INFORMED CONSENT Form FOR RESEARCH

[Insert Title of Study]

***Note to investigators:*** *this template encompasses all of the required and some additional elements of informed consent, as required by federal regulations.*

*In the header above, enter the appropriate information for your department, and title of your study. For non-Wright State PIs, please either delete the logo or replace with the appropriate logo or letterhead.*

*Text that does not apply to your research should be deleted or modified as appropriate. The text is intended to be instructional rather than declarative. Be sure to delete all instructive text, which is in red, italicized font throughout the document, before submitting the informed consent for IRB review. Sections in brackets and/or italics are meant for you to fill in.*

**Key Information**

*Key Information: Studies are required to begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate.*

*Focus on five items: (1) Statement that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. This should be accomplished in 1-2 short paragraphs.*

### About This Research Study

You are asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide if you want to participate. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

**This study is being conducted by:** [Name of researcher, department, affiliation.]

***\*\*****If the Researcher is a Student, add the following:* ,under the direction of [Name of Faculty Adviser, department, affiliation.]

**This study is being funded by:** [Insert Sponsor or Funding Agency, if none, delete this section].

**Why is This Study Being Done?**

The purpose of this study is to [Insert general statement about the study]. You were selected as a possible participant because [Explain how participant was identified.] If you agree to participate, you will be one of [insert number of participants] participants taking part in this study.

**Taking Part in this Study is Voluntary**

You may choose not to take part in this study or choose to leave the study at any time. Deciding to not participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled. *If your study involves an interview or a survey:* You can skip any questions that make you uncomfortable and can stop the interview/survey at any time. *(If applicable)* Your decision whether or not to participate in this study will not affect your *(Example:* *employment; medical care; grades in school, etc.)* [insert description].

**What Will Happen During the Study?**

**If you agree to be in this study, we would ask you to do the following things:** *Provide a detailed description of what participants will be asked to do, taking care to use easily understandable language and terms. It may be helpful to use pictures, tables, and/or flowcharts to improve participant comprehension of the procedures involved. If the participant will be photographed, audio taped, or videotaped, include a description in this section. Designate which activities are experimental and which activities would be completed even if the participant does not participate. If your study involves deception, please give as much information as possible without using false statements.* [Insert description.]

*If the study involves biospecimens, or HIPAA please use the Biomedical Informed Consent Template instead.*

*Include for research subject to GDPR. Otherwise delete.*

The study staff will collect identifiable information about you, such as your name, demographic information, the information you give to study staff as part of the study, and the results of any tests, surveys or procedures described in this informed consent form. It may also include information about your *insert as applicable: past and present health conditions and medications, genetics, sexual activity, HIV/AIDS status, tuberculosis status, substance use disorders, mental health disorders, race, ethnicity, religious beliefs, genetic information, sexuality, sexual orientation, political beliefs, and trade union membership* [insert description.]

*Include for research subject to FERPA. Otherwise delete.*

As part of this study, researchers will be collecting data that is protected by the Federal Educational Records Protection Act. The records will be collected for [state the purpose of the disclosure]. These records will include: [Specify the exact records to be disclosed *(must be very specific)*.]These records will be collected [state how often records will be disclosed *(e.g. once per semeste*r) ], and disclosed to only [to identify the party to whom the disclosure is to be made.]

**Participation in the study involves the following time commitment:** *If the study includes multiple sessions, describe the amount of time that is required for each task, session, experiment and the total time for all sessions*.[Insert description.]

### What are the Risks of Taking Part in the Study?

**The study involves the following foreseeable risks or discomforts:** *Describe the risks and what you will do to minimize the risks. Include all possible physical, psychological, professional or personal risks and/or hazards for the participants in this section. Any risks listed in the protocol must be addressed in the consent form. The most common risk is breach of privacy and should be included in most consent documents. However, it is important to not overstate the risks as well*..[Risks] In order to assist with the offset of these risks, [Protections] will be provided. *Describe the conditions under which you will terminate the study.*

*If physical injuries or mental health risks are present, a sentence must be included that states whether treatment will be provided from the research team or from the research team’s resources. [Delete if not applicable.].* In case of injury or illness resulting from this study, emergency medical treatment will be available [state how and where]. No funds have been set aside by [insert institution name] to compensate you in the event of illness or injury. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

*OR*

*If no risks:*

There are no known risks associated with this project, which are greater than those ordinarily encountered in daily life.

*For In-person studies:*

### What Steps Are Being Taken to Reduce Risk of Coronavirus Infection?

The following steps are being taken to address the risk of coronavirus infection:

**Screening:** Researchers and participants who show potential symptoms of COVID-19 (fever, cough, shortness of breath, etc.) will NOT participate in this study at this time.

**Physical distancing**: Whenever possible, we will maintain at least 6 feet of distance between persons while conducting the study.

**Mask/Covering**: Researchers will wear and participants *(SELECT ONE)* will be advised *or* will be required to shield their mouth and nose with a cloth face cover or mask during the study, even when maintaining at least 6 feet of distance. Tissues will be available to cover coughs and sneezes.

**Handwashing**: Researchers and participants will wash hands before/during [activity] or use a hand sanitizer.

**Disinfecting materials:** When feasible, researchers will clean and disinfect surfaces between participants, using an EPA-registered disinfectant or a bleach solution (5 tablespoons of regular bleach per gallon of water) for hard materials and by laundering soft materials. Disinfected materials will be handled using gloves, paper towel, plastic wrap or storage bags to reduce the chance of re-contamination of materials.

**Electronics:** Alcohol-based wipes or sprays will be used to disinfect shared touch screens, mice, keyboards, etc. Surfaces will be dried to avoid pooling of liquids.

### What are the Potential Benefits of Taking Part in the Study?

**The benefits to participation are:** *List direct benefits to subjects. This section must be consistent with the benefits as explained in the protocol submitted to the IRB. DO NOT include compensation, payments, or extra credit in this section.* The benefits which may reasonably be expected to result from this study are [explain direct benefits]. We cannot guarantee or promise that you will receive any benefits from this study.

*OR*

*If no direct benefits:*

There are no direct benefits to you. More broadly, this study may help the researchers learn more about [explain topic] and may help [future populations with a similar issues/future researchers design intervention to help with topic.].

### Will I Receive my research results?

*Insert appropriate statement.*

We may learn things about you from the study activities which could be important to your health or well-being. [Insert a description under what circumstances participants will be provided research results and how participants will be notified.] You may need to meet with professionals with appropriate expertise to help you learn more about your research results. The study team will not cover the costs of any follow-up consultations.

*OR*

We may learn things about you from the study activities which could be important to your health or well-being; however, we do not plan to share any of these results with you.

**Will I be Paid to Participate in the Research?**

*If participants will receive a small token or chance in a drawing, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw. If using a Drawing: Describe the odds of winning the drawing. If using Extra Credit: If participants will receive class points, please note the number of points as a percentage of the grade and include the alternative assignment.* You will receive [describe compensation] as payment for your participation.You will be given this payment [describe distribution method]. *If compensation is over $100:* You may need to provide your social security number to receive payment. *If necessary:* To be eligible to receive the compensation, you need to [describe prorated payment plan].

*OR*

*If no compensation:* You will receive no payment for participating in this study.

*Include if using mTurk:*

mTurk does not allow for prorated compensation. In the event of an incomplete Human Intelligence Task (HIT), you must contact the research team and compensation will be determined based on what was completed and at the researchers' discretion.

**PLEASE NOTE: This study contains a number of checks to make sure that participants are finishing the tasks honestly and completely. As long as you read the instructions and complete the tasks, your HIT will be approved. If you fail these checks, your HIT will be rejected.**

**How Will my Information Be Protected?**

*Use this section to describe how you will keep the participant’s data private and confidential. This should include a brief statement about how you will collect their data, store it, and use it in your study.* *Select the text appropriate for your particular study. Address then delete instructional text once complete. These examples will not cover all situations, please adjust as needed for your study.*

*Anonymous. Reseacher does not know who completed the study at any point in time:*

The information you give in the study will be anonymous. This means that your name will not be collected or linked to the data in any way. The researchers will not be able to remove your data from the dataset once your participation is complete.

OR

*Anonymous Results But Researchers Can Identify Who Participated:*

The information you give in the study will be stored anonymously. This means that your name will not be collected or linked to the data in any way. Only the researchers will know that you have participated in the study. The researchers will not be able to remove your data from the dataset once your participation is complete.

OR

*Coded Data/Pseudonym linked with identifying information:*

The information that you give in the study will be handled confidentially. Your information will be assigned a code number/pseudonym. The list connecting your name to this code will be kept in a locked file separate from the research data. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report

OR

*Confidentiality cannot be Guaranteed:*

*In some cases it may not be possible to guarantee confidentiality (e.g. an interview of a prominent person, a focus group interview, ethnographic research, oral history projects).*

Because of the nature of the data, I cannot guarantee your data will be confidential and it may be possible that others will know what you have reported. The researchers will make every effort to ensure that information about you remains confidential, but cannot guarantee total confidentiality. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. *If applicable:* However, it may be possible for someone to recognize your particular story/situation/response. *If your research is in a group setting:* While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.

AND

Your data will be stored *(Examples: a locked drawer in a restricted-access office, on an encrypted flash drive/external hard drive, in a restricted access folder on Dropbox.com, an encrypted, cloud-based storage system, etc.)* [insert data storage method]. *If the data has identifiers that will be separated and destroyed, state the timeframe for doing so:* When the study is completed and the data have been analyzed, all code lists linking names to study numbers will be destroyed. This is expected to occur no later than [state time frame]. *If the data has audio/visual recording, please state the timeframe for destruction of the recording and what, if anything, will be kept:* The audio/video recording will be transcribed. The recording will be deleted after the transcription is complete and verified. This process should take approximately [state time frame]. *OR* The audio/video recording will be kept as part of the study records *(example: indefinitely until no longer useful, for five years, etc.)* [state time frame]. *All:* This informed consent form will be kept for [state time frame] *(Required minimum is 3 years)* years after the study is complete, and then it will be destroyed.

*Include the following text if using an online survey or data collection tool. Delete if not:*

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person’s everyday use of the internet. If you have concerns, you should consult the survey provider privacy policy at [insert link to online privacy policy].

*Include if using mTurk:*

Your Mechanical Turk Worker ID will be used to distribute payment to you but will not be stored with the research data we collect from you. Please be aware that your MTurk Worker ID can potentially be linked to information about you on your Amazon public profile page, depending on the settings you have for your Amazon profile. We will not be accessing any personally identifying information about you that you may have put on your Amazon public profile page.

*Use if you HAVE NOT received an NIH Certificate of Confidentiality: This will be for most studies.*

It is unlikely, but possible, that others responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. Organizations, in addition to the Wright State Institutional Review Board (IRB) and research investigators, that may inspect your research records include [ if federally funded add Office of Human Research Protections (OHRP), Food & Drug Administration (FDA), and Sponsor, as appropriate.] We will only share your information if law or policy requires us to do so. *If working with children, the elderly, disabled persons, or other vulnerable populations that carries a reporting requirement, please modify the bracketed language appropriately and include the following statement:* If the researchers learn that you are [describe condition. Examples: abusing/neglecting/going to engage in self-harm/intend to harm another], state law requires the researchers report this [behavior/intention] to the authorities. Finally, confidentiality could be broken if materials from this study were subpoenaed by a court of law.

*OR*

*Use if you HAVE received an NIH Certificate of Confidentiality: this section below is required for all NIH funded research, and any other research, with a NIH Certificate of Confidentiality.*

**Certificates of Confidentiality**

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate doesn’t protect against disclosure of your personally identifiable information:

* when the US government is inspecting or evaluating federally-funded studies
* when information must be disclosed to meet FDA requirements
* if you give someone written permission to receive research information or you voluntarily disclose your study information
* if the researcher reports that you threatened to harm yourself or others
* in cases of child abuse reported by the researcher
* if the investigator reports cases of contagious disease (such as HIV) to the state

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

*If the study is an NIH-funded clinical trial, insert the following:*

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**Will My Information Be Used for Research in the Future?**

Information collected from you may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. *If you are uploading data to a data sharing site (databrary, data verse project, or Open Science Framework, etc*.: Data, without identifying information, will be made publically available in [state which database], an online database for analysis by other researchers. Results of this study may be presented at conferences, or published in journals, books, and the popular media.

*If there is financial conflict of interest by any of the study team:*

**What Financial Interest does the Researcher have?**

One or more individuals involved in this study may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

**Who Should I Call with Questions?**

If you have questions about the research study itself, please contact the Principal Investigator at [phone number and e-mail address]. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (937) 775-4462 or irb-rsp@wright.edu. All reports or correspondence will be kept confidential.

***You will be given a copy of this information to keep for your records.***

**Statement of Consent**

I have read the above information provided in this form. I have had the opportunity to ask questions and have my questions answered. In consideration of all information provided in this form, I give my consent to participate in this research study. You will be provided with a copy of this form to keep for your records.

*Include the following if applicable. Add statements as needed.*

Indicate Yes or No:

I give consent to be audio and/or video-taped during this study.

 \_\_\_Yes \_\_\_No

I give consent for my identity to be revealed in written materials resulting from this study:

 \_\_\_Yes \_\_\_No

I give consent to be contacted for follow-up in this study or future similar studies:

 \_\_\_Yes \_\_\_No

*Include the following for Parent/Guardian Permission Form:*

Name of Child:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Use the following for Written Informed Consent:*

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

Printed Name:

Signature of Person Obtaining Consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_

*OR*

*If you have applied for a Waiver of Documentation of Consent (No Signature Line) Use the following instead:*

**If you agree to participate in this research, please** [description]. *(Describe what the participant must do to indicate agreement to participate. Example: “complete the attached survey”, or “click I Agree to continue”).*