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

WHAT ARE MY RESPONSIBILITIES AS A PRINCIPAL INVESTIGATOR (PI) OR

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;

Revised:

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 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 A

- 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

Table 1. Accelerated Review Categories

No.	Category Description	Definition of Terms
1	Research conducted in established or commonly accepted educational settings, that specific ir normal educational practices that are not likely to adversely impact students' opportunity to learn	

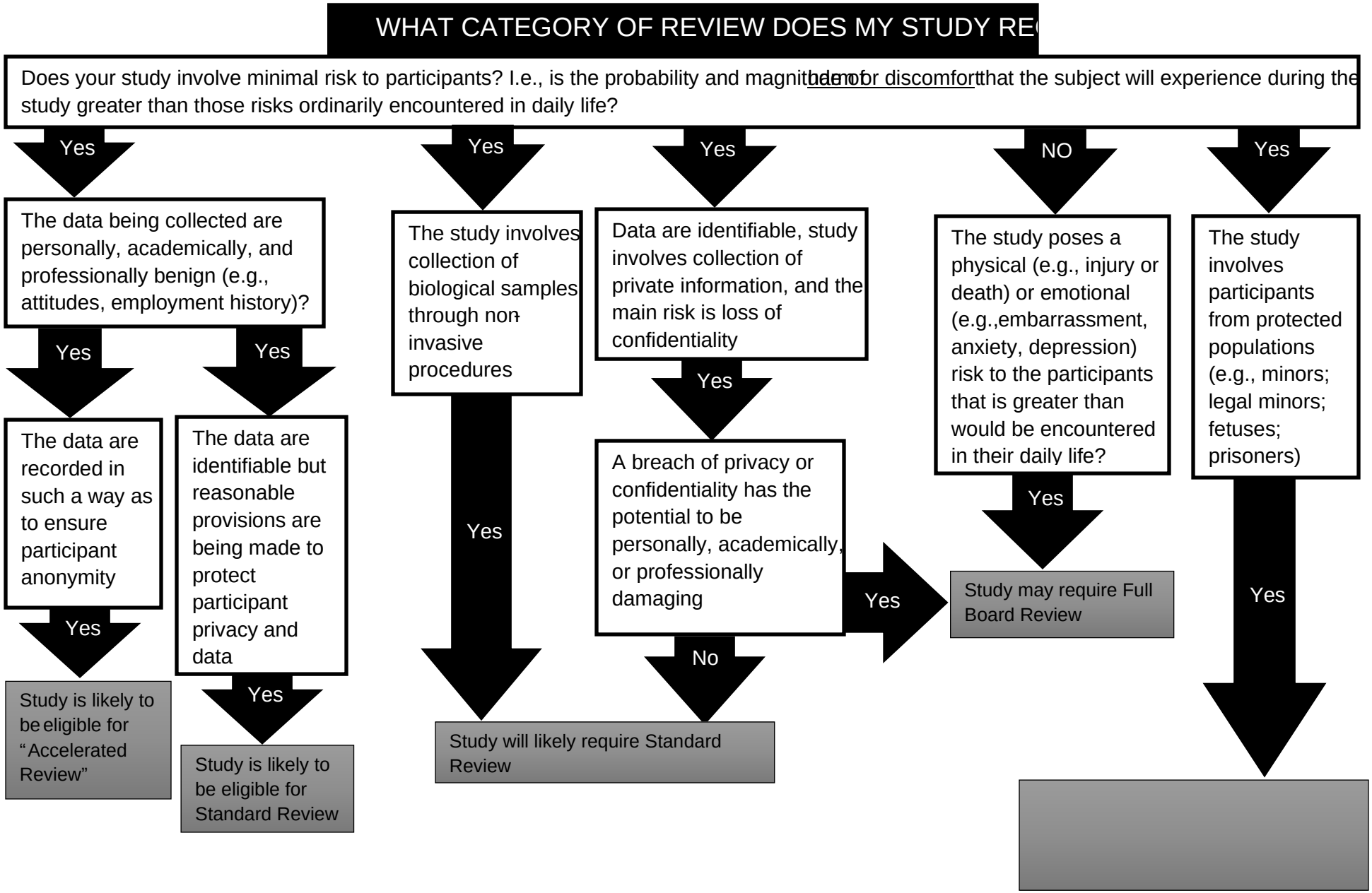
may be sufficient to mitigate the risk and therefore could qualify the study for standard review. Studies involving potential physical or emotional harm will always require Full Board Review.

Table 2a. “Expedited” Research Requiring Standard Review (continued)

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

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

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

a.

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 c lev6327c (o)-9.6 (rs).9 (ic)-1 (ad)2.2 (ab)2.2 eTw [o-4.3 ( )roa-2.5 (

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 abos.4 (ab)13.1 (o w.6 (m)-6w8-c3 (e)f2.3 (e)6ye)-2 (is)-1(ab)13.1a(?)]TJ 0 g /1 (h

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.

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.

Revised:

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.

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 INDIVIDUALSr74.14 r74.14

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 (il(e I)-714 (.(m)4.).ts(Th)5.E-an <(m7 (Tc -0.009 Tw 4.574(m)4.7 (.6 (u)5.3.

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

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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, to include PI and CPI's names and contact information or if the PI is a student, the name and contact information for the Faculty Advisor.

APPENDIX B. CONSENT TEMPLATE RECOMMENDED/REQUIRED LANGUAGE

The recommended or required language for each section of the consent form is listed below. If specific

Examples

Youwill 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

> TTw -21.9y3 (n)2.3 (t)7.9 (fo)-6.ic6-01 (72)-2.2 (>.-.002.6)-2.9 (11.1 o)-3.6 ny pu.441 ogwil4et((e)-3

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.

_____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

Printed name of child: _____

Signature of Parent or Legal Guardian _____

Date: _____

Signature of Investigator: _____

Date: _____

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