker.

**Risks/Discomfort (REQUIRED)**

*Suggested Stems*

To our knowledge, there is no risk (or possible harm) to you from your participation in this study.

There are some risks involved in this study that you should know about. One potential risk is…

*RECOMMENDED/REQUIRED LANGUAGE*

*If the study may cause distress, use the following language (REQUIRED)*:

You may experience distress when answering certain questions or completing study procedures. If you become upset, you can discontinue the study at any time without penalty. You may also skip any questions you do not want to answer. If you are experiencing distress for any reason, whether related to the study or not,…

If participants are TU students on the Main Campus finish the stem as follows: … you are encouraged to seek services through the Towson University Counseling Center. You may find information about the counseling center, as well as contact information, at the following website: http://www.towson.edu/counseling/. You will also be provided with a list of resources you can access if you are experiencing distress, whether or not it is related to your study participation. If you have a crisis at a time when TUCC is not available, please call the **National Suicide Prevention Lifeline** 24/7 at 1 (800) 273-8255.

If participants are TU students on the TUNE campus, finish the stem as follows*: …* you may contact the Towson University Counseling Center (TUCC) on the main campus in Towson, MD for an evaluation. Following that meeting, staff at TUCC will refer you to a therapist in your local area. If you do not wish to travel to Towson, you may contact Margie Tversky (Phone: 410/704-3285; mtversky@towson.edu), Director of Student Services, who can help you with a referral to a community provider in your area. If you have a crisis at a time that it outside regular business hours, please call the **National Suicide Prevention Lifeline** 24/7 at 1 (800) 273-8255.

If participants are not TU students, finish the stem as follows: …you are encouraged to see your own mental health provider (if you have one) or contact the **National Suicide Prevention Lifeline** 24/7 at 1 (800) 273-8255.

*If the study involves the possibility of physical health consequences such as illness or injury, use the following language (RECOMMENDED)*:

There is a risk that you could <*select one*> get injured from completing the study procedure; experience a medical crisis. <*list or describe all possible health risks involved*> In the event this occurs, staff are trained to… <*describe the credentials of the staff and their ability to handle a medical crisis; note any specialized medical devices, such as AEDs that are available*> You must understand that neither the PI nor Towson University will pay for any medical care or hospitalization you may require from a research-related injury. You, and or your insurance, will have to pay for any medical costs incurred.

*If there is a potential financial cost to participants (e.g., if the study involves sending text messages and participants are responsible for any costs incurred as a result, use the following language (RECOMMENDED)*:

The study involves sending text messages to you. You should understand that you will be responsible for covering the costs associated with sending or receiving text messages for the purposes of this research.

**Benefits (REQUIRED)**

*Suggested Stems*

You are not expected to benefit in any way from your participation in this research. However, the results of the study will help…
The current study will help us to… You may benefit from your participation by <*specify how*>

*Examples*
You are not expected to benefit in any from your participation in this study. However, results of this research will help us understand the factors that contribute to problematic substance use among college students.

The current study is intended to help use evaluate whether a new approach to treating social anxiety is effective. You may benefit from your participation in that you may experience an improvement in your symptoms of social anxiety.

**Alternatives to Participation (REQUIRED)**

*Suggested Stems*
If you do not want to participate in this study, …

*REQUIRED LANGUAGE ABOUT VOLUNTARY NATURE OF PARTICIPATION*
Participation in this study is voluntary (that is, it is up to you whether or not to participate). You are free to withdraw or discontinue participation in this study at any time without…

<*choose one of the following to end the second sentence*> affecting any compensation to which you are already entitled; affecting your standing with the university or your grade in your class; penalty.

You may also choose not to answer any questions that you do not want to answer.

*REQUIRED LANGUAGE ABOUT ALTERNATIVE TO PARTICIPATION*
If you do not want to participate in this study…

<*choose one of the following to end this sentence if treatment is provided or extra credit in a course is awarded*> you may seek services through ….; you will be given other opportunities to earn extra credit in this course;
<*if there is no treatment provided and no extra credit awarded, use the following*>, then do not sign this consent form; click NO at the bottom of this page.

**Cost Compensation (REQURED)**

*Suggested Stems*
You will receive no compensation for your participation in this study.
To compensate you for your time, you will receive

*Examples*

You will receive no compensation for your participation in this study.

In order to compensate you for your time, you will…

…receive X point(s) of extra credit on your final exam.

…receive $10 in cash once you have completed all study procedures

…$10 gift cards for each study session you complete for up to a total of XX$ if you complete all study sessions.

**Confidentiality (REQUIRED)**

*REQUIRED LANGUAGE*

<*For confidential* studies> To ensure the confidentiality of the data you provide, your responses will be coded using a unique identification number. A master list that links your name and unique identification number will be maintained in a locked file cabinet in the PI's office and will be accessible only to study staff. <*also include anyone else who may have access to the data; e.g., for federally funded studies, the funding agency may request to see deidentified data*> This list will be destroyed <*specify either*> after data collection has been completed <*or*> after a period not to exceed XX years after the study has been completed.

<*For anonymous studies*> To ensure your anonymity, we are not collecting any identifying information that could be used to identify you. <*If you are using an online data collection platform*> The program used to house the questionnaire will be set to remove all identifying information from the dataset including IP addresses. <*In addition, include the following*> The consent form, which has your name on it, will be stored separately from the rest of your data. We ask that you NOT place your name or other information that could identify you on your questionnaires. Any publications or reports that result from this research will not include identifying information on any participant.

<L*anguage required for online studies*> The data are being collected via the online platform <*specify*>. To address any concerns you may have about the confidentiality of data collected in this manner, please see <*specify the company's*> Data Privacy Policy at <*include the URL here*>. You should specifically look at the section entitled, <*direct participants to the relevant section of the data privacy policy*.>

<L*anguage required for studies involving data panels*> If you are a member of a data panel, the extent to which your confidentiality is guaranteed depends upon the Data Privacy Policy that you agreed to when signing up as a panel member. You should be certain to revisit the privacy policy to familiarize yourself about how/if the company managing the data makes use of any data collected by its customers.

**Limits to Confidentiality (OPTIONAL)**

*REQUIRED LANGUAGE*

<*Include some or all of the following, as relevant*> Although we will do everything we can to assure your confidentiality, the researchers are bound by Maryland law to report to Maryland Child Protective Services as well as the University President or her designee, any instances of child or elder abuse (including sexual, physical, or emotional abuse as well incest) and neglect,

regardless of when they occurred and regardless of whether you, or someone else, are/were the victim or perpetrator. The researchers are also required to intervene on your, or an intended victim's, behalf should you indicate an intention to harm or kill yourself or someone else. University System of Maryland policy also requires that the researchers inform University Officials about any instances of sexual contact between students and either faculty or staff members. Finally, in the event of a medical emergency, the research team is permitted to release any information about you that is necessary to ensure that you receive adequate medical care.

# APPENDIX C. DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA) CONSENT/ASSENT FORMS

**DEPARTMENT OF KINESIOLOGY**
**CONSENT FOR ADULTS TO PARTICIPATE IN RESEARCH INVOLVING DXA TESTING**

**Introduction**
The purpose of this *form* is to provide you information that may affect your decision to participate in this research study.

**Purpose of the Study**
The purpose of this research is to evaluate your body composition.

**Background on DXA**
DXA (or DEXA) stands for dual energy X-ray absorptiometry. It is a method by which two intensities of X-rays are scanned across the body. The resulting image is analyzed to provide estimates of body composition. This includes total body fat, lean tissue, and bone.

**Benefits**
The advantages of DXA over other body composition assessments are that the results are most accurate and highly reproducible.
This is not intended to provide a medical or therapeutic diagnosis or treatment.

**Risks**
The DXA scanner emits a small amount of radiation. Using the standard way of describing radiation exposure, from one DXA scan you will receive an effective does of **less than one thousandth of one rem (i.e. less than 1 mrem).** By comparison, the average person in the United States receives this much radiation every day from natural background sources, such as the sun and from radioactive materials that are found naturally in the earth's air and soil. The Food and Drug Administration (Title 21 CFR Part 361) and the National Institutes of Health (NIH) Radiation Safety Committee guidelines for radiation exposure allow for research subjects to be subjected to 5000 mrem per year. If you have received high dose X-ray testing or radiation treatment in the last year that may cause you to exceed this guideline, please inform the DXA operator. The table below can be used to calculate the annual radiation exposure from common medical procedures.

**Doses from Medical Procedures (x-ray, single exposure)**

| Procedure | Dose (mrem) | Procedure | Dose (mrem) |
|---|---|---|---|
| Chest | 10 | Mammogram (2 views) | 72 |
| Dental | 1.5 | CT-Full Body | 1000 |
| Hand/Foot | 0.5 | CT-Chest | 700 |
| Abdomen | 60 | CT-Head | 200 |
| Pelvis | 70 | Nuclear Medicine (injected radionuclides) | 400 |

Source: U.S. Nuclear Regulatory Commission: https://www.nrc.gov/about-nrc/radiation/around-us/doses-daily-lives.html

I certify that my combined radiation exposure from medical devices/treatments did not exceed 5000 mrem over the last year

_____ (please initial)

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**Females of childbearing potential**

If you are pregnant you **will NOT** be permitted to undergo a DXA scan. Please indicate your pregnancy status by placing your initials on the appropriate line below.

_____ I am NOT pregnant or trying to become pregnant at this time.

_____ I am pregnant and will not undergo DXA testing.

If you are unsure of your pregnancy status, and would like to undergo a pregnancy test, a test kit will be provided to you. You must complete the pregnancy test prior to undergoing the DXA scan. Your test results will remain confidential between you and the researcher. If your test result is positive, you will not be able to undergo the DXA scan. Please indicate whether the DXA operator offered to provide you with a pregnancy test kit.

_____ I was provided with the opportunity to complete a pregnancy test.

Please indicate if you refused the offer to complete a pregnancy test.

_____ I refused the opportunity to complete a pregnancy test.

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**Questions**
The Department of Kinesiology has a special committee set up to oversee the operations of the DXA protocol and facility. If you have any questions concerning your test or the DXA facility, you can contact the Kinesiology Department Chair at 410-704-2772.

**Signature**
You are deciding to receive a DXA scan. Your signature below indicates that you have read the information provided above and have decided to undergo DXA testing.

**Signature of Participant**: _____

**Date:** _____

**Signature of Investigator:** _____

**Date:** _____

**DEPARTMENT OF KINESIOLOGY**
**PARENTAL PERMISSION FOR ADOLESCENT MALES TO PARTICIPATE IN RESEARCH INVOLVING DXA TESTING**

**Introduction**
The purpose of this *form* is to provide you (the parent or legal guardian of a prospective research study participant) information that may affect your decision to allow your child to participate in this research study. If you allow your child to enroll in this research study, this form will be used as a record of your permission.

**Purpose of the Study**
The purpose of this research is to evaluate the body composition of the participant.

**Background on DXA**
DXA (or DEXA) stands for dual energy X-ray absorptiometry. It is a method by which two intensities of X-rays are scanned across the body. The resulting image is analyzed to provide estimates of body composition. This includes total body fat, lean tissue, and bone.

**Benefits**
The advantages of DXA over other body composition assessments are that the results are more accurate and highly reproducible.
This is not intended to provide a medical or therapeutic diagnosis or treatment.

**Risks**
The DXA scanner emits a small amount of radiation. Using the standard way of describing radiation exposure, from one DXA scan you will receive an effective does of **less than one thousandth of one rem (i.e. less than 1 mrem).** By comparison, the average person in the United States receives this much radiation every day from natural background sources, such as the sun and from radioactive materials that are found naturally in the earth's air and soil. The Food and Drug Administration (Title 21 CFR Part 361) and the National Institutes of Health (NIH) Radiation Safety Committee guidelines for radiation exposure allow for research subjects to be subjected to 5000 mrem per year. If your child had high dose X-ray testing or radiation treatment in the last year that may cause him to exceed this guideline, please inform the DXA operator. The table below can be used to calculate the annual radiation exposure from common medical procedures.

**Doses from Medical Procedures (x-ray, single exposure)**

| Procedure | Dose (mrem) | Procedure | Dose (mrem) |
|---|---|---|---|
| Chest | 10 | Mammogram (2 views) | 72 |
| Dental | 1.5 | CT-Full Body | 1000 |
| Hand/Foot | 0.5 | CT-Chest | 700 |
| Abdomen | 60 | CT-Head | 200 |
| Pelvis | 70 | Nuclear Medicine (injected radionuclides) | 400 |

Source: U.S. Nuclear Regulatory Commission: https://www.nrc.gov/about-nrc/radiation/around-us/doses-daily-lives.html

I certify that the combined radiation exposure to my child from medical devices/treatments did not exceed 5000 mrem over the last year

_____ (please initial)

**Questions**
The Department of Kinesiology has a special committee set up to oversee the operations of the DXA protocol and facility. If you have any questions concerning your test or the DXA facility, you can contact the Kinesiology Department Chair at 410-704-2772.

**Signature**
You are deciding to allow your child to receive a DXA scan. Your signature below indicates that you have read the information provided above and have decided to allow your child to undergo DXA testing.

**Printed name of child:** _____

**Signature of Parent or Legal Guardian**: _____

**Date:** _____

**Signature of Investigator:** _____

**Date:** _____

**DEPARTMENT OF KINESIOLOGY**
**ASSENT FOR ADOLESCENT MALES TO PARTICIPATE IN RESEARCH INVOLVING DXA TESTING**

**Purpose of the Test**
The purpose of this study is to measure the density of the bones, muscles and fat in your body.

**Background on DXA**
DXA (or DEXA) stands for dual energy X-ray absorptiometry. It is a method that uses X-rays to produce an image that helps us to measure your total body fat, muscle, and bone mass. The test takes about 5 to 10 minutes to complete. During that time, you will lie on your back while the scanning arm passes over your body.

**Benefits**
The advantages of DXA over other body composition assessments are that the results are more accurate and highly reproducible.
This is not intended to provide a medical device but you may find it helpful to know how much muscle and fat you have on your body.

**Risks**
The DXA scanner emits a small amount of radiation. Using the standard way of describing radiation exposure, from one DXA scan you will receive an effective does of **less than one thousandth of one rem (i.e. less than 1 mrem).** By comparison, the average person in the United States receives this much radiation every day from natural background sources, such as the sun and from radioactive materials that are found naturally in the earth's air and soil. The Food and Drug Administration (Title 21 CFR Part 361) and the National Institutes of Health (NIH) Radiation Safety Committee guidelines for radiation exposure allow for research subjects to be subjected to 5000 mrem per year. If you had high dose X-ray testing or radiation treatment in the last year that may cause you to exceed this guideline, please inform the DXA operator. The table below can be used to calculate the annual radiation exposure from common medical procedures.

**Doses from Medical Procedures (x-ray, single exposure)**

| Procedure | Dose (mrem) | Procedure | Dose (mrem) |
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| Chest | 10 | Mammogram (2 views) | 72 |
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| Abdomen | 60 | CT-Head | 200 |
| Pelvis | 70 | Nuclear Medicine (injected radionuclides) | 400 |

Source: U.S. Nuclear Regulatory Commission: https://www.nrc.gov/about-nrc/radiation/around-us/doses-daily-lives.html

I certify that the combined radiation exposure from medical devices/treatments did not exceed 5000 mrem over the last year

_____ (please initial)

**Questions**
The Department of Kinesiology has a special committee set up to oversee the operations of the DXA protocol and facility. If you have any questions concerning your test or the DXA facility, you can contact the Kinesiology Department Chair at 410-704-2772.

**You should know that:**
You do not have to complete this test and will not be in trouble from your school or the DXA operator. Your parent/legal guardian has been asked if it is okay for you to be tested. Even if your parent/legal guardian said it is OK to be tested, it is still your choice whether to have the test. You can ask questions before or after the test. If you have questions when you leave the laboratory, you may contact the above number at any time.

**Signature**

By signing this form, you (1) understand what you will be doing during the test, (2) have had all your questions answered, (3) have talked to your parent/legal guardian about this test, and (4) agree to do this test.

**Printed name:** _____

**Signature**: _____

**Date:** _____

**Signature of Investigator:** _____

**Date:** _____