

**This form effective June 27, 2024**

This form is the **Learning Innovation and Lifetime Education (LILE) IRB protocol template** for SoTL (scholarship of teaching and learning) projects being conducted by Duke instructors in partnership with Learning Innovation office. This template is only for use by Duke faculty or Duke Learning Innovation staff to submit protocols that meet the criteria described in section 5.1 below.

This template includes the LILE Student Consent Form that is used to ask students to share their data from a course for research purposes. This template only covers SoTL projects that use data collected as part of standard educational activities. Faculty whose project seeks to use additional data, such as data collected through non-instructional focus groups, demographic surveys, and/or audio or video recordings, should consult with LILE about revisions to this protocol specifying those instruments and protocols. We are also happy to discuss specific questions or variations in your study that may require different information in your IRB protocol. Please contact us at learninginnovation@duke.edu with questions.

**Complete sections 1- 4 and any highlighted portion and then gather signatures from all people listed as PI or researchers.**

**The completed protocol application should be submitted as a Microsoft Word file.
Submitting the protocol in multiple files or as a PDF will delay the pre-review of your application.**

Please submit the completed protocol application to **campusIRB@duke.edu**.

Do **not** use this form if your research activities are [**limited to analysis of existing data**](https://research.duke.edu/policy/analysis-existing-data/). Instead, visit the [**Forms page of our website**](https://research.duke.edu/campusirb/forms/) for the appropriate protocol form.

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| Section 1: General Information |

**Protocol Title**: Click or tap here to enter text.

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| Section 2: Key Study Personnel |

**Principal Investigator**

Identify one Principal Investigator (PI) on this project and sign below.

* This person is responsible for the overall conduct of the research.
**For all students, fellows, and post-docs, this is your faculty advisor.**
* If there is more than one PI, only choose one.
* By signing, the PI certifies to the following:
	+ I have read and approved the protocol.
	+ I will conduct this study as described in the approved protocol.
	+ I assume responsibility for ensuring that my advisees are aware of the responsibilities as researchers
	+ I will not begin the research until written approval is secured from the IRB.  Note: Approval will not be provided unless [certification to conduct research with human subjects](https://research.duke.edu/policy/required-training/) for each researcher named on the protocol is current.
	+ If any changes are anticipated, I will submit a [Request to Amend an Approved Protocol](https://research.duke.edu/campusirb/forms/), and I will not implement the changes until I receive approval from the IRB.
	+ I ensure that the IRB will be immediately notified in the event of [unanticipated risks to participants, protocol deviations, or findings during the study that would affect the risks](https://research.duke.edu/policy/reporting-problems/) of participation.

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| **Name**:Click or tap here to enter text. | **Department or School**: Click or tap here to enter text. |
| **Duke E-mail Address**: Click or tap here to enter text. | **NetID**: Click or tap here to enter text. |
| [ ]  **Faculty Advisor** [ ]  **Faculty Researcher** [ ]  **Staff**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**:(Insert your electronic signature. We cannot accept a typed name.) | **Date**: Click or tap to enter a date. |

**Duke Research Team**

Please list the other Duke members of the research team AND indicate their role on the project. **Do not list non-Duke researchers.** These team members can be added in a later section.

Feel free to copy and paste, or delete the blocks as necessary.

All signatories agree to the following:

* + I will conduct this study as described in the approved protocol.
	+ I will not begin the research until written approval is secured from the IRB.  Note: Approval will not be provided unless [certification to conduct research with human subjects](https://research.duke.edu/policy/required-training/) for each researcher named on the protocol is current.
	+ If any changes are anticipated, I will submit a [Request to Amend an Approved Protocol](https://research.duke.edu/campusirb/forms/), and I will not implement the changes until I receive approval from the IRB.
	+ I ensure that the IRB will be immediately notified in the event of [unanticipated risks to participants, protocol deviations, or findings during the study that would affect the risks](https://research.duke.edu/policy/reporting-problems/) of participation.

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| **Name**:Click or tap here to enter text. | **Department or School**: Click or tap here to enter text. |
| **Duke E-mail Address**: Click or tap here to enter text. | **NetID**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**:(Insert your electronic signature. We cannot accept a typed name.) | **Date**: Click or tap to enter a date. |

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| --- | --- |
| **Name**:Click or tap here to enter text. | **Department or School**: Click or tap here to enter text. |
| **Duke E-mail Address**: Click or tap here to enter text. | **NetID**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**:(Insert your electronic signature. We cannot accept a typed name.) | **Date**: Click or tap to enter a date. |

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| --- | --- |
| **Name**:Click or tap here to enter text. | **Department or School**: Click or tap here to enter text. |
| **Duke E-mail Address**: Click or tap here to enter text. | **NetID**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**:(Insert your electronic signature. We cannot accept a typed name.) | **Date**: Click or tap to enter a date. |

**If there are more members of the research team, copy and paste the researcher information and signature block as needed.**

**Other Study Contacts**

If there are additional personnel (e.g. a departmental staff member) who assist in protocol preparation and record keeping, and would like to be copied on correspondence from the IRB, please add them here.

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| **Name**:Click or tap here to enter text. |
| **E-mail Address**: Click or tap here to enter text.**NetID**: Click or tap here to enter text. |
| **Type of Correspondence:**[ ] Approval and Reminder Notices[ ]  All correspondence related to the submission, including feedback |

**IRB USE ONLY**

This section is to be completed by IRB staff or IRB members only.

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| **APPROVED as** [ ]  **Exempt** [ ]  **Expedited or** [ ]  **Full** |
|  |  |
| [ ]  IRB Designee or [ ]  IRB Member | Date |

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| Section 3: Departmental & Institutional Affiliations |

1. **Identify the department, institute, or center that you consider the home of the study.**

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| Click or tap here to enter text. |

1. **Will you be collaborating with researchers at other institutions?**

[ ]  Yes [ ]  No

# **If NO, click the  to close this section and hide questions specific to collaborating with researchers at other institutions.**

See our [Collaborative Research](https://research.duke.edu/policy/collaborative-research/) policy. Or, contact IRB staff at campusIRB@duke.edu to determine whether you are engaged in an inter-institutional collaboration.

**If YES, please specify the following for each collaborator:**

|  |  |
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| Collaborator’s Name: | Click or tap here to enter text. |
| Role in Research: | Click or tap here to enter text. |
| Research Activities/ Responsibilities: | Click or tap here to enter text. |
| Organization/Institution: | Click or tap here to enter text. |
| Has your collaborator reached out to their organization/institution about IRB or ethics review? |
| [ ]  Yes**\*** [ ]  No [ ]  Collaborator’s organization/institution does not have an IRB or ethics review board |
| **\***If you indicated that your collaborator has reached out to their organization/institution’s IRB or ethics review board, please describe their determination or the status of the request: Click or tap here to enter text. |

**Important items to note:**

* *Review by the Campus IRB extends only to members of the Duke research team unless there is a formal, fully executed reliance agreement among the IRBs engaged in the research.*
* *Campus IRB may not be able to provide oversight for collaborators who are unaffiliated with an institution or whose institution does not have an active Federalwide Assurance (FWA) with DHHS Office of Human Research Protections (OHRP).*
* *If your collaborator is a foreign entity, you may be asked to provide in-country IRB approval. In addition, your protocol may require additional reviews or agreements.*

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| Section 4: Funding Sources and Conflict of Interest |

1. **Please identify your funding sources**:

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| Click or tap here to enter text. |

1. **Are any of the above funding sources a U.S. Federal Agency or Department?**

[ ]  Yes [ ]  No

**If YES, please append the grant application to this protocol request. The budget information can be omitted.**

1. **Are any of the above funding sources a component of the Department of Defense?**

[ ]  Yes [ ]  No

**If YES, please complete and append the** [**DOD attachments**](https://research.duke.edu/campusirb/forms/) **to this protocol request.**

1. **Do you have an outside interest (financial or otherwise) that is in any way related to this study?**

[ ]  Yes [ ]  No

**If YES, please explain.**

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| Click or tap here to enter text. |

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| Section 5: Research Question |

1. **What is your research question or the purpose of your research?**

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| This project is being submitted using the LILE IRB Protocol Template. All the projects submitted using this template meet the following criteria:* Research only involves standard educational practice, defined as:
	+ Activities that would happen in a class regardless of whether research was being conducted or not, *and*
	+ Activities that fall within the bounds of commonly-accepted educational practices, such as classroom activities, assessments, or assignments, *and*
	+ Activities that all students in a course engage in, whether or not they consent to share their data for the associated research
* Data are collected in a class where the course instructor is participating in the research team in partnership with LILE staff
* Research analysis is conducted only after final grades for a given course have been submitted to the Duke Registrar’s Office
* Informed consent records are collected, held, and managed by LILE
* After grades are submitted, LILE will provide data with direct identifiers removed to the course instructor

The specific research question being analyzed in this project is: |

1. **Provide background information about the research that will help the reviewer understand your project.** Avoid discipline-specific jargon.

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| Scholarship of Teaching and Learning (SoTL) describes research and evaluation that seeks the goal of improved learning, especially in higher education environments. To this end it encourages, supports, and publicizes course-focused research projects that include course instructors as active members of the research team. SoTL is a way for course instructors and university researchers to systematically examine practices around teaching and learning in a way that invites peer review and open critique from other scholars doing similar work with the ultimate goals of improved student learning, teaching effectiveness and enjoyment, faculty development and the creation of a deeply collegial academic community of and for teaching and learning.The purpose of the study is to enhance teaching and learning at our institution, as well as others, through data-driven innovation and iterative course design. Although programs’ and instructor teams’ specific questions will vary (see 2.1 above for specific description of this project), investigations address one or both of these two kinds of questions:1. What is the effectiveness of particular teaching strategies or course/curricular structures (with or without using educational technology)?
2. How do sub-groups of students learn differently?
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| Section 6: Participant Population |

1. **If you are specifically recruiting participants that involve any of the groups below,
please select them:**

[ ]  Children or minors**\***, as defined by the research site (e.g., under 18 years old in NC)

[ ]  Cognitively impaired persons, for example, people with dementia

[ ]  Department of Defense, active-duty military, or civilian personnel

[ ]  Indigenous populations (e.g., Native American/American Indian, First Nations, etc.)

[ ]  Prisoners**\***

[ ]  Refugees

[ ]  Stigmatized populations

[ ]  Undocumented immigrants

[ ]  Victims of abuse

[ ]  Duke employees

[x]  Duke students

[ ]  Other vulnerable populations (please specify: Click or tap here to enter text.)

**If your research participants include children or prisoners, your data meet Duke’s sensitive data classification. Please complete Section 15.**

1. **Describe all participant populations you intend to include in your research. Please describe each, unique population group separately.** If your research will include children, please include their age ranges and the age of majority of the population where your participants reside.

Duke students age 18 and older who are enrolled in Duke’s programs or courses in which their program coordinator or instructors are engaged in SoTL research in partnership with LILE will be asked to participate in this study by consenting to share their educational data from the associated course for research purposes.

This protocol covers the following courses taught by the researchers (Note: add name of instructor for any courses that you include that are not taught by the researchers).

Course name/s:
Estimated student enrollment per course:

1. **Will you use the Psychology Undergraduate SONA Pool?**

[ ]  Yes [x]  No

**Research involving participants from the Psychology Undergraduate SONA Pool requires an educational debriefing**. **Include the educational in the Appendices.**

1. **Will interactions with participants be carried out in a language other than English?** For example, your participants’ primary language is not English.

[ ]  Yes [x]  No

# **If NO, the  to close this section and hide questions specific to your participants’ primary language.**

**Please indicate your participants’ primary language.**

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| Click or tap here to enter text. |

**Please indicate and your proficiency in speaking, reading, and writing your participants’ primary language.**

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| Click or tap here to enter text. |

**If you are not proficient in your participants’ primary language, will you need an interpreter?**

[ ]  Yes [ ]  No

**If YES, how will you obtain the services of an interpreter?**

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| Click or tap here to enter text. |

1. **Will any of your research activities be physically conducted outside of the U.S.?** Duke requires all research taking place in a foreign country to undergo review by the [Export Controls](https://research.duke.edu/oec/) and [Privacy](https://oarc.duke.edu/our-focus-areas/privacy/) offices for ancillary reviews.

[ ]  Yes [x]  No

# **If NO , the  to close this section and hide questions specific to research activities being physical conducted outside of the U.S.**

**Please identify the countries where you will carry out your research.** If you have more than one study or participant populations, elaborate on the specific studies or participant populations that will be located outside of the U.S.

Click or tap here to enter text.

**Do you need community-level, institutional-level, or national level approval in the countries where the research will take place? Please elaborate.**

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| Click or tap here to enter text. |

**Include documentation of the appropriate reviews in the Appendices.**

1. **If the research will take place in a U.S. elementary or secondary school, please list the schools and/or school districts:**

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| Click or tap here to enter text. |

**You may be asked to provide documentation that confirms the school or school district has approved your research. If you already have obtained this confirmation, please include it in the Appendices.**

**Please answer questions #6.7 and #6.8 if your research activities will involve children/minors.**

See the Campus IRB’s [**Research with Children**](https://research.duke.edu/policy/research-children/) policy. Also note that Duke requires individuals interacting with minors to complete a minors training. For more information, visit the [**Minors in Duke Programs**](https://forms.hr.duke.edu/minors/training/)website.

1. **Describe the scope of the interaction your research team will have with the children/minors.**

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| Click or tap here to enter text. |

1. **Identify which members of your research team will interact with the children/minors.**

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| Click or tap here to enter text. |

**If your research participants include children or minors your data meet Duke’s sensitive data classification.
Please complete Section 15.**

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| Section 7: Recruitment |

1. **Describe the procedures for recruiting each potential participant population.**

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| Students enrolled in the courses and programs under study will be recruited to share their data for the research project. A verbal announcement will be made in person by the instructor or a Duke Learning Innovation representative. During class. A LILE representative will introduce the study to students whenever this is logistically possible. “Your instructor in this course is conducting research on teaching and learning. You are being asked to share your course data for this research project. A representative from LILE owns the consent form in Qualtrics and will only release de-identified data from students that consent to share their data with the instructor after grades have been submitted. Please read through the information in the consent form and indicate if you are willing to share your data.” |

1. **Check all the recruitment methods that apply:**

[ ]  Introductory letter or email messages

[ ]  Flyers/posters

[ ]  Newspaper ads

[ ]  Text for social networking sites or other online recruitment

[x]  Scripts for personal contact

[x]  Other (please specify: verbal description of the project

**Include all recruitment materials in the Appendices.**

1. **Describe any inclusion or exclusion criteria that participants will need to know about before enrolling.**

N/A

1. **Will you screen participants before they enroll in the study?**

[ ]  Yes [x]  No

**If YES, explain why you need to screen participants, how you will screen them, and what will happen to any information collected during the screening (both for those who are eligible and who are not eligible).**

Click or tap here to enter text.

**Include all screening materials in the Appendices, including consent processes and instruments specific to screening**

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| Section 8: Description of Activities |

1. **Describe the study activities and what participants can expect if they agree to be part of the research.**

### **Click the to see questions to consider when describing the study activities.**

This list of questions is not intended to be exhaustive, but we hope you find it helpful.

* *For surveys*: What surveys will participants be asked to answer? How will participants complete the survey? Will there be more than one survey? How long will each survey take to complete?
* *For interviews and focus group discussions (FGDs)*: What will be the focus or topic of the interview/FGD? What kind of questions will be asked? Will interviews/FGDs be conducted virtually, in-person, or some other way? Will participants be invited to take part in more than one interview? How many participants will be part of each FGD? What is the expected duration for each interview/FGD?
* *For observations*: Where will the observations take place? What will be observed? How long will the observations last? Will individuals be notified they are being observed for research purposes?
* *For experimental manipulations*: What is the manipulation? How will the manipulation be introduced? What stimuli will be used? How will the stimuli be presented?
* *For collection of samples*: What kind of samples are being collected- biological (blood, hair, saliva, etc.) or inorganic (soil, water, dust, etc.)? How will the samples be collected? Where will samples be collected? Who will collect the samples?

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| All the activities involved in this research fall within the scope of “standard educational practices”; students will complete all activities regardless of whether they elect to subsequently share their data for research purposes. The research activities will not involve anything additional specific to research participants.The time required of each participant would be the time they are spending completing the assigned course or program activities. Only data collected through standard educational practice activities will be included in this research. The specific activities for this project include: |

**Include all study documents (including, instruments, measures, stimuli, and survey, interview and focus group questions, etc.) in the Appendices.**

1. **Do the study activities described in #8.1 (above) include the collection of biological samples?** Biological samples include any material derived from a human, such as blood, urine, saliva, hair and nail clippings, etc.

[ ]  Yes [x]  No

1. **Do the study activities described in #8.1 (above) require participants to use an app on a personal device, or give you access to data collected on a personal device?** Apps include any applications created by the research team or another developer. Personal devices include participants’ mobile phones, computers, laptops, tablets, or wearables.

[ ]  Yes [x]  No

*Description of Activities | Recordings and Photographs*

See our [Guide for Releases for Images and Recordings](https://research.duke.edu/resource/releases-images-and-recordings/).

1. **Will participants be audio-recorded or video-recorded, either individually or in groups?** Check all that apply. Audio- and video-recordings of focus groups are allowed only if all participants in the group have given their explicit permission to be recorded. Audio-recordings are considered identifiable.

[ ]  Yes – Audio-recordings [ ]  Yes – Video recordings [x]  No

# **If NO to either audio or video recordings, click the  to close this section and hide questions specific to the collection of audio and video recordings.**

**8.4.1 Elaborate on the recordings and what will be recorded:**

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| Click or tap here to enter text. |

**8.4.2 What devices will you use to record participants?**

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| Click or tap here to enter text. |

**8.4.3 If recordings will be transcribed, who will carry out the transcription?** Microsoft Stream and Zoom have automatic transcription capabilities that are available under a Duke license. Third party transcription services (e.g., GMR, Rev.com, TranscribeME, TransPerfect) may need to undergo review an ancillary review by other institutional oversight offices.

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| Click or tap here to enter text. |

**Campus IRB staff will inform you if the collection and transcription of your recordings will need to undergo review an ancillary review by other institutional oversight offices.**

**8.4.4 What will the recordings or transcriptions be used for?** Check all that apply:

[ ]  For my *current* project’s research, as part of my records

[ ]  For my *future* research use, as data for **my** future projects

[ ]  For *general research* use, including sharing with other researchers beyond my current project

[ ]  For *public use*, including sharing in presentations, publications, and for educational purposes

[ ]  Other (please specify: Click or tap here to enter text.)

**8.4.5 Elaborate on the above.** If the recordings or transcriptions will be shared publicly or saved for any future use after this project, explain how they will be used, where they will be stored, and how you will obtain permission from participants for their future use.

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| Click or tap here to enter text. |

See [our website](https://research.duke.edu/resource/releases-images-and-recordings/) for more information about obtaining releases for recordings.

1. **Will participants be photographed? Photographs of participants’ faces are considered identifiable?** Photographs of participants’ faces are considered identifiable.

[ ]  Yes [x]  No

# **If NO, click the  to close this section and hide questions specific to the collection of photographs.**

**8.5.1 Elaborate on the photographs and who/what will be included:**

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| Click or tap here to enter text. |

**8.5.2 What will the photographs be used for?** Check all that apply:

[ ]  For my *current* project’s research, as part of my records and for transcription/coding purposes

[ ]  For my *future* research use, as data for **my** future projects

[ ]  For *general research* use, including sharing with other researchers beyond my current project

[ ]  For *public use*, including sharing in presentations, publications, and for educational purposes

[ ]  Other (please specify: Click or tap here to enter text.)

**8.5.3 Elaborate on the above.** If the photographs will be shared publicly or saved for any future use after this project, explain how they will be used and where they will be stored. Explain why the images of participants are necessary to share publicly or save for the future.

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| Click or tap here to enter text. |

**8.5.4 Where will the images be displayed, presented, or distributed outside of the research team?**

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| Click or tap here to enter text. |

**8.5.5 How will you obtain photographs of participants?** For example, what device will you use to capture their image? Will you ask participants to send you a photograph (and how)?

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| Click or tap here to enter text. |

**8.5.6 How will the releases for the use of the images be secured?** Generally, releases need to be documented with a signed form or recorded statement. The informed consent process can include the releases

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| Click or tap here to enter text. |

See [our website](https://research.duke.edu/resource/releases-images-and-recordings/) for more information about obtaining releases for images.

*Description of Activities | Deception and Debriefing*

1. **Does the research include deception?**

### **Not sure if you are using deception? Click the for more information.**

There are a number of ways to use deception in research, for example:

* Telling participants something you know is not true, such as providing false feedback about performance
* Using a confederate who pretends to be another participant but is actually a member of the research team

You are not deceiving participants if you do not tell them your research hypothesis. Researchers are under no obligation to tell participants their research hypothesis if doing so would undermine the scientific validity of the research. However, participants have the right, according to the ethical principle of respect for persons, to decide whether to take part in research based on information provided to them during the consent process. If the participants will be deceived, the ethical and regulatory requirement to fully inform participants **must be waived** by the IRB.

**The following criteria must be met in order to use deception in your research:**

1. The risk must be no more than minimal.
* “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the 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.”
1. The rights and welfare of the participants will not be adversely affected. Examples of deceptions that do not adversely affect rights and welfare of participants include:
* The study will involve subliminal priming, but the content of the primes would not be offensive or disturbing if known to the participants.
* Participants will be video-recorded without their knowledge, but will be given the opportunity to request that their recordings not be retained.
* Participants will be reassured after the study that the feedback they received on their performance was false.
1. The research could not practicably be carried out without the waiver.
* This does not mean that it would be inconvenient to conduct the study without the waiver. It means that unless participants are deceived, you could not collect valid data.
1. When appropriate, participants will be provided with pertinent information after participation.
* This information is provided through debriefing. A good debriefing provides enough information about the study’s purpose and methodology to make clear why deception was necessary.

5. If participants were recorded without their knowledge, they must be given the option to have the recording erased.

[ ]  Yes [x]  No

### **If YES, click the to expand this section and answer questions specific to using deception.**

**8.6.1 Describe the deception.**

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| Click or tap here to enter text. |

**8.6.2 Using the definition of minimal risk provided above, explain why using deception would not cause more than minimal risk to participants.**

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| Click or tap here to enter text. |

**8.6.3 Explain why using deception would not adversely affect the rights and welfare of participants.**

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| Click or tap here to enter text. |

**8.6.4 Explain why deception is necessary to accomplish the goals of the research.**

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| Click or tap here to enter text. |

**8.6.5 Will participants be debriefed?**

[ ]  Yes [ ]  No

**If YES, explain when participants will be debriefed and include the debriefing statement in the Appendices.**

Click or tap here to enter text.

**If NO, explain why participants will not be debriefed participants.**

Click or tap here to enter text.

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| Section 9: Additional Data |

1. **Will you be** [**provided with existing data**](https://research.duke.edu/policy/analysis-existing-data/) **about your participants or other individuals that you will analyze as part of this project?** Existing data may include individual records (e.g., academic, medical, financial), data sets, interview notes, biospecimens, online profiles and posts (e.g., social media), and audio- or video-recordings.

[ ]  Yes [x]  No

### **If NO, the  to close this section and hide questions specific to the inclusion of additional data in your research.**

1. **Will any of your data be provided by the North Carolina Educational Research Data Center (NCERDC)?**

[ ]  Yes [x]  No

**If YES, append all the completed NCERDC forms to this protocol.**

1. **Do any of these existing data include (check all that apply):**

[ ]  Medical records provided by Duke Health (clinic, department, or facility)

[ ]  Medical records provided by a non-Duke entity

[ ]  Academic records

[ ]  Financial, credit, income, banking

[ ]  Data provided by a component of the DOD (Department of Defense)

[ ]  Specimens or biological samples from humans or animals

[x]  None of the above

1. **Identify the datasets and the individuals and/or organizations providing the existing data.**Include the estimated number of records you will receive in each set.

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| Click or tap here to enter text. |

1. **Describe the variables included in the existing datasets.** The description should include any direct identifiers (names, email addresses, images, or home addresses) and/or indirect identifiers (data points that, when combined, would allow someone to deduce the identity of the participants).

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| Click or tap here to enter text. |

1. **Do you plan to connect or merge the existing data with the data you are collecting?**

[ ]  Yes [x]  No

1. **Describe the process or mechanism to obtain the existing data.** For example, you may need to create an account, register a study, submit an application, or enter into an agreement (e.g., a data use agreement or DUA). The process or mechanism could also include a personal arrangement with a colleague to provide you with the data. Data are considered “public” if they are readily available for research purposes without making a formal request. That is, anybody can download the data with a simple click from an open, public-facing website without signing any kind of agreement. If your data are public, provide information about how they are obtained.

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| Click or tap here to enter text. |

**Include in the Appendices any documentation that explain or describe the process or mechanism for obtaining the data. Documentation may include an agreement, copies of confirmation emails from the data provider, or screenshots of a completed online data request application.**

**Important items to note:**

* If the mechanism to obtain the data specifies requirements for how Duke must securely store or protect the data, the data meet Duke’s “sensitive” [data classification standard](https://security.duke.edu/policies-procedures-and-standards/data-security/data-classification-standard/). The “Sensitive” Data Classification questions (Section 7) must be completed.
* If the mechanism to obtain the data requires an institutional signature, researchers may not sign on behalf of the university.
1. **Describe how Duke will receive the existing data.** For example, Duke researchers may need to download the data via a secure FTP service. If data will not be transferred to Duke please explain. For example, a data provider may require that Duke researchers remote into their internal servers to access the data.

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| --- |
| Click or tap here to enter text. |

1. **Who will have access to the existing data? If any non-Duke researchers will have access to the data, please identify them, and describe how they plan to access the data.**

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| Click or tap here to enter text. |

1. **Where will the existing data be stored when they are “at rest” (i.e., not in use)?**

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| Click or tap here to enter text. |

Please review the [Developing Data Protection Plans](https://research.duke.edu/resource/developing-data-protection-plans/) guide for a list of best practices and recommendations from the IT Security Office (ITSO). Note: Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

1. **Where will the existing data be analyzed?**

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| Click or tap here to enter text. |

Please review the [Developing Data Protection Plans](https://research.duke.edu/resource/developing-data-protection-plans/) guide for a list of best practices and recommendations from the IT Security Office (ITSO). Note: Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

1. **Will the existing data, as described in 9.6 (above), include any identifying information, either direct or indirect?**

[ ]  Yes [ ]  No

1. **If the existing data includes any identifying information (direct or indirect), will the identifiers be removed from before or after you receive them?**

[ ]  Yes [ ]  No [ ]  N/A - data do not include identifiers

**If YES, describe the process for removing the identifiers, including when they will be removed and by whom.** In some cases, a third-party may be required to remove identifiers from the data.

|  |
| --- |
| Click or tap here to enter text. |

**If NO, explain why the identifiers will not be removed.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Would an inadvertent release of identifying data place individuals at risk of harm?**

[ ]  Yes [ ]  No

**Please elaborate.** For example,explain why you are confident they are no risks, or if risks are possible, describe the risks and how they may be mitigated.

|  |
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| Click or tap here to enter text. |

**If an inadvertent release of identifying data may place individuals at risk of harm your data meet Duke’s sensitive data classification. Please complete Section 15.**

1. **Do any of your data providers require that the data be returned or destroyed after you have completed your analysis?**

[ ]  Yes [ ]  No

**If YES, by what date will your data be returned or destroyed?**
Click or tap here to enter text.

1. **Please indicate whether your research requires that you re-consent participants for the secondary use of their data.** If you must re-consent participants, please explain how participants will be re-consented and include the consent process in the Appendices.

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| Click or tap here to enter text. |

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| Section 10: Compensation |

See our [**Guide on Compensating Research Participants**](https://research.duke.edu/resource/compensating-research-participants/).

1. **Will participants be compensated (e.g. cash, gift cards, lottery entries, study credit)?**

[ ]  Yes [x]  No

### **If NO, click the  to close this section and hide questions specific to compensation.**

1. **How will participants be compensated?** Check all that apply.

[ ]  Bonus Payments

[ ]  Cash

[ ]  Check

[ ]  Study Credit

[ ]  Gift Card – Electronic Amazon Gift Card

[ ]  Gift Card – Other (please specify: Click or tap here to enter text.)

[ ]  Lottery/Drawing

[ ]  Online and/or Pre-arranged Panel Payments (e.g. Lucid, Mturk, Qualtrics Panel, YouGov, etc.)

[ ]  Other (please specify: Click or tap here to enter text.)

1. **Please describe the amount of each type of compensation and how they will be distributed.** If your research involves more than one participation population, please describe if and how compensation will differ per each population

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| Click or tap here to enter text. |

1. **Under what conditions will participants receive partial or no compensation?**For example:
* Participants must answer every question or complete all tasks.
* Participants must pass attention checks.
* Participants must achieve a certain accuracy score.
* Participants must spend a certain amount of time completing the study.
* Participants must complete multiple sessions.
* If participants are Duke University student or employees, they must provide their Duke Unique IDs (DUIDs) as a condition of payment.

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| Click or tap here to enter text. |

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| Section 11: Benefits |

1. **Describe any anticipated direct benefits of the research for individual participants.**
* The opportunity to participate in research is not a benefit
* Compensation is not a benefit
* If the research provides no direct benefits to participants, state “None”

|  |
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| Click or tap here to enter text. |

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| Section 12: Risks of Harm |

1. **Will the research activities (e.g. questions, images) upset or distress participants?**

[ ]  Yes [x]  No

1. **Please elaborate on why you feel the research activities may or may not upset or distress participants.** If the answer to the above is “Yes”, describe the strategies you will use to mitigate the risks.

|  |
| --- |
| All data for this project are a result of standard educational practice, which students will complete as part of the course regardless of whether they consent to share their data for research purposes |

1. **Are there any risks of physical harm or discomfort?**

[ ]  Yes [x]  No

1. **Please elaborate on why you feel like there will or will not be risks of physical harm or discomfort.** If the answer to the above is “Yes”, explain what the risks are and what steps you will take to mitigate the potential risks.

|  |
| --- |
| All data for this project are a result of standard educational practice, which students will complete as part of the course regardless of whether they consent to share their data for research purposes. All university procedures, especially related to accommodations will be followed as part of the class, regardless of the research.  |

**If participants need to screen out because of physical risks, please make sure this is addressed in the Recruitment section.**

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| --- |
| Section 13: Confidentiality |

See our [**Guide to Confidentiality**](https://research.duke.edu/resource/confidentiality/).

The next set of questions asks about the confidentiality of your participants and their data throughout the life of your project. Confidentiality will relate to the collection, storage, sharing, and future use of the data, including any direct and indirect identifiers.

**Direct identifiers** refer to any information that may readily identify someone, such as their name, email address, and phone number.

**Indirect identifiers** refer to a set of information that, when combined, can be used to figure out someone’s identity. Indirect identifiers depend on the population, and can include demographic information or a set of descriptors, such as job title and organization, that are unique to an individual or community.

Note: Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

*Confidentiality | Recruitment*

1. **Do you need individually identifying information, such as email addresses or phone numbers, to contact and recruit participants?**

[ ]  Yes [x]  No

**If YES: What identifiers do you need to recruit participants? How will identifiers be collected? Where will identifiers be stored? What will happen to the identifiers after the recruitment process is complete?**

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|  |

*Confidentiality | Data Collection*

1. **Do you plan to collect and/or store any *direct* identifiers that will be linked to participants’ responses?** If you have a key linking identifiers with unique identification numbers, the data are considered identifiable. Audio recordings and images of participants’ faces are considered direct identifiers.

[x]  Yes [ ]  No

**If YES: What are the direct identifiers? Why are the direct identifiers necessary? How will the direct identifiers be collected? Where the direct identifiers be kept/stored? How long will the direct identifiers be kept?**

|  |
| --- |
| **As the owner of the consent form, the LILE representative will collect student NetIDs and UniqueIDs (embedded in Qualtrics) so that they can remove data from students that do not consent to share their data. Once de-identification of data occurs, LILE will delete any direct identifiers before sharing the data with the PI.** |

1. **Do you plan to collect and/or store any *indirect* identifiers about your participants?** Indirect identifiers are any descriptors, such as demographic or background information, that can be used to deduce your participants’ identity.

[ ]  Yes [x]  No

**If YES: What are the indirect identifiers? Why are the indirect identifiers necessary? How will the indirect identifiers be collected? Where the indirect identifiers be kept/stored? How long will the indirect identifiers be kept?**

|  |
| --- |
| Click or tap here to enter text. |

1. **If the data include any identifying information (direct or indirect), will the identifiers be removed from the data?**

[x]  Yes [ ]  No [ ]  N/A - data do not include identifiers

**If NO: Explain why the identifiers will not be removed.**

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|  |

**If YES: Describe the process for removing the identifiers, including when they will be removed and by whom.** If you will have documentation (e.g. a key) that links a participant’s identifiers to their responses where it will be stored, how it will be protected, and who will have access to it. In some cases, a third-party may be required to remove identifiers from the data or maintain the key.

|  |
| --- |
| **As the owner of the consent form, the LILE representative will collect student NetIDs and UniqueIDs (embedded in Qualtrics) so that they can remove data from students that do not consent to share their data. Once de-identification of data occurs, LILE will delete any direct identifiers before sharing the data with the PI.**  |

*Confidentiality | Reporting/Publishing*

1. **Will you use participants’ identities (e.g. names, indirect identifiers, photos, etc.) while sharing your research findings (e.g. in reports, publications, etc.)?**

[ ]  Yes [x]  No [ ]  N/A - data do not include identifiers

**If YES: Please explain how you will secure permission to do so.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Based on your research topic, setting, and reported characteristics of your participants, could their identities be readily deduced by someone who read your findings?**

[ ]  Yes [x]  No

**Please provide a rationale for your response:**

|  |
| --- |
| Data are generated by students participating in standard educational activities in their classes. Unless someone were to access the class roster, which is unlikely, we do not believe an inadvertent release of identifiable information is likely given that direct identifiers are being removed before data are provided to the instructors. |

1. **If someone outside the research team figured out who your participants are and the information you have collected about them, would your participants be at risk of harm?** Risks could include harm to their reputation, employability, increased social stigma, etc.

[ ]  Yes [x]  No

**If YES, your data meet Duke’s sensitive data classification. Please complete Section 15.**

**Please elaborate.** For example, explain why participants would not be put at risk of harm, or describe the specific harms that could occur if individually identifying data were accidentally made available to those outside the research team**.**

|  |
| --- |
| Data are generated by students participating in standard educational activities in their classes. Unless someone were to access the class roster, which is unlikely, we do not believe an inadvertent release of identifiable information is likely given that direct identifiers are being removed before data are provided to the instructors. In addition, this data is reported in aggregate and anonymously. |

**Will you apply for a Certificate of Confidentiality (CoC) if, for example, you have identifying data about illegal or unlawful behavior?**

[ ]  Yes – This research is NIH-funded and NIH will automatically issue me a CoC

[ ]  Yes – I will need to apply for a CoC and will consult Campus IRB staff**\***

[x]  No – A CoC is not needed for my research

**\* Please notify Campus IRB staff prior to applying for a CoC.**

*Confidentiality | Data Storage and Access*

1. **Who will have access to the data?** If any non-Duke researchers will have access to the data, please identify them, and describe how they plan to access the data.

|  |
| --- |
| **A LILE representative, listed as the data manager on this protocol, will have access to the data for de-identification processes and to ensure that the researchers do not have access to the consent information.**  |

1. **Where will data be stored when they are “at rest” (i.e., not in use)?**

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| **Duke Box** |

Please review the [Developing Data Protection Plans](https://research.duke.edu/resource/developing-data-protection-plans/) guide for a list of best practices and recommendations from the IT Security Office (ITSO). Note: Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

1. **Where will the data be analyzed?**

|  |
| --- |
| Click or tap here to enter text. |

Please review the [Developing Data Protection Plans](https://research.duke.edu/resource/developing-data-protection-plans/) guide for a list of best practices and recommendations from the IT Security Office (ITSO). Note: Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

|  |
| --- |
| Section 14: Public and Future Use |

1. **Will you use the data you gather for future research?**

[x]  Yes [ ]  No

1. **Is there a possibility that you may want to share the data with researchers (other than anyone who has been listed as collaborators in Section 3) outside of the Duke research team listed on this protocol?**

[ ]  Yes [x]  No

**If YES: Describe the accessibility of the data (e.g. will it be shared with specific researchers who request it, will it be uploaded to a restricted or public research archive, etc.).**

Click or tap here to enter text.

**If YES: Will the shared data include direct/indirect identifiers?**

[ ]  Yes [ ]  No [ ]  N/A - data do not include identifiers

**If YES: Please describe the identifiers.**

Click or tap here to enter text.

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| Section 15: Sensitive Data Classification |

This section should be completed if your study involves the collection or storage of data that meet Duke’s “sensitive” [data classification standard](https://security.duke.edu/policies-procedures-and-standards/data-security/data-classification-standard/). Data are considered “sensitive” if an of an inadvertent disclosure of the data would pose risk of harm to participants or Duke is required to protect the data. Data are also considered “sensitive” if participants include minors and children.

* If an accidental release of the data will place participants at risk of harm, the data are classified as **sensitive**.
* If a data mechanism specifies how Duke must be securely store or protect the data, the data are classified as **sensitive**.
* If research participants include minors or children, the data are classified as **sensitive**.

**Research oversight offices apart from the Campus IRB may need to conduct an ancillary review before the IRB can issue a protocol approval. Campus IRB staff will notify you in the event your research must undergo an ancillary review.**

1. **Do your data meet Duke’s “sensitive” data classification?** Data are considered “sensitive” if an accidental release of the data will place participants at risk of harm, if a data mechanism specifies how Duke must securely store or protect the data, or participants include minors or children.

[ ]  Yes [x]  No

### **If NO, click the  to close this section and hide questions specific to data that meet Duke’s sensitive data classification.**

1. **Identify the individuals who will have access to the data and describe their role in the project.** If non-Duke individuals will also have access to the data, please clarify whether data access will be on their local storage or if they will remote in to a Duke server.

|  |
| --- |
| Click or tap here to enter text. |

1. Sensitive data must be stored securely. Select the ITSO-approved environment where you will store the data.

[ ]  Duke’s Box

[ ]  Duke's Microsoft OneDrive

[ ]  Duke's Qualtrics

[ ]  Duke's Zoom

[ ]  Duke University Protected Network (“PN”) for Research

If data will not be stored on an ITSO-approved environment (above), where will they be stored? Be specific.

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| Click or tap here to enter text. |

Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

1. Sensitive data must be analyzed in a secure environment. Select the ITSO-approved environment where you will analyze the data.

[ ]  Duke University Protected Network (“PN”) for Research

[ ]  Data provider enclave (please specify: Click or tap here to enter text.)

[ ]  Duke managed machine

If data will not be analyzed on an ITSO-approved environment (above), where will they be analyzed? Be specific.

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| Click or tap here to enter text. |

Duke University has determined that [the use of non-Duke cloud services, like Google Drive, Apple iCloud, and DropBox are not approved](https://security.duke.edu/policies/duke-services-and-data-classification) for official Duke use.

1. **Describe the devices (laptops, tablets, mobile phones, etc.) that will be used to collect, transfer, store, and/or analyze data.**

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| Click or tap here to enter text. |

1. **Describe how the devices identified in 15.5 (above) will be protected.**

|  |
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| Click or tap here to enter text. |

IT Security (ITSO) has identified [minimum security standards](https://security.duke.edu/policies-procedures-and-standards/device-security/minimum-security-standards-laptops-desktops/) that include encryption of the mobile device or laptop, application of security patches, installation and regular updates of antivirus, and a password-protected screensaver.

1. Who is your departmental or unit IT contact?

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| --- |
| Click or tap here to enter text. |

1. Who is responsible for data security, including upgrades?

|  |
| --- |
| Click or tap here to enter text. |

**Question 15.9 (below) must be answered if your data include direct and/or indirect identifiers. Refer back to Section 13, if necessary.**

1. **How will access to the identifying information be controlled?** For example, identify any individuals responsible for authorizing access to identifying information.

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| Click or tap here to enter text. |

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| Section 16: Informed Consent Process |

See our [**Guide to Informed Consent**](https://research.duke.edu/resource/informed-consent/).

1. **Describe how and where the consent process will take place for each unique participant population. Your response should explain where, how, and who will consent participants.**If someone is expected to provide consent or permission for your participants, please explain. For example, parents are expected to provide permission for their child to participate; legally authorized representatives (LAR) provide consent for those with diminished capacity.

|  |
| --- |
| **The course instructor/reseacher or a LILE representative will administer the consent form to students. This will take place in class or through a learning management system announcement. A LILE representative, listed as the data manager on this protocol, will create and own the consent form in Qualtrics. Researchers will not have access to that form.**  |

**Include all consent materials in the Appendices.**

1. **Are you requesting a waiver of the requirement that participants physically sign the consent process (i.e. a waiver of documentation of consent)?**

[x]  Yes [ ]  No

**If YES, please select all that apply.**

[ ]  Participants do not read and write. (If there is a risk of harm, a third-party witness will be present.)

[x]  Data will be collected on-line. Participants will have the option to “click” to the survey if they would like to take part in the study.

[ ]  The study data will be collected through a telephone or online/virtual interview. If appropriate, provide a copy of the consent process for the participant’s reference.

[ ]  Participants will complete a mailed survey. Prepare a cover letter that includes all the elements of informed consent. People who wish to take part will return the survey; thereby, demonstrating their consent. They do not need to sign a consent form.

[ ]  The research will take place in settings where written consent is considered disrespectful or in settings in which asking people to sign a document would cause distress.

[ ]  The primary risk to participants is a breach of confidentiality and a signed consent form or audio-recorded statement would be the only documented link between individuals and their participation in the study. (Example: a study about people engaged in illegal behaviors.)

**In most cases, other than telephone interviews, where the consent process is oral, researchers should give participants contact information in case the participants have any questions later. It may be appropriate to give them a copy of the oral script for reference.**

1. **Are you requesting that one or more** [**elements of informed consent**](https://research.duke.edu/resource/elements-informed-consent/) **be** [**altered or waived**](https://research.duke.edu/resource/waiver-or-alteration-elements-informed-consent/)**?**

There should always be a process for sharing information about the research study with prospective participants. However, a consent procedure does not have to include all of the required elements of informed consent. For example, the IRB can waive the inclusion of the purpose statement if there is valid justification that it might affect how participants respond.

[ ]  Yes [x]  No

**If YES, please complete #16.5 (below).**

**If YES, please describe what elements you are asking to waive or specify that you are asking to waive consent entirely.**

|  |
| --- |
| Click or tap here to enter text. |

1. **Are you asking to** [**waive**](https://research.duke.edu/resource/waiver-or-alteration-elements-informed-consent/) **parental permission and/or child assent?**

[ ]  Yes [ ]  No [x]  N/A - my research does not include children/minors

**If YES, please complete #16.5 (below).**

1. **The IRB may approve your request to** [**waive elements of informed consent**](https://research.duke.edu/resource/waiver-or-alteration-elements-informed-consent/) **if your research meets the following criteria.** Please address each criterion to explain why a wavier is necessary for your study (do not just copy and paste the criteria into the responses).

**Criterion 1**: The research involves no more than minimal risk to the participants.

|  |
| --- |
| Click or tap here to enter text. |

**Criterion 2**: The waiver or alteration will not adversely affect the rights and welfare of the participants.

|  |
| --- |
| Click or tap here to enter text. |

**Criterion 3**: The research could not practicably be carried out without the waiver or alteration.

|  |
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| Click or tap here to enter text. |

**Criterion 4**: Whenever appropriate, the participants will be provided with additional pertinent information after participation.

|  |
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| Click or tap here to enter text. |

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| Appendices: Study Documents and Consent Processes |

In this section, please include all study documents and consent processes that are a part of this research protocol:

* Study documents include recruitment and screening, research materials (instruments, measures, stimuli, and survey, interview and focus group questions), data use and materials transfers agreements, documentation of local review/approval, etc.
* Consent processes include informed consent forms and scripts, parental permission and child assent, and releases for recordings and images, etc.

**Consent to Participate in Research**

**Page 1**

* Are you 18 years or older?
	+ Yes (If yes, participant is taken to Page 2).

No (If no, survey ends for participant and they see the following: “Thank you for your interest this study. We can only ask consent from those who are 18 years or older. Please come back after you turn 18 to complete this consent form.”).

**Page 2**

**Key Information**

You are being asked to participate in a research study being conducted by **[**name and titles of researchers]at Duke University. The purpose of this study is to: [purpose of study]. The primary question we are trying to answer is: [research question/s]. We are asking you to share your coursework, assignments, and grades from this course. This includes your [list of data sources].

**Voluntariness and Confidentiality**

Your participation is completely voluntary, and you may withdraw at any time for any reason. You do not have to agree to release any of your data from this course to be used in research. Your decision will have no impact on your grades in this or any other course you have taken or will take in the future. Your professor will not know whether or not you agreed to share your information until after this course has ended and final grades have been recorded.

Directly identifying personal information (e.g., name or email address) will be used to remove data from students who elect not to participate. Data will not be made public or used for future research purposes.

**Release of Course Data for Research**

We are asking that you release to us your data from this course to be used in research. Your data will be used to help us better understand the teaching and learning experiences here at Duke University. We are absolutely not making any judgments about any individual participants. None of your directly identifying personal information will be included in any analysis or publications of our findings; however, it is possible that background information, like your demographics, may be used. Please select one of the following:

* Yes, I agree to release my course data to be used for research purposes
* No, my course data CANNOT be used for research purposes

**Contact Information**

For questions about this research, please contact [researcher] at [email@duke.edu].

If you agree to be in this study but later change your mind and want to withdraw, you can return to this survey any time during the semester and change your response. You may also contact Duke Learning Innovation at learninginnovation@duke.edu and ask to be removed from the research.

For questions about your rights as a participant in this research, please contact the Duke Campus IRB at campusirb@duke.edu with reference to Protocol #[TBD by the IRB Office]. Please print this page if you would like a copy for your records.