WIDENER UNIVERSITY

**INSTITUTIONAL REVIEW BOARD**

APPLICATION AND CONSENT FORM COMPLETION INSTRUCTIONS

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GENERAL APPLICATION INSTRUCTIONS

## Initial/First Time Applications

Please complete and submit the following materials for all applications regardless of the level of review being requested:

1. one electronic copy submitted via https://sites.widener.edu/irb/submissions/.

**When submitting the electronic application to the IRB, please include your last name in the file names. Not doing so will delay the review of your application.**

ALL applications should be submitted as a **WORD document in** **a single file**. Signed forms, materials or attachments in a PDF format may be submitted separately in a single file (applicants may only submit two files).

Application materials requiring a **Full Committee Review** must be received no later than two weeks prior to the scheduled date of the IRB committee meeting. **Exempt and Expedited Reviews** are not subject to committee meeting deadlines and can be submitted at any time.

Applications **will not** be reviewed until the complete electronic application, including appropriately signed forms (Assurance and Conflict of Interest forms), is received by the IRB.

Please visit the Widener University IRB website (www.widener.edu/irb) for the schedule of meeting dates and to download any application materials.

Please allow a minimum of two weeks for the committee to respond to a submission for exempt and expedited reviews, once all materials have been submitted**.** Applications requiring a full committee review can take longer.

## Revised/Resubmitted Applications

If you are requested to **re-submit/revise** your application or related materials, please do all of the following:

1. create a revised version of the application that addresses all of the points identified by the committee using the track changes feature in Microsoft Word
2. in a separate letter, respond with bullets or outline the points for each recommendation made by the committee by indicating the specific change that was made; and
3. submit the electronic copies via the website, at https://sites.widener.edu/irb/submissions/.

Please allow two weeks for a response to a resubmission**.**

PART A: APPLICATION

Answer all of the questions in the section. A response is required in each of the sections of the application. An incomplete application will be returned without review which will delay the review process.

Applications will not be reviewed until the electronic copy of the IRB application and ALL necessary supporting documents have been uploaded.

For *students submitting* applications, review will not occur without the signature of your faculty adviser indicating that the proposal has been reviewed and approved.

PART B: BRIEF SUMMARY OF THE EXPERIMENTAL PROTOCOL

In the summary of the proposed research protocol, please address **ALL** of the following elements:

1. Purpose

* State the rationale for your research study and include a purpose statement.

2. Background and Review of the Literature

* Describe the background for the study, including a brief literature review with supportive references.
* Please limit the background to a maximum length of three double spaced pages.
* Clearly identify your research question(s) or hypotheses in this section.

3. Participants & Recruitment Procedures

* Identify the anticipated sample size or number of participants that will be involved in the study.
* Indicate the approximate age of participants. Participants under 18 years of age will require a parental/guardian consent process and a child assent process.
* List the participant inclusion and exclusion criteria.
* Describe the screening process that will be implemented to ensure that the participants meet the study enrollment requirements identified as part of the study inclusion and exclusion criteria.
* Indicate where participant recruitment will occur. Identify if permission is required to recruit from the identified locations or in the manner identified. When permission is required, a signed letter on the organizational letterhead is required to be submitted with the application. E-mails will not be accepted. The application will not be reviewed until the necessary permissions have been provided.
* Indicate who will be responsible for recruiting study participants.
* Describe the recruitment procedure indicating (1) when, (2) where and (3) how the participants will be recruited, contacted, selected, and assigned to groups.
* Include copies of all recruitment materials with the application.
* When creating recruitment materials which can include printed, audio/video or electronic materials, please address all of the following: (1) the study title, (2) a simple and concise description of the study purpose, (3) a clear statement that the activity and recruitment are for research purposes, (4) general eligibility criteria for participation, (5) amount of time required to participate in the study, (6) a general and concise description of the study procedure, (7) investigator contact information, and (8) notice of IRB review and approval for the solicitation of study participants.
* For minors under 18 years of age, parental or guardian consent and child assent are needed. The process of obtaining parental/guardian consent and child assent must be described in detail. The IRB website contains templates to help with the creation of the assent form.

4. Data Collection Instruments & Materials

* Describe the apparatus, stimuli, questionnaires, or any type of measures to be used in the study.
* Include copies of all questionnaires, interview guidelines, and measures to be used.
* Briefly describe the psychometric properties of the instrument(s).
* Describe the demographic data that will be collected as part of the study.
* If conducting a qualitative study, provide a listing of the questions that will be asked.

5. Methodology

 Informed Consent Procedure

* If an informed consent process is not necessary, please provide a rationale (for example, archival data collection).
* Describe the informed consent and/or assent procedure, including **who** will be explaining the process to participants, **when** and **where** the consent and/or assent procedure will occur and **how** the process will occur.
* If indicated, describe the child assent process and indicate **who** will be explaining the process to participants, **when** and **where** the consent and/or assent procedure will occur and **how** the process will occur.
* If the participant is unable to read the informed consent document due to language or literacy problems, describe the process that will be used to obtain informed consent.

**Study Procedure or Protocol**

* Identify the research design that will be used in the study
* Identify where data collection will occur.
* Indicate who will be collecting the data
* Describe each step of the procedure or study protocol, including the instructions participants will be given and if appropriate, any experimental manipulations that will be administered.
* For data that is archival, please also indicate how and when the data were collected and the intended purpose of the original data collection. Indicate if prior IRB review was conducted.

Data Analysis Procedure

* Identify the independent and dependent variables.
* Include a brief description of all data analysis procedures.

Amount of Time Required for Study Completion

* Indicate how much time will be required for the participant to complete the study.

**6. Ethical Issues**

**Risk.**

* Describe the possible risks to which participants will be exposed and what will be done to minimize such risks. Please consider the guidelines listed below.

**Guidelines for Determining Risk.** Risk relates to the probability of harm or injury - physical, psychological, emotional, social, economic, legal - occurring as a result of participation in a research study. Risks also include invasion of privacy and loss of confidentiality.

Types of risk include: (1) physical - exposure to minor pain, discomfort or injury from procedures that may be permanent or transient; (2) psychological - undesired changes in thought processes and emotion (e.g. episodes of depression, confusion, feelings of guilt, stress and loss of self-esteem, invasion of privacy), which may be transitory, recurrent or permanent; (3) social, legal and economic harm - invasions of privacy and breaches of confidentiality may result on embarrassment within one’s business or social group, loss of employment, loss of insurability or criminal prosecution. Areas of particular sensitivity include HIV / AIDS, information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior.

**A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**
Internet research involving recruitment of subjects through Facebook, chat rooms, and other social mediums, as well as research methodology involving electronic surveys, cell phones and other mobile devices may be associated with breaches of confidentiality, invasion of privacy, mixed or comingled data, track ability or secondary data analysis by social media data, access by 3rd parties, digital malfeasance and lost devices.

* Describe how the investigator and the study design or methodology will minimize potential study risks.

* Indicate who will be responsible for the liability associated with the occurrence of the risk, i.e. who will assume the cost associated with the consequences of the identified risk occurring. If the study participant assumes liability for any and all study risks, please indicate.

**Benefits.**

* Describe the possible benefits for the participant associated with study participation. Compensation in the form of payment for study participation, entry into a drawing or course credit are not benefits. If there are no anticipated benefits clearly indicate in the application.
* Indicate the benefits for the larger society that will result from the study being conducted.

**Confidentiality.**

* Check the appropriate box indicating how long the data will be kept.
* Indicate where the data will be stored.
* Describe how the data will be stored, including both paper copies and any electronic copies.
* Discuss how participant’s rights to privacy and confidentiality will be protected by the study methodology and data storage process.
* For studies that are anonymous, describe how the data collection process ensures that the investigator is unable to link participant identity to specific responses.

**Alternate Therapies or Procedures.**

* Check the appropriate box that describes the alternative procedure that will be made available to the participant.
* Indicate the alternatives for participants who (1) do not want to be in the study after being approached for recruitment or (2) elect to drop out of the study after agreeing to be a participant in the study.

**7. Compensation**

* Describe any type of compensation that the participant might receive for agreeing to be in the study. Compensation includes both money and non-monetary gifts.
* Describe what is required to receive compensation, such as completion of the study.
* Indicate when and how the compensation will be provided.

8. Potential Significance of the Study

* Discuss the significance of the study for society, science, and/or knowledge development.

**9. References**

* Please include a brief listing of study references included in the application.

**10. Appendices & Attachments**

* Check off the types of materials that will be included with the application.
* When submitting additional supportive materials electronically, use the following naming convention: Appendix# - Investigator’s Last Name
* In the body of the application, please reference the specific appendix for the materials that were submitted separately from the application.
* Letters verifying cooperation and/or access to data (e.g., from other institutions or individuals), approvals from other Institutional Review Boards and recruitment materials. All letters must be on the institution’s or supporting individual’s professional letterhead and must be signed and dated.
**E-mail communications are not acceptable.**
* Types of Attachments (Any supporting materials that could not be included in the application document must be included in a single file that is submitted with the application document)
	+ **Recruitment Materials.** Copies of any e-mails, letters or posters/flyers that will be used to recruit participants have been included in the application or as an appendix.
	+ **Research Study Authorizations.**
		- Any authorizations or letters of permission necessary to access information necessary to recruit the research study participants have been included as an appendix.
		- Any authorizations or letters of permission necessary to conduct the study at a particular site or location have been included as an appendix.
	+ **Research Study Instrumentation and Materials.** All instruments used to collect data from the participants are appended to the application including demographic forms have been included.
	+ **Consent & Assent Forms**
		- Consent form using the Widener IRB template have been included.
		- Child assent form using the Widener IRB Template have been included.
	+ **Other attached materials:** Please identify the material and the relationship to the research study.

**11. Conflict of Interest and/or Disclosure Statement**

Conflicts of Interest are situations in which financial, personal, or professional situations may compromise, or have the appearance of compromising an Investigator’s professional judgment in conducting, reporting or reviewing research.

If the investigator(s) work(s) at the facility or organization where data collection will occur, describe their role.

All investigators on the application are required to provide a signed conflict of interest disclosure.

PART C: CONSENT FORM AND INFORMATIONAL LETTERS

Introduction

In preparing the consent and/or assent form, the investigator may seek the advice of the members of the Institutional Review Board.

The Consent Form Template must be used by all investigators. All areas of the template must be completed. Please use the headers contained in the template.

There are two situations in which a **signed consent** form would not be necessary: (1) the study is being conducted using archival data or (2) the study is an anonymous survey. A survey is considered anonymous if the data collected do not contain identifiers that can link the participants’ identity to their responses. However, an informational letter using the Widener University IRB template is still required. When accessing archival data, the investigator must explain in Part B of the application how the data were acquired and the intended purpose of the original data collection process.

### Informational Letters

An informational letter is one method to provide informed consent for studies that are anonymous. Studies are considered anonymous when the investigator cannot determine the identity of the participants. A survey is anonymous if the data collected do not contain identifiers that can link the participants’ identity to their responses.

Informational letters must contain the same information as a consent form with primary exception being the requirements for a signature. Informational letters must use the Widener University IRB Template. Usually a statement that reads, “My completion and return of \_\_\_\_\_\_\_\_\_\_ constitutes my consent to be a participant in the study. I can print a copy of this letter for my records.” The guidelines for creating an informational letter are the same as the consent form, which is described in detail below.

### Assent Form

Assent is an affirmative agreement to participate in a research study by someone who is younger than 18 years of age or an adult deemed not legally competent to sign documents. An assent form or process is always necessary when participants (1) are under 18 years of age or (2) are not deemed legally competent to enter into contractual agreements. For these groups, a signed agreement is still necessary, in addition to a signed agreement by any custodians, legal guardians and/or parents to allow participation in the study. All of the elements of the consent form described below must be included in the assent form. The reading level is determined by the participant’s grade level. It is the investigator's responsibility to devise appropriate assent forms. Written assent can be obtained from children as young as 7 years of age.

If an investigator chooses not to obtain written assent from children in the 1st or 2nd grade, a verbal consent/assent process must be in place. This process must be clearly described in the IRB application. The verbal consent process from children must be appropriate to their age, maturity and psychological state. The IRB application should detail the process of obtaining assent and must include a script detailing the discussion between the researcher and the child. The assent form script must also be age appropriate to the participant.

The IRB may waive the assent process only in cases where the mental, cognitive or psychological capacity of the participants is so limited that they cannot reasonably be consulted. However, consent is still necessary from the person’s parental or legal guardian.

### Consent Form

A consent form is always necessary when any data collected can be linked to the identity of the participants by the investigator. The consent form should be a brief and clear statement that is approximately 3-4 pages in length, which gives reasonable information about the study, the procedures, possible benefits and risks, the duration of the person's participation and alternative therapy, if applicable. The consent form should be a stand-alone document, meaning that a potential participant can read the document and understand what is required to be in the study without any additional explanation from the investigator.

**The consent form must be written in the first person.** The following link can provide information about first person language: H<http://en.wikipedia.org/wiki/Grammatical_person>H

The purpose of the information provided in the consent form is to facilitate the participant's ability to make a meaningful decision about being in the study. The entire consent form should be written at the level that the average 8th grader would understand. Avoid dense paragraphs using lengthy sentences.

When creating the consent form, do not cut and paste information about the procedure from Part B of the application into the consent form.

**Flesch-Kincaid Grade Level**

To assess the readability of your letters of explanation and participant consent forms, you should run these documents through the grammar check available in the Microsoft Word (most other major word processing programs have a similar feature).

This index computes readability based on the average number of syllables per word and the average number of words per sentence. A score of 8.0, for example, means that an eighth grader would be able to understand the document.

**You should make sure that the reading level of your Informed Consent Form/Letter of Explanation to participants is appropriate for your sample. For the general population, the maximum acceptable reading level for adults is 8th grade.**

**WHEN DETERMINING THE FLESCH-KINCAID GRADE LEVEL SCORE, FOCUS PRIMARILY ON THE PURPOSE AND DESCRIPTION SECTIONS (EXCLUDING SOME OF THE LANGUAGE REQUIRED BY THE IRB).**

## Consent Form Checklist

For studies that require a consent process, the investigator must complete the consent form checklist that is included as part of the application packet.

## Consent Form Content – Creating the Consent Form

The consent form should contain the following information, and usually in the order listed below:

1. **Top of Page:** At the top of the page must contain the heading "Consent Form", which is followed by the title of the study and a listing of the investigator's name(s) and affiliations.
2. **Purpose Statement:** In language understandable to lay reader, indicate (1) the general purpose of the study and(2) why the person is being approached to be a participant in the study.
3. **Description of the Study:** Describe the study and its procedures in sufficient detail to allow the reader to clearly understand the requirements of participation. Clearly indicate that the study involves research. Include a statement describing why the participant was selected to be in study. Indicate the amount of time required to participate in the study. Describe any costs associated with participation.
4. **Risks and Discomforts:** Describe **in lay language** all reasonably foreseeable risks, discomforts, and the side effects of any procedure(s). Describe the methods that will be used by the investigators to minimize any risk.

**Guidelines for Determining Risk.** Risk relates to the probability of harm or injury (physical, psychological, social, economic, legal) occurring as a result of participation in a research study. Risks also include invasion of privacy and loss of confidentiality. Types of risk include: (1) physical - exposure to minor pain, discomfort or injury from procedures that may be permanent or transient; (2) psychological - undesired changes in thought processes and emotion (e.g. episodes of depression, confusion, feelings of guilt, stress and loss of self-esteem, invasion of privacy), which may be transitory, recurrent or permanent; (3) social, legal and economic harm - invasions of privacy and breaches of confidentiality may result on embarrassment within one’s business or social group, loss of employment, loss of insurability or criminal prosecution. Areas of particular sensitivity include HIV/AIDS, information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Internet research involving recruitment of subjects through Facebook, chat rooms, and other social mediums, as well as research methodology involving electronic surveys, cell phones and other mobile devices may be associated with breaches of confidentiality, invasion of privacy, mixed or comingled data, track ability or secondary data analysis by social media data, access by 3rd parties, digital maleficence, and lost devices. There is always the potential for a loss of privacy and confidentiality.

1. **Injury Compensation Statement:** In cases where the research may pose more than a minimal physical, emotional or psychological risk to participants, a statement must be included that reads as follows:

*"Neither Widener University nor any government or other agency funding this research project will provide special services, free care, or compensation for any injuries resulting from this research. Treatment for such injuries will be at the expense of the participant and/or paid through the participant’s medical plan."*

If compensation is being provided for any injuries arising out of the study, clearly indicate the source of the compensation, how compensation can be obtained, and who to contact.

1. **Benefits:** Describe any benefits to the participant or others, now or in the future, which reasonably may be expected from the study. If no direct benefit to the participant can be expected, that should be stated.
2. **Alternative Procedures:** State appropriate alternative procedures (if available) or treatments that might be advantageous to the participant. If there are no alternatives, then indicate the alternative is to not participate in the study.
3. **Confidentiality:** The following standard statement of confidentiality must be included in all consent forms. The language may be edited to reflect an appropriate reading level for participants, as needed.

*All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. I understand that data generated by the study may be reviewed by Widener University's Institutional Review Board, which is the committee responsible for ensuring my welfare and rights as a research participant, to assure proper conduct of the study and compliance with university regulations. If any presentations or publication result from this research, I will not be identified by name.*

In addition to the required language, indicate the specific process for protecting the confidentiality of the participants.

If audio or video recordings or other forms of recorded data will be used, describe how they will be kept secure, where they will be stored, for how long and how and when they will be destroyed.

1. **Termination of Participation:**  Clearly indicate that the participant may withdraw from the study at any time and without penalty. State any consequences of the participant's decision to withdraw from the research and a description of procedures for orderly termination of participation if necessary. Also describe what happens to any data that are collected if the participant withdraws from the study.
2. **Compensation:** Describe any compensation (e.g., financial reimbursements or credit toward a course grade) for participation in the study or study-related expenses that may be distributed to the participant. Or state there will be no financial or other type of compensation for participation. If there is a “token of appreciation” for participation (e.g., pizza and soda; raffle for a gift basket, bookmark; pencils; etc.) state this. Describe process as to when and how one obtains the compensation.
3. **Questions:** The participants and/or parents or guardians should be encouraged to ask questions. If the proposed procedures are complex or involve a considerable risk, there should be adequate time provided for participants to think about and discuss their decision with the investigator or other respected person before deciding. Most importantly, the investigator should be as certain as possible that the participants understand the purpose, the procedures involved, the risks and discomforts, and the benefits, if any, of participating in the study.

The following statement must be included in the Consent Form:

*"All of my questions were answered to my satisfaction before I consented to participate in this study, but if I have any further questions about the study I may call Dr./Mr./Ms./Mx. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (this is the investigator) at telephone number \_\_\_-\_\_\_-\_\_\_\_. If I have any questions about the rights of research participants I may call Widener University's Institutional Review Board at 610-499-4110 or email them at irb@widener.edu."*
4. **Voluntary Consent:** A statement such as the following should appear at the end of the consent form just before the signatures:

 *"I am free to withdraw or refuse my consent (or to discontinue my child's participation in this study) at any time without penalty or consequence."*

1. **Signatures:** Signatures on the consent form should, in most cases, appear as follows:

I voluntarily give my consent to participate/to have my child participate in this research study. I understand I will be given a copy of this consent form.

Signatures:

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

Participant’s Name (Print)

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

Participant’s Signature Date

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form has had the study fully and carefully explained by me and have been given an opportunity to ask any questions regarding the nature, risks, and benefits of participation in this research study.

Print Principal Investigator's Name

Investigator’s Name (Print)

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

Investigator’s Signature Date

**Participant signatures are NOT required on Informational letters used for anonymous studies.**

1. **IRB Approval:**  The last item to be included on your consent form, include the following statement:

*“Widener University’s IRB has approved the solicitation of participants for the study until \_\_\_\_\_\_\_\_\_\_\_.”*

Copies of the signed consent form must be:

1. given to the person signing the form.
2. kept on file in a secured location by the investigator(s) for a reasonable time (i.e., up to 3 years following the study's completion) or longer if required for NIH or FDA-regulated studies or if required by a commercial sponsor.

PART D. CHILD ASSENT/PERMISSION FORM

An assent form is a simplified version of the consent document, written at a reading level that is appropriate for the anticipated grade level of the participant. Depending on the age and reading level of the child, a separate child assent form is required in addition to the parental or legal guardian consent form. An assent process for children or young adults is not required if the child is found incapable of providing assent. Parent or guardian consent is always required.

The Assent/Permission Form should be brief and study specific. Studies involving older children or adolescents can include more information and may use more complex language than studies involving younger children.

Assent is required for children age seven or older. Children under age seven should provide verbal agreement.

At the top of page include the title of the study and the investigator's name(s) and affiliations.

Explain the following in a manner that is appropriate to the child’s maturity level:

1. Describe why the study is being done
2. Indicate what will happen
3. Expected duration of participation
4. The reason why the child is being approached and/or selected for the study
5. Indicate participation is voluntary and withdrawing from the study at any time is possible
6. Indicate it is okay for the child to say no at any time
7. Describe the child’s other choices
8. Describe any compensation and the requirements to receive the promised compensation
9. Risks and benefits
10. To whom the child can go to ask questions about the study or in case of injury

Signatures

I agree to be in the study. I can keep a copy of this form.

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

Child’s Name (Print)

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

Child’s Signature Date

I certify that the study described above has been explained to the child in terms they could understand and that were appropriate to their age and ability to comprehend, and that they freely assented to participate in this study.

Print Principal Investigator's Name

Investigator’s Name (Print)

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

Investigator’s Signature Date

Copies of the signed assent/permission form must be:

* 1. Given to the person signing the form and the parent or legal guardian.
	2. Kept on file in a secured location by the investigator(s) for a reasonable time (i.e., up to 3 years following the study's completion) or longer if required for NIH or FDA-regulated studies or if required by a commercial sponsor.