PETITION FOR THE REVIEW OF HUMAN SUBJECTS RESEARCH

**Instructions:** Submit completed petition form and required documents to irbpetition@wittenberg.edu. For additional information on the IRB process and procedures see the [*Policy on Institutional Review Board and Procedures*](https://www.wittenberg.edu/sites/default/files/media/provost/IRB-PolicyIRBProcess-20160420.pdf). The IRB will determine the type of review required for the submitted petition. There are three (3) types of review:

**Exempt** – Research involves no more than minimal risk and all research activity involving human subjects falls into one or more specific [exemption categories](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html). Research involving only normal educational practices, educational tests, survey procedures, interview procedures, public observation, or publicly available information may be eligible for exemption. Research that collects personally identifiable information may require expedited review. Allow four (4) working days for review.

**Expedited** – Research involves no more than minimal risk and all research activity involving human subjects falls into one or more specific [expedited review categories](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html). Research that is not eligible for exempt review may be eligible for expedited review. Allow ten (10) working days for review.

**Full Board Review** – Research that involves greater than minimal risk and/or does not fall within an exempt or expedited review category must be reviewed by the full board of the IRB. Allow twenty (20) working days for review.

# 1. PROJECT TITLE (type in the space below)

# 2. PRINCIPAL INVESTIGATOR (Wittenberg faculty or staff member, or faculty advisor for student investigators)

Name: E-mail:

Department: Phone:

# 3. CO-INVESTIGATOR(S) (list all investigators by Name, Email, and Phone Number)

1.

2.

3.

4.

5.

# 4. CITI TRAINING: RESPONSIBLE CONDUCT OF RESEARCH

Submit CITI Training Completion Report for all investigators named in this proposal showing a minimum 80% pass rate on each training module. Completion Reports will be recognized for three years after which time investigators must complete refresher training. The proposal will not be eligible for approval until such time as all CITI Training Completion Reports are submitted.

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| I/we affirm that valid CITI Training Completion Report(s) is/are attached or already on file for every investigator named in this proposal.  | [ ]  Yes[ ]  No |

# 5. SUMMARY OF THE RESEARCH

1. Provide a brief summary of the proposed research. Describe the research question to be studied and the purpose of the research using language appropriate for a general audience (limit 300 words).
2. Provide the estimated beginning and end dates of the data collection time period pending IRB approval (be as specific as possible). No data collection may take place prior to approval from the IRB.

# 6. PARTICIPANT POPULATION

1. Are any of the following participant populations to be included in the research (check all that apply):

[ ]  Children (<18 years) [ ]  Prisoners [ ]  Pregnant women

[ ]  Those diagnosed with developmental delays [ ]  Those living with mental illness

If the proposed research includes any of the above sub-populations, the petition may require a full IRB review.

1. From what population will the participants/sample be drawn? What is the expected sample size?
2. Describe the demographic characteristics of the participants in your research.
3. Explain the rationale for intentional inclusion or exclusion of any subpopulation beyond convenience sampling (e.g., males only, females only).

# 7. PARTICIPANT INDENTIFICATION, RECRUITMENT, & SELECTION

Provide copies of proposed recruitment materials (e.g., email invitations, ads, flyers, website postings, recruitment letters, and oral/written scripts).

1. Describe how potential participants will be identified and how the investigator(s) will gain access to this population.
2. Describe the recruitment process (including the setting or online environment in which recruitment will take place) and how the process respects potential participants’ privacy.

# 8. INCENTIVES TO PARTICIPATE

|  |  |
| --- | --- |
| 1. Will any participants receive compensation or other incentives (e.g., free services, cash payments, gifts, parking, classroom credit, travel reimbursement) to participate in the research study?
 |  [ ]  Yes [ ]  No |

1. If yes, describe the incentive, including details of distribution. (*For studies allowing course credit for participation in research, please describe how those choosing not to participate in research can receive equivalent course credit.)*

# 9. INFORMED CONSENT PROCESS

1. Indicate the consent process(es) and document(s) to be used in the study. Check all that apply and provide copies of relevant documents.

[ ]  Informed Consent – Signed Form

[ ]  Assent – Signed Form (<18 years)

[ ]  Parental Consent – Signed Form

[ ]  Request waiver from IRB for signed informed consent

[ ]  Informed Consent – Verbal consent/Online Check box

[ ]  Assent – Verbal assent/Online Check box (<18 years)

[ ]  Other (Specify):

1. Describe the consent process. Explain when and where consent will be obtained and how participants and/or their legally authorized representatives will be provided sufficient opportunity to consider participation. If seeking approval to waive informed consent signature, provide rationale. Include copies of the Informed Consent/Assent Forms with the submission of this petition. [A template is available online](https://www.wittenberg.edu/research-ethics-compliance).

# 10. RESEARCH METHODS & ACTIVITIES

1. Mark all research activities that are involved in the proposed research and attach copies of any materials to be used (e.g., interview/focus group questions, instruments, data collection forms).

[ ]  Audio, video, digital, or image recording

[ ]  Collecting biological samples, e.g., blood, saliva.
(Note: Increased risk, other precautions will apply.)

[ ]  Existing data, publicly available

[ ]  Existing data, not publicly available

[ ]  Experiment(s)

[ ]  Focus groups or group interviews

[ ]  Ingesting substances, e.g., food or drink.
(Note: proper food storage techniques apply.)

[ ]  Observation of participants (from field notes or standardized data collection such as tally sheets)

[ ]  Surveys, questionnaires, or interviews

1. Describe the research procedures and protocols. Describe each step the researchers will take when interacting with participants and collecting the data (including interactions with different groups such as a control group and an experimental group). Attach separate documents as necessary to explain the protocols.

|  |  |
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| 1. All research involves some risk to participants, which may include physical distress, emotional distress, social distress, and/or financial distress. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?
 |  [ ]  Yes [ ]  No |

1. If yes, provide an explanation of the risks involved, and the measures taken to minimize those risks.

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| 1. Does any part of the research require deception or incomplete disclosure of information to participants? If yes, please describe the nature of the deception, the rationale, and debriefing procedures/form.
 |  [ ]  Yes [ ]  No  |

1. Where will the research take place? Please be as specific about the location of the data collection as possible (e.g., internet data collection, Wittenberg’s campus, another physical location with address).

# 11. PRIVACY OF PARTICIPANTS and HANDLING OF DATA

1. Describe how participant privacy will be protected.
2. Research-related records must be retained for a period of at least three years after the research has been discontinued (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.) If student investigators will be leaving Wittenberg within this timeframe, research-related records must be retained by the faculty advisor for the same time period. Explain how collected data (both electronic and hard copy records) will be handled, including storage, security measures, and who will have access to the information.

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| 1. Does the research require access to or collection of personally identifiable information (e.g., name, contact information, signed consent forms)?
 |  [ ]  Yes [ ]  No |

1. If yes, please describe the personally identifiable data involved in the research and list the source(s) of information (e.g., participant-reported, educational records, surveys, medical records).
2. Indicate what will happen to the identifiable data (including signed consent forms) at the end of the study.

[ ]  Identifiers permanently removed from the data and destroyed (de-identified)

[ ]  Identifiable/coded (linked) data are retained

[ ]  Identifiable data not collected

# 12. ADDITIONAL ITEMS TO BE SUBMITTED WITH THE PROPOSAL PETITION

[ ]  CITI Training Completion Reports

[ ]  Data Collection Form(s)

[ ]  Recruitment Materials (e.g., ads, flyers, telephone or other oral script, radio/scripts, internet solicitations)

[ ]  Script(s), Instructions, or Information Sheet(s)

[ ]  Instruments (e.g., questionnaires or surveys to be completed by participants)

[ ]  Consent form(s), Assent Form(s)

[ ]  Experimental protocol/procedures documents if additional sheets are needed

[ ]  Experiment stimuli materials (i.e., PowerPoint slides, audio clips, links to YouTube videos)

[ ]  Debriefing Form with Principal Investigator, Co-Investigator(s), and the IRB Chair contact information

[ ]  Completed and signed [*Financial Conflict of Interest Form*](https://www.wittenberg.edu/administration/provost/ir/sponsored-research), if applicable.

# 13. ASSURANCE: INVESTIGATOR(S)

I/We certify that all investigators listed above have read Wittenberg’s policies on the [*Protection of Human Subjects in Research*](https://www.wittenberg.edu/sites/default/files/media/provost/IRB-PolicyHumanSubjects-20160420.pdf), and the [*Institutional Research Board (IRB) and Procedures*](https://www.wittenberg.edu/sites/default/files/media/provost/IRB-PolicyIRBProcess-20160420.pdf).

I/We agree to follow all applicable policies and procedures of Wittenberg University, federal, state, and local laws, guidance regarding the protection of human participants in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators.

I/We will initiate the research only after written approval has been received from the IRB.

I /We will promptly report to the IRB events that may represent unanticipated problems involving risks to participants or others.

I/We will submit a new Petition for Review to the IRB in the case of any modifications in the research or informed consent process prior to changes being implemented.

I/We understand that IRB approval expires in 12 months. If data collection is not complete, I will seek an extension of IRB approval.

I/We will maintain and protect research-related records for at least three years after the research has ended.

**SIGNATURES OF ALL INVESTIGATORS (may be signed electronically with name and date)**

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| **Investigator Name(s)** | **Date** |
| Principal Investigator:  |  |
| Co-Investigator(s): |  |
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Form Revision Date: 05/2022 **OFFICE USE**

IRB Tracking Number:

Date Received:

Date Verified Complete: