

**This form effective October 30, 2020**

This form is the **Duke Learning Innovation WALTer Protocol Template** for SoTL (scholarship of teaching and learning) projects being conducted by Duke instructors in partnership with Duke’s 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. All text that is specific to this proposal, e.g., research description, is highlighted.

This template includes the WALTer 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 Duke Learning Innovation 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.**

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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 you have more than one PI, only choose one
* By signing, the PI certifies to the following:
	+ I have read and approved the protocol
	+ I assume responsibility for ensuring that my advisees are aware of the responsibilities as researchers
	+ 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://campusirb.duke.edu/node/101) of participation.

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| **Name**:Click or tap here to enter text. | **Department or School**: 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. | **Phone Number**: Click or tap here to enter text. |
| [ ]  **Faculty Advisor** [ ]  **Faculty Researcher** [ ]  **Staff** [ ]  **Other**:Click or tap here to enter text. |
| **Signature**: | **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 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://campusirb.duke.edu/node/57) for each researcher named on the protocol is current.
* I will conduct this study as described in the approved protocol.
* If any changes are anticipated, I will submit a [Request to Amend an Approved Protocol](https://campusirb.duke.edu/node/22), and I will not implement the changes until I receive approval from the IRB.
* I will contact the IRB staff promptly if any of the following events occur: [unanticipated risks of harm to participants, protocol deviations, and findings during the study that would affect the risks](https://campusirb.duke.edu/node/101) of participation.

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| **Name**:Click or tap here to enter text. | **Department or School**: 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. | **Phone Number**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**: | **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. |
| **E-mail Address**: Click or tap here to enter text.**NetID**: Click or tap here to enter text. | **Phone Number**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**: | **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. |
| **E-mail Address**: Click or tap here to enter text.**NetID**: Click or tap here to enter text. | **Phone Number**: Click or tap here to enter text. |
| [ ]  **Faculty** [ ]  **Undergraduate** [ ]  **Graduate** **student** [ ]  **Postdoc** [ ]  **Research associate**[ ]  **Other**:Click or tap here to enter text. |
| **Signature**: | **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**: **Grey Reavis** |
| **E-mail Address**: grey.reavis@duke.edu**NetID**: gr85 |
| **Type of Correspondence:**[x] Approval and Reminder Notices[x]  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 researcher(s) at other institution(s)?**

Please contact IRB staff at campusirb@duke.edu to confirm that you are engaged in inter-institutional collaborations.

[ ]  Yes [ ]  No

**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. |

1. **If your collaborator is a foreign entity, have you already obtained approval from the** [**Duke University Office of Export Controls**](https://export.duke.edu/)**?**

[ ]  Yes [ ]  No [ ]  N/A

If NO, IRB staff will forward this protocol to the Export Controls office.

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| Section 4: Funding Sources and Conflict of Interest |

1. **Please identify your funding source(s)**:

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| Click or tap here to enter text. |

1. **Are any of the above funding source(s) a U.S. Federal Agency or Department?**

[ ]  Yes [ ]  No

If YES, please include the grant application with this protocol request (the budget information can be removed).

1. **Are any of the above funding source(s) a component of the Department of Defense?**

[ ]  Yes [ ]  No

If YES, please complete and include the DOD attachments (found at <https://campusirb.duke.edu/forms>) with this protocol request.

1. **Is there a financial conflict of interest (COI) which needs to be reported or has been reported to the Duke University Office of Scientific Integrity (DOSI)?**

[ ]  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 Duke Learning Innovation WALTer 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 Duke Learning Innovation 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 Duke Learning Innovation
* After grades are submitted, Learning Innovation 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 undergraduate learning. 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 through data-driven innovation and iterative course design. Another outcome of this initiative is to share findings about how students learn in different contexts. 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. **Will any of your research activities be physically conducted outside of the U.S.?**

[ ]  Yes – All of them [ ]  Yes – Some of them [x]  No

**If YES, please identify the countr(ies) 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.

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| **N/A** |

**IF YES, have you already obtained approval from the Duke University Office of Export Controls?**

☐ Yes ☐ No

If NO, IRB staff will forward this protocol to the Export Controls office.

1. **Will any of your research activities be conducted online, by telephone, or by other electronic communication?**

[ ]  Yes – All of them [ ]  Yes – Some of them [x]  No

**If YES, will any of your participants be located outside of the U.S. while participating in your research?**

[ ]  Yes - All of them [ ]  Yes – Some of them [x]  No

**If YES, please identify the countr(ies) where you will carry out your research.** If you have more than one study or participant population, elaborate on the specific studies or participant populations that will be located outside of the U.S.

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| Click or tap here to enter text. |

1. **If the research is not taking place in the U.S., does it need community-level, institutional-level, or national level approval in the countr(ies) where it will take place? Please elaborate.**

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| **N/A** |

***\*\*****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 identify the school(s) and/or school district(s):**

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| **N/A** |

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

[ ]  Children\*, 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

[ ]  Native American/American Indian

[ ]  Prisoners

[ ]  Refugees

[ ]  Stigmatized populations

[ ]  Undocumented immigrants

[ ]  Victims of abuse

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

\*See our [**Research with Children**](https://campusirb.duke.edu/node/63) policy. Please see questions 6.9-6.10.

1. **Describe each proposed participant population.** Include the expected number of participants in each population. If your research will include children, please include their age ranges and the age of majority of the population where your participants reside.

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| 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 Duke Learning Innovation 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. **Is the primary language of your participants English?**

[x]  Yes [ ]  No

**If NO, please indicate their primary language and your proficiency in speaking, reading, and writing it.**

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| Click or tap here to enter text. |

1. **If you are not proficient in the language your participants speak, will you need an interpreter?**

[ ]  Yes [ ]  No [x]  N/A

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

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| Click or tap here to enter text. |

Please answer the following questions if your research activities will involve children/minors.

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

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| **N/A** |

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

*Note: Duke requires individuals interacting with minors to complete training:* [*https://forms.hr.duke.edu/minors/training/*](https://forms.hr.duke.edu/minors/training/)*).*

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| **N/A** |

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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 statement about the research (see below) will be included in the corresponding course syllabi and/or Sakai course site, and a verbal announcement will be made in person by the instructor or a Duke Learning Innovation representative. A Duke Learning Innovation representative will introduce the study to students whenever this is logistically possible. All students in participating courses and programs will be informed of the research being conducted. Instructors will include a paragraph in their syllabus or on their course Sakai site with the following wording and/or intent:“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. Duke Learning Innovation will send you a consent form through Qualtrics that describes what data you are being asked to share and how it will be used. Please read through the information provided there and indicate if you are willing to share your data.”Additionally, the instructor or, whenever possible, a representative of Duke Learning Innovation will read this statement verbally during a class session and answer any student questions. |

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

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

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

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

[ ]  Yes [x]  No

**If YES, please describe the inclusion or exclusion criteria.**

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| Click or tap here to enter text. |

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).**

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| Click or tap here to enter text. |

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| Section 8: Description of Activities |

1. **Describe the study activities and how long each activity will take.**

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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) in the Appendices\*\**

*Description of Activities | Recordings and Photographs*

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. *Note: Audio-recordings are considered identifiable.*

See our [Guide for Releases for Images and Recordings](https://campusirb.duke.edu/node/78)

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

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

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| Click or tap here to enter text. |

**8.2.2 What will the recordings 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.)

**8.2.3 Elaborate on the above.** If the recordings will be shared publically 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. |

*Note: See* [*our website*](https://campusirb.duke.edu/node/78) *for more information about obtaining releases for recordings.*

**8.2.4 What device(s) will you use to record participants?**

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| Click or tap here to enter text. |

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

[ ]  Yes [x]  No

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

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| Click or tap here to enter text. |

**8.3.2 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.)

**8.3.3 Elaborate on the above.** If the photographs will be shared publically 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 publically or save for the future.

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| Click or tap here to enter text. |

**8.3.4 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. |

**8.3.5 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. |

**8.3.6 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 release(s)

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| Click or tap here to enter text. |

*Note: See* [*our website*](https://campusirb.duke.edu/node/78) *for more information about obtaining releases for images.*

*Description of Activities | Deception and Debriefing*

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

[ ]  Yes [x]  No

**8.4.1 Describe the deception.**

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| Click or tap here to enter text. |

**8.4.2 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. |

**8.4.3 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. |

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

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| Click or tap here to enter text. |

1. **If participants will be debriefed, explain when they will be debriefed and include the debriefing statement in the Appendices.** *Note: Research involving participants from the* Psychology & Neuroscience SONA Subject Pool *requires an educational debriefing.*

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| **N/A** |

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| Section 9: Additional Data |

1. **Will you be provided with data about your participants or other individuals that you will analyze as part of this project?** For example, U.S. census records, medical records, academic records, financial records, client/member data, or user/customer data.

[ ]  Yes [x]  No

1. **Please describe the data and the data providers.** This includes the variables, estimated number of records, and identifying the organizations and/or individual(s) providing the data.

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| Click or tap here to enter text. |

1. **Do any of above 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

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

[ ]  None of the Above

1. **Do the data contain any identifiable information?**

*For more information on what types of data may be considered identifiable, please see the descriptions in Section 13: Confidentiality.*

[ ]  Yes [ ]  No

**If YES, will the data be de-identified (either before or after you receive them)?**

[ ]  Yes [ ]  No

**If YES, please describe the de-identification process.** If Duke is responsible for de-identifying the data, who will do that, when will this occur, and where will it occur?

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| Click or tap here to enter text. |

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

[ ]  Yes [ ]  No

1. **Does your data provider require you to enter into an agreement, such as a data use agreement (DUA), or do they specify guidelines or restrictions that describe how to transfer, protect, or store the data?**

[ ]  Yes [ ]  No

If NO, include documentation in the Appendices that confirms this. Documentation can be an email from a representative of your data provider or a screenshot from their website.

If YES, complete Section 14: ITSO Questions, and upload the agreements in the Appendices.

* Agreements must be signed by the data provider and by a Duke institutional official
* The IRB will facilitate securing the institutional signature
* Researchers may not sign on behalf of the university
1. **Will the data require destruction?**

[ ]  Yes [ ]  No

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

1. **Does your research require that you re-consent participants for the secondary use of their data?**

[ ]  Yes [ ]  No

**If YES, please describe the process for re-consenting participants.**

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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://campusirb.duke.edu/node/70).

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

[ ]  Yes [x]  No

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

[ ]  Bonus Payments

[ ]  Cash

[ ]  Check

[ ]  Course 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 each type of compensation and how they will be distributed.** If multiple payments will be made, please describe.

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| Click or tap here to enter text. |

1. **Under what conditions will participants receive partial or no compensation?** If skipping any or all questions would affect compensation, please specify.

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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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| **None** |

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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.

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| 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.

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| 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. |

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

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| Section 13: 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.

See our [Guide to Confidentiality](https://campusirb.duke.edu/node/72).

*Confidentiality | Recruitment*

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

[x]  Yes [ ]  No

**If YES, explain how the information will be collected, where they will be stored, and what will happen to the identifiers after the recruitment process is complete.**

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| Duke Learning Innovation will share the consent form through Qualtrics using student email addresses available on the course roster/s. Instructors will not recruit or consent their students. |

*Confidentiality | Storage*

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, please describe the *direct* identifiers, explain why they are necessary for your research, where you will store them, and how long you will keep them.** Be specific about your storage space (e.g. if it’s a “secure server at Duke”, specify which secure server).

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| The email address used to contact students will be linked to students’ consent forms in Qualtrics. Duke Learning Innovation will use the consent information and email address to remove data from students who do not consent to share their information. Learning Innovation will remove students email address using a Duke managed computer, and direct identifiers will be deleted as soon as that process is complete. Then, the data without the direct identifiers will be shared with the PI via Duke Box. |

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, please describe the *indirect* identifiers, explain why they are necessary for your research, where you will store them, and how long you will keep them.** Be specific about your storage space (e.g. if it’s a “secure server at Duke”, specify which secure server).

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| Click or tap here to enter text. |

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.

[x]  Yes [ ]  No

**If YES, describe the specific harms that could occur if individually identifiable data were accidentally made available to those outside the research team.**

|  |
| --- |
| **Data are generated by students participating in standard educational activities in their classes. It is possible that answers to test questions or other materials could expose their performance in class. However, 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, no indirectly identifiable information is being collected, and data approved under this protocol is not made public or used for future research purposes.** |

**If YES, will you apply for a Certificate of Confidentiality to protect the data from subpoena if, for example, you have identifiable data about illegal or unlawful behavior?** (If your research is funded by the NIH, please select “Yes.”)

[ ]  Yes [x]  No

1. **Do you plan to have documentation (e.g. a key) that links a participant’s identifiers to their responses?**

[ ]  Yes [x]  No

**If YES, please describe the documentation, where it will be stored, how it will be protected, and who will have access to it.** Be specific about your storage space (e.g. if it’s a “secure server at Duke”, specify which secure server).

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| Click or tap here to enter text. |

1. **Where will the data be stored?** Be specific about your storage space (e.g. if it’s a “secure server at Duke”, specify which secure server).

|  |
| --- |
| **Duke Box** |

1. **Who will have access to the data?**

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| --- |
| **Duke Learning Innovation will have access for the purposes of third party de-identification (removing direct identifiers); otherwise, only to PI and research team listed on the protocol will have access to the de-identified data.** |

*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

**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:**

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

*Confidentiality | Future Research and Data Sharing*

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

[ ]  Yes [x]  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 identifiers?**

[ ]  Yes [ ]  No

**If YES, please describe the identifiers.**

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

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| Section 14: ITSO Questions |

This section should be answered if your data are considered sensitive and identifiable AND/OR you have a Data Use Agreement (DUA) for this project.

If accidental release of the data will place participants at risk of harm, the data are classified as **sensitive**.

If the data include any information that could directly or indirectly allow someone to figure out who individual participants are, then the data are considered **identifiable**. This also includes photographs, audio recordings, and video recordings.

1. **Are your data both sensitive and identifiable and/or do you have a DUA for this project?** Mark all that apply. Your answers in the Description of Activities (questions 8.2 and 8.3), Additional Data (questions 9.4- 9.6), and Confidentiality (questions 13.2-13.5, 13.8, 13.9, and 13.11) sections can help you answer this.

[x]  Yes - Sensitive and Identifiable Data [ ]  Yes - DUA [ ]  No\*

If YES, The following questions are intended to collect information about your data protection procedures. Your responses will be reviewed by the IRB and Duke’s Information Technology Security Office (ITSO). ITSO will review the data protection plan to ensure appropriate measures are in place to protect the data. The IRB will be unable to approve a submission without confirmation from ITSO.

Please review the [Developing Data Protection Plans](https://campusirb.duke.edu/node/96) guide for a list of best practices and ITSO recommendations. If you have any questions about data protection, contact security@duke.edu.

1. **Will you use devices such as laptops, tablets, and/or mobile phones to collect, transfer, store, or analyze data?**

[x]  Yes [ ]  No

**If YES, what devices will be used and how will they be protected?** Please note that security best practices include encryption of the mobile device or laptop, application of security patches, installation and regular updates of antivirus, and a password-protected screensaver.

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| --- |
| The data will be analyzed using password-protected laptops or computers that use whole disk encryption, regular patching, screen lock and anti-virus. Only the merged, de-identified data set will be on laptops.While data may be stored locally on temporary basis; the data will be stored on Duke Box for long-term purposes (see #14.11). All laptops will have current security updates. |

1. Who is your departmental or unit IT contact?

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| --- |
| **Computing Support/IT Manager** -  **Provide the name of your department’s IT manager** |

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

|  |
| --- |
| **Computing Support/IT Manager (Provide the name of your department’s IT manager)** is responsible for IT upgrades. The research team on this proposal is responsible for keeping the data secure by storing it only on Duke Box. |

1. Data need to be stored securely. Select the ITSO-approved environment where you will store and analyze the data.

[x]  DukeBox

[ ]  OIT Protected Network

[ ]  Protected Research Data Network (PRDN)

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

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

|  |
| --- |
| **N/A** |

1. **Will both direct and indirect identifiers be removed from the data**?

[x]  Yes [ ]  No

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

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

**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.**

|  |
| --- |
| Duke Learning Innovation will collect consent through Qualtrics. The PI will share data with Duke Learning Innovation through a Duke Box folder. Once course grades are submitted, Duke Learning Innovation will remove any data from students who do not consent to share their data. All data will remain in a Duke Box folder for this purpose.  |

1. **Please identify each individual (including non-Duke researchers) who will have access to the data and describe their role in the project.**

|  |
| --- |
| The research team identified on this protocol are the only people who will have access to the data. Duke Learning Innovation will coordinate the data set creation and de-identification. |

1. **How will access to the identifying information be controlled and who will authorize access to the identifiable data?**

|  |
| --- |
| Access to identifying information will be controlled through permissions on the Duke Box folder where the data are stored. Duke Learning Innovation will manage authorization and access control for that folder. |

1. **Will data be transferred for analysis?**

[x]  Yes [ ]  No

1. **How will data be transferred and where will they be analyzed?**

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| --- |
| The data will be stored at all times on the Duke Box folder. When necessary for analysis, the data will be temporarily copied to local storage on a password-protected laptop. Once each session of analysis is complete, the data will be re-stored on Duke Box and no local copy will be retained. No data will remain in local storage when not being actively used in analysis. |

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| Section 15: Informed Consent Process |

Here you will answer questions about your informed consent process. You will be asked to upload your consent language in the Appendices.

See our [Informed Consent Guide](https://campusirb.duke.edu/node/73).

1. **Describe how and where the consent process will take place.** 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.

|  |
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| **Duke Learning Innovation will collect consent online through a Qualtrics survey emailed to student participants.** |

*Note: Please include your protocol ID number within your consent process.*

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.)

*Note: 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://campusirb.duke.edu/resources/guides/elements-informed-consent) **be altered or waived?**

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 describe what element(s) you are asking to waive or specify that you are asking to waive consent entirely, and complete Question 15.5.**

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

1. **Are you asking to waive parental permission and/or child assent?**

[ ]  Yes [x]  No [ ]  N/A

If YES, please complete Question 15.5.

1. **The IRB may approve your request to waive element(s) of 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 subjects.

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

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

|  |
| --- |
| 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 subjects 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 any study documents (e.g. recruitment materials, survey/interview questions, measures and instruments, DUAs, etc.) and consent processes that you will use in your study.

**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**

We are learning too!

**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. 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.

Identifying information 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 personal information will be included in any analysis or publications of our findings. 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.