**INSTITUTIONAL REVIEW BOARD DESCRIPTION OF RESEARCH FORM**

For Research Projects Involving Human Participants

**GENERAL INFORMATION**

**This form is to be filled out by the Principal Investigator (PI) of the research project being submitted to the Institutional Review Board (IRB) of Wesleyan University for exemption or review.**

*The required convention for IRB project labels is YYYYMMDD-username-project (e.g., 20090215-jross-memoryproj). The project label you use here should match the name you use for the folder you create to submit this document. If you would like other members of your research team to have access to the folder you create, please put asterisks after their names below.*

**Project title:**

**IRB project label:**

**Submission date:**

**Principal Investigator:**

**Affiliation:**

**Department:**

**Email:**

**Phone:**

**Faculty/Staff Advisor:**

**Advisor email:**

*Advisor name required for student submissions.*

**Research team members (investigator, affiliation, department, email):**

**Organizations affiliated with project (e.g., student groups):**

**RESEARCH OVERVIEW**

**(a) Describe the type of research being proposed by checking as many boxes as appropriate:**

**[ ] [ ]  Administrative or institutional research**

 **[ ] [ ]  Faculty research[ ]  (including student involvement in faculty project)**

**[ ]  Thesis or independent undergraduate research**

**[ ]  Thesis or independent graduate research**

**[ ]  Course-related research**

**[ ]  Off-campus research**

**[ ] [ ]  Other (describe):**

**(b) If this is faculty research funded by an external research grant (e.g., from a federal agency) to the faculty member, provide the granting agency and grant number:**

**(c) Provide a brief paragraph overview of the proposed research including the specific goal of the research and the methods by which the goal will be achieved.**

**RESEARCH EXEMPTION STATUS**

If you believe that this research is exempt from IRB review, please check any one or more of the below that jointly describe your proposal in its entirety. You should then fill out the Participants and Research Methods sections but can omit the other sections of this form. If the Board does not concur that the work is exempt, you will be asked to complete the rest of the form at that time.

[ ] [ ]  **Research conducted in established or commonly accepted educational settings involving normal educational practices such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods. The research must also not be likely to adversely impact the student’s opportunity to learn required educational content or the assessment of educators who provide the instruction. Research involving prisoners as participants is excluded from this exemption. (45 CFR 46.104(d)(1))**

**[ ] [ ]  Research that only involves use of educational tests, surveys, interviews or observations of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified directly or indirectly through identifiers linked to the subjects; (ii) any disclosure of subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or damage their financial standing, employability, reputation, or educational advancement. This exemption may include recording identifiable information (even if sensitive), provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. Research involving children may only be included in this category for education tests or observation of public behavior, and only when the investigator does not participate in the activities being observed. Research involving prisoners as participants is excluded from this exemption. (45 CFR 46.104(d)(2))**

**[ ] [ ]  Research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. Research may qualify for this exemption only if it meets the following criteria: (i) the information recorded cannot be readily linked back to the subjects in such a manner that subjects’ identity can be readily ascertained, directly or through identifiers linked to the subjects; or (ii) any disclosure of this information would not place the subjects at risk of certain harms, or (iii) the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. This exemption applies to behavioral interventions only. It is not applicable to biomedical research. Research involving prisoners, children, or individuals with impaired decision-making capacity as participants is excluded from this exemption. (45 CFR 46.104(d)(3))**

**[ ] [ ]  Research involving the collection or study of existing data, documents, records, pathological specimens, or biospecimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This exemption also applies to research using identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that 1) the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, 2) the investigator does not contact the subjects, and 3) the investigator will not re-identify subjects, or (iii) Research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities (45 CFR 46.104(d)(4))**

**Feel free to further explain why you believe an exemption is appropriate, or if your you think your research may be exempt under a different exemption category listed in the Federal Guidelines:**

**DETAILED PRESENTATION OF RESEARCH**

Some questions here will not be relevant to research methods using existing records or data sets. However, even in these cases, please try to interpret the questions in such a way that they apply to your work whenever possible. E.g., describe the types of participants in the data set you have obtained, or the data collection procedure you will use for extracting information from confidential personal records, etc.

**PARTICIPANTS**

**(a) Check all groups that are central in your study (by design or likely circumstance):**

**[ ]  Adults (18 years of age or older)**

**[ ]  Minors (below 18 years old)**

 **[ ]  Economically or educational disadvantaged persons**

**[ ]  Persons with impaired decision-making capacity**

**[ ]  Pregnant women**

**[ ]  Prisoners**

**[ ]  Other (describe):**

**(b) Please describe what types of participants you will seek out and how you will recruit them. As applicable: How will they be recruited and how many will be recruited? Are there specific eligibility or screening criteria? Will you offer incentives or compensation? Are there circumstances that might lead to the perception of coercion or undue pressure on the part of participants and, if so, how will you ameliorate this perception? Describe or separately upload recruitment flyers, letters, and/or ads.**

***Statement on AI*: Researchers, students, affiliates might collect, use, and share data as part of their research with generative AI tools. It is the user’s responsibility to review the terms and conditions of the software’s user agreement before uploading their research data to ensure their use of AI complies with all relevant data protection and privacy laws, especially when handling sensitive or confidential research data, and also that the user understands whether the AI tool is allowed to ingest supplied data to expand the AI tool’s model. If you intend to use AI for research purposes, please also describe how participant confidentiality will be maintained.**

**RESEARCH METHODS**

**(a) Check all of the research methods that you will use in your study:**

**[ ] [ ]  Observation of public behavior**

**[ ]  Educational testing or assessment**

**[ ] [ ]  Interview, focus group, or questionnaire**

**[ ]  Experimental procedures or testing**

**[ ]  Physiological monitoring**

**[ ] [ ]  Specimen collection (e.g., blood)**

**[ ]  Use of records (e.g., medical) or information that is HIPAA protected**

**[ ] [ ]  Existing data set from:**

**[ ]  Other:**

 **(b) Please describe your research procedure. As applicable: Describe the number and duration of sessions, the location where research will take place, who will interact with participants and their qualifications for doing so, what participant will be asked to do, what behaviors or other measures will be collected and how, whether audio and/or video tape will be used, and whether different participants will receive different experimental treatments. If you are using only existing data, describe the source and content of the data set, whether or not it is de-identified, and whether IRB approval was obtained for the original study. Describe or separately upload all questionnaires, interview questions, or experimental materials that you plan to use.**

**(c1) If you intend to collect data by video ( for example, Zoom), please describe how you will protect participants’ confidentiality.**

**(c2) If you intend to collect data in-person, please describe how you will follow the general University guidelines and policies to determine whether in-person data collection is permitted and for Covid-19 precautions for safety currently in force at the time the research is conducted.**

***Stop here if you have submitted a request for an exemption, otherwise continue.***

**INFORMED CONSENT**

1. **Check all of the types of informed consent that you will use in your study:**

**[ ] [ ]  Written participant consent**

**[ ]  Written parent/guardian consent**

**[ ] [ ]  Oral participant consent**

**[ ]  Oral parent/guardian consent**

**[ ]  I will not be documenting consent**

**[ ]  Other (explain):**

1. **Written consent of the participant or of his or her parent/guardian (for minors) is expected unless waived by the IRB. If you will not be obtaining written consent, please explain why. For participants under the age of 18 years old, both parental consent and participant agreement to participate (“assent”) is expected unless waived by the IRB. If you will not be obtaining some form of parental consent and participant assent, please explain why.**

1. **Please separately upload copies of consent forms. If oral consent is planned, include the verbal consent script below or in an uploaded file. Note that when written consent forms are used, a copy must be given to the research participant. If consent will be obtained electronically via the web, please describe below the procedure by which consent will be obtained.**

**TREATMENT OF DATA**

1. **Check all that describe the privacy conditions of your study:**

 **[ ]  No names or any identifying information will be collected or retained**

 **[ ]  Identifying information will be collected but will not anywhere be associated with data**

**[ ] [ ]  Identifying information will be linked to data in a file stored separately from data**

**[ ]  Identifying information will be collected and stored with data**

**[ ]  Data themselves provide identifying information (e.g., audio/video data)**

1. **Check all that apply in terms of how individual data will be reported:**

**[ ] [ ]  Names and identifying information will never be reported**

**[ ]  Names or identifying information will be reported with participant permission**

**[ ]  Names or identifying information will always reported**

1. **Please explain your privacy goals (e.g., anonymity, confidentiality, giving public recognition) and how you will ensure that these goals are met. If you will be linking participant names with identifiers to data in a file separate from the data, please explain your procedure. For confidential data, be sure to describe where data files will be stored, in what format, who will have access to them, password protection procedures, and when/how data will be destroyed. Note: Anonymity can be achieved only when no identifying is collected in any form.**

**RISKS AND BENEFITS**

1. **Please check the types of potential risks, if any, that might reasonably occur with this study:**

**[ ]  Physical or psychological risks**

**[ ]  Informational risk (e.g., if data were inadvertently made public)**

**[ ]  Risk by association with study (e.g., participant perceived as informant)**

1. **Please elaborate on physical, psychological, and informational risks to participant as well as any risks of being associated with the study. What steps are you taking to minimize these risks?**

1. **Please elaborate on whether there are specific benefits to society for your study or to the participant other than cash or other payment for participation (e.g., medical study might treat illness, etc.). If necessary, explain why you believe these benefits outweigh the risks.**

**DEBRIEFING**

**(a) If applicable, describe how individuals will be debriefed as to the purpose of the study or provided further information. If a formal oral or written debriefing sheet will be used (required for studies involving Introductory Psychology Participant Pool participants), please upload it separately.**

**CONFLICTS OF INTEREST**

**(a) Discuss any conflicts of interest for any of the researchers involved in this study. How are such conflicted being removed, minimized, or otherwise managed?**

**CO-INVESTIGATORS, COOPERATING DEPARTMENTS, COOPERATING INSTITUTIONS**

**If you are working with/conducting your research at another institution or organization and the research is federally-funded and located in the U.S. , you will need to provide or obtain a Single IRB Authorization Agreement. Please contact the IRB Director to discuss the Single IRB Authorization Agreement process.**

**ELECTRONIC SIGNATURES**

**As Principal Investigator, by typing my name below, I accept the following pledge:**

I acknowledge the rights and welfare of the subjects of my research as described in the [Belmont Report](http://ohsr.od.nih.gov/guidelines/belmont.html) of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. I acknowledge my responsibility as an investigator to weigh the risks of their participating in the research against the potential benefits of the investigation, and to take whatever steps are practicable to minimize those risks. I assure the IRB that this research will be conducted in accordance with federal regulations that govern research involving human subjects as described in the [Code of Federal Regulations](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm) (Title 45, Part 46) of the U.S. Department of Health and Human Services. Any deviation from the project as described here (e.g., change in principal investigator, research methodology, subject recruitment procedures, etc.) will be submitted to the IRB in the form of a change of protocol for its approval prior to implementation. The PI agrees to report all protocol deviations or adverse events IMMEDIATELY to the IRB.

I will also follow the general University guidelines and policies for Covid-19 precautions for safety currently in force at the time the research is conducted, and will further adhere to Wesleyan’s Covid-19 Guidelines for Research with Human Participants, as approved by the Wesleyan Pandemic Response Physician (Dr. Thomas McLarney), currently in force at the time that the research is being conducted.

**Principal Investigator:**

**As Faculty Advisor (if applicable), by typing my name below, I accept the following pledge:**

I have supervised my student in the development of this proposal, I have read the proposal in its entirety, I fully support the research as proposed, and I will work my student to implement the proposal. (Student proposals will not be accepted unless accompanied by this faculty acknowledgement.)

**Faculty Advisor:**

*See instructions at* [*www.wesleyan.edu/IRB*](http://www.wesleyan.edu/IRB) *for how to submit this document. Contact the IRB Administrative Coordinator if you have any difficulty submitting materials.*