**Exemption Determination Request and Instructions**

IRB Application Instructions

**Directions: How to apply for an Exemption with the NC State University IRB:**

1. Only complete and submit this application for projects considered NC State University [regulated research](https://docs.google.com/document/d/1jgmeWpFSJhkFyawppbB3BGo44rm_FYSv_aha4cazW44/edit#heading=h.ieaatb7t50yr) with [human subjects](https://docs.google.com/document/d/1WVDuyi5_t_oblhiffsucf7V0liwUBtNXSTIFMV_kYVs/edit).
   * The NC State University IRB does not regulate projects solely done as a [class project](https://docs.google.com/document/d/1-tsGE5TPmVe-F_TO8Xpv1o1vubRQ8_St8N0zluZbBGM/edit#heading=h.daojk6fohvw9), [assessment, evaluation, quality improvement](https://drive.google.com/file/d/168OmPHTFvi1zT8-GqcCWOia25CMIV-bJ/view), journalism, or [oral history](https://docs.google.com/document/d/1Emd5k4cHJuzXqeH0Bk5yPHKWcyOMJq6c/edit#heading=h.gjdgxs).
2. Prepare to submit an application to the IRB by reviewing this document, links within it, its appendices, and the NC State [standard for exemption determinations](https://docs.google.com/document/d/1vVbB4aGlK_elrRioTIR9aNj3ps7cbYRb/edit?usp=share_link&ouid=111628324854172758765&rtpof=true&sd=true).
3. The IRB expects you to follow other NC State University regulations.
   * When using software for research, make sure it is properly [licensed with NC State University](https://software.ncsu.edu/)
   * When completing survey research with the NC State population(s) such as NC State students, faculty, or staff, you must [register](https://isa.ncsu.edu/surveys/administering-a-survey-at-ncstate/register-your-survey) your survey.
   * When engaging with minors for research, adhere to the [NC State University Regulation 01.25.18](https://policies.ncsu.edu/regulation/reg-01-25-18/).
4. Open an [eIRB](https://www3.acs.ncsu.edu/hs/irb.php) application (refer to the [IRB website](https://research.ncsu.edu/administration/compliance/research-compliance/irb/preparing-and-submitting-an-application/) for the eIRB tutorial).
5. Complete the first two tabs in the eIRB which include the “Title” and “Description” tabs. **Leave all other eIRB application tabs blank.**
6. Upload the following to the eIRB’s “Supporting Documentation” page:
   * A completed “Exemption Determination Request Application” (starting on p. 2 of this form).
   * Proof of [human subjects research training](https://drive.google.com/file/d/15On0UevTEaZz9cXk9pVPdSstZPFgjnbO/view) for all NC State University members of the research team, including the faculty advisor for the protocol.
   * [Consent material](https://docs.google.com/document/d/1b-5-3XPkwTfPJoXagCe7ye3EzUGB7uur/edit?usp=sharing&ouid=118314250343958183913&rtpof=true&sd=true) – please use the appropriate exemption consent form template and “broad consent” addendum (if broad consent is sought).
   * All stimuli, measures, and instruments (ex: surveys, interview protocols, focus group protocol, observation protocol, benign behavioral intervention protocol, taste test protocol).
     + You do not need to provide recruitment materials, scheduling emails, or other basic communications for studies qualifying for exemption.
7. If any of the following apply to your study, upload them to the eIRB’s “Supporting Documentation” page:
   * The [NIH data management and sharing plan](https://docs.google.com/document/d/1bho1Fpadb075_YNyd7cfMz0cUYODP-bL/edit?rtpof=true&sd=true) if your study is supported by NIH.
   * A completed [data access and security plan](https://drive.google.com/file/d/17vi6gPC1f_34eSW7X7_miLyh0VHIdJX5/view) form for protocols collecting highly-sensitive (“red”) or ultra-sensitive (“purple”) data.
   * Relevant agreements such as a [data use agreement](https://research.ncsu.edu/administration/data-use-agreements/) or a [material transfer agreement](https://research.ncsu.edu/commercialization/inventors-guide-to-commercialization/).
   * The implemented [broad consent addendum](https://drive.google.com/file/d/1R0fkGq4KUCydAe0y9Wft_6YGup1qAfSB/view) form used at primary data collection (if protocol will use secondary data where broad consent was sought and given by participants).
   * All debriefing materials if [deception or incomplete disclosure](https://docs.google.com/document/d/14olPHJTWxRQUZY6RERk1Qu5gjrCiaAse/edit?usp=sharing&ouid=111628324854172758765&rtpof=true&sd=true) will occur.
   * The “opt out form” sent to participants/guardians regarding recordings in classrooms (outside of NC). Refer to the [IRB guidance for images and recordings in research with humans](https://docs.google.com/document/d/1SNbPGc2sXzmvxyARkAXtCLVYiRd3V148/edit?rtpof=true&sd=true#heading=h.gjdgxs) and for K-12 education review the school’s processes and procedures related to the [NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights”](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf).
   * The HIPAA authorization used with participants/guardians or the submission of a HIPAA waiver request form. Refer to the [IRB’s HIPAA unit standard.](https://docs.google.com/document/d/1LWpYDOyDUW0cZOkzAKTkx9dG8ugtMFW7/edit?usp=drive_link&ouid=118314250343958183913&rtpof=true&sd=true)
   * The FERPA consent information used with participants/guardians. Refer to the [IRB’s FERPA unit standard.](https://docs.google.com/document/d/181Bc0Q-PFhhG8nIEMgASj_8kt-68Ys-n/edit?usp=drive_link&ouid=118314250343958183913&rtpof=true&sd=true)

**Study Title:** Implementing Oral Exams

**eIRB Protocol Number:** 26585

**Research Team:**

**Faculty Advisor/Chair/Point of Contact**: Justin post

**Student Researcher (if for dissertation or thesis)**:

**Other NC State Researchers:**  Matthew Ferrell

**Other Non-NC State Researchers:**

**Funding Source Information:**

Is this study funded? ☒ No ☐ Yes

Is this study federally funded? ☒ No ☐ Yes, provide funder name:

Is this study privately funded? ☒ No ☐ Yes, provide funder name:

Is this study funded internally by NC State? ☒ No ☐ Yes, detail:

Is this study self-funded? ☒ No ☐ Yes, detail:

☒ Yes, this project is not solely being done for a [class project](https://docs.google.com/document/d/1-tsGE5TPmVe-F_TO8Xpv1o1vubRQ8_St8N0zluZbBGM/edit#heading=h.daojk6fohvw9), [assessment, evaluation, quality improvement](https://drive.google.com/file/d/168OmPHTFvi1zT8-GqcCWOia25CMIV-bJ/view), journalism, or [oral history](https://docs.google.com/document/d/1Emd5k4cHJuzXqeH0Bk5yPHKWcyOMJq6c/edit#heading=h.gjdgxs). I need [IRB approval](https://research.ncsu.edu/administration/compliance/research-compliance/irb/determining-approval/) because this project is being done to [contribute to generalizable knowledge](https://docs.google.com/document/d/1jgmeWpFSJhkFyawppbB3BGo44rm_FYSv_aha4cazW44/edit#heading=h.ieaatb7t50yr) which includes (but is not limited to) designing the project to serve as [pilot work](https://docs.google.com/document/d/1TCablyUuYCshVUSAMYcjVyB7G8m5aOL-/edit?usp=sharing&ouid=118314250343958183913&rtpof=true&sd=true), or for journal publications, dissertations, master’s theses, presentations at conferences, some symposiums, etc.

**Briefly describe the research project purpose and research questions** *(no more than one paragraph)*:

This study investigates graduate student instructor concerns and attitudes when implementing oral exams in a flipped programming course. Processes for preparation and implementation of the exams are also considered.

**Participants**

**1. How many participants do you anticipate enrolling in the research (provide a meaningful range)?** *If you have several participant groups, provide number ranges for each participant group. If this is an application for secondary data/specimens, tell the IRB how many people are included in the secondary dataset(s)/specimens you wish to access for research purposes.*

6-10

**2. Is there a relationship between anyone on the research team and the participants such as teacher/student, doctor/patient, supervisor/supervisee, participants who are family members, etc.?**

☐ Yes. If yes, describe the relationship and what steps you will take in the research design to mitigate any subsequent undue influence/coercion because of participation in this study:

☒ No

**3. Does this study involve people under the age of 18 or anyone legally considered a minor?**

☐ Yes

☒ No

**4. Does this study involve people who are also** [**incarcerated**](https://drive.google.com/file/d/1AkPLIO0hMwZRNqC-HriCpZJJ27C50cnk/view?usp=sharing)**, are involuntarily detained or committed, or are in a program or hospital as an alternative form of sentencing?**

☐ Yes. If yes, describe their status and if they are incidentally included. *If you are targeting people who are also incarcerated, the study is not eligible for an exemption determination*:

☒ No

**5. Can any of the participants be considered vulnerable due to their identity, status, or research context (ex: participants who have an identity that may experience discrimination, people who are not “out,” or people who are undocumented)?**

☐ Yes. If yes, discuss the participant group(s) contextual vulnerability**:**

☒ No

**6. Is data collection limited to people currently located within the United States?**

☒ Yes

☐ No. If no, describe in what country participants will be located**:**

*Note, if this study includes people residing in the EEA, the GDPR applies. Please refer to the* [*IRB’s GDPR guidance*](https://drive.google.com/file/d/1AUGmOl7nXsPrliti2LVpPF-JkpW9BCm0/view?usp=sharing) *for additional responsibilities.*

**Recruitment and Site Access**

**7. How will you recruit participants?**

☐ N/A

☐ Group Announcements

☐ Direct email

☐ Fliers

☐ Listservs

☐ M-Turk

☐ Newspaper

☐ Social Media

☐ SONA

☐ Qualtrics Panel

☐ Billboards/Community Boards

☒ Other:  Graduate student instructors teaching specific courses (ST 307, ST 308)

**8. Briefly describe your recruitment procedures** **for each participant group in the research** (*You do not need to provide recruitment materials for review for exemption determinations):*

Instructors for the course will be asked to participate voluntarily in the study during an instructor meeting period. It will be made clear to them they are under no obligation to allow their data to be used, there will not be any extra work required that is uncompensated, and that their information may be identifiable due to the small group of instructors.

**9. Will you be seeking “site permission” via a “gatekeeper” to complete your research activities? This applies to any location where research procedures take place** *(IRB approval is not site or records release permission)***:**

☐ Yes, I will seek site permission from:

☐ I will comply with all site policies, procedures, and expectations.

☒ No, site permission is not required due to location or the research procedures are taking place.

**General Research Procedures**

**10. Modes of Data Collection:**

**10a. Primary Data Collection** *(check all that apply)***:**

☐ N/A, this study is not collecting data from participants through an interaction or intervention.

☐ Activities Completed Only Face-to-Face.

☐ Activities Completed Only Virtually.

☒ Activities Completed Virtually and Face-to-Face.

☐ Augmented Reality.

☐ Benign Behavioral Intervention.

☐ Driving Simulator.

☐ Focus Groups.

☐ Interviews.

☐ Normal Educational Practices *(question 12 requests details).*

☐ Observations.

☐ Photovoice.

☐ Q-Sort.

☒ Surveys.

☐ Taste Tests.

☐ Usability/likability testing.

☐ Using a Device.

☐ Using an App or Software.

☐ Viewing Photos or Videos.

☐ Virtual Reality.

☐ Other:

**10b. Secondary Data Collection** *(check all that apply)***:**

☒ N/A: This study is not requesting to access or use secondary information as data for research in any way.

☐ Use of information subject to FERPA to be used as a sampling frame.

☐ Use of information subject to FERPA to be used as data for research.

*IRB approval is not permission from a site to release records. That permission solely comes from an appropriate record holder from that site.*

☐ Use information subject to HIPAA to be used as a sampling frame.

☐ Use information subject to HIPAA to be used as data for research.

*IRB approval is not permission from a site to release records. That permission solely comes from an appropriate record holder from that site.*

☐ Use of information subject to the GDPR to be used as a sampling frame.

☐ Use of information subject to the GDPR to be used as data for research.

☐ Use of research data from another IRB approved study where “broad consent” was sought.

☐ Other:

**11. Briefly (about a paragraph or two) describe what each participant group will be doing as a part of this study.** *Include all primary data collection procedures and any secondary data collection procedures (i.e., recruitment and consent, if applicable) that each group of participants will experience for research. If a study involves activities that would occur regardless of the research taking place (such as coursework), please do not describe those, only the research procedures and secondary data relevant to the research study***:**

Study participants will participate in meetings with the course coordinator (Justin Post – PI) as normal parts of their duties. During this time they will also take surveys (via google forms) about their thoughts and concerns about administering oral exams also as a normal part of their duties. When implementing a change to how a class is run, surveys would have been given regardless of this research being done or not. Post exam discussions will be recorded via a voice recorder. Any relevant email correspondence between the instructors and course coordinator will also be logged.

☒ This study involves normal educational practices and details are provided in question 12.

☐ N/A: This study is exclusively using secondary information as data for research and at no point will there be any interactions or interventions with participants. *IRB approval is not permission from a site to release records. That permission solely comes from an appropriate record holder from that site.*

**Normal Educational Practices**

**12. Are you completing research activities via normal educational practice and in an established/commonly accepted educational setting?**

☐ N/A: This application is only requesting the secondary use of FERPA information that is generated as a part of normal coursework.

☐ No.

☒ Yes. If yes, please answer the following questions:

**12a. Describe the established or accepted educational setting:** Oral exams will be given via zoom.

**12b. Describe the normal educational practice and if it is being done because this research is occurring or if it would occur regardless of this proposed:** These oral exams would be done regardless of this study.

**12c. Describe how the research will NOT adversely impact students' opportunity to learn required content or the assessment of educators:** The study simply considers instructor concerns and attitudes toward giving the exams. There should be no impact on the students’ learning.

**12d. Is this study being done “on behalf” of the educational institution where the research activities are taking place?**

☒ No.

☐ Yes. If yes, describe how the research is being done “on behalf” of the institution:

**12e. Does the study aim to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction?**

☐ No.

☒ Yes. If yes, describe how the research is being done “on behalf” of the institution: The hope is to understand concerns of instructors and form good practices for training and creation of future oral exams by similar instructors.

**12f. Will you be audio recording, video recording, or taking pictures of people’s faces or other identifying physical attributes during normal educational activities?** *Answer N/A to this question if recordings are not related to the normal educational practice.*

☐ N/A.

☐ No.

☒ Yes. If yes, please describe in detail why it is needed, how it will not affect student learning, and your plan for notification through an “opt out” form for recording purposes: In order to best document student concerns after implementing the exams audio recordings of meetings will be made.

**12f.i. The recordings or images are of**: graduate student instructors

**12f.ii. The recordings or images will be taken via**: voice recorder and/or video camera

**12f.iii. Will individuals be blurred/masked during analysis?**

☐ Yes ☐ No ☒ N/A

**12f.iv. Will individuals be blurred/masked when images are published or presented publicly?**

☐ Yes ☐ No ☒ N/A

**12f.v. The identifiable video or photos will be stored (where and how)**:

**12f.vi. The recordings or images will be transferred via**: Google drive and SD cards

**12f.v.ii. The recordings or images will be destroyed when**: the study is completed

☐ **The audio or video recording will occur in a K-12 classroom in a public school in NC.** I understand that because of the [NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights”](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf) that the school will require parental/guardian permission to be sought in order for the audio or video recordings to occur.

* For exempt research, this law makes it a requirement to seek parental/guardian consent for audio/video recording in NC schools required regardless of the federal regulation governing research with human subjects.
* This also means that you may be required by the K-12 school to have a plan to ensure those without parental/guardian permission are not audio or video recorded.
* I will follow the school’s procedure or requirements for this to occur.
* If I have more questions about this topic, I will reach out to NC State University [General Counsel](https://generalcounsel.ncsu.edu/).

☒ **I understand that if using Zoom to record human subjects’ data, I must comply with the** [**NC State University required settings for use of Zoom in human subjects’ research**](https://docs.google.com/document/u/2/d/e/2PACX-1vS2_q6sITeONul76lLzoUP9Qe0WVQ6xgHhWk6CfwsTDTiNs9kQFnnaqL7eqUk_bq5vZMR5az1x1soZ4/pub?urp=gmail_link)**.**

☐ **The classroom intervention or interaction takes place in a K-4 classroom in a public school in NC and it addresses gender identity, sexual activity, or sexuality, and can be considered instruction.** I understand that because of the [NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights”](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf) that the NC school may not allow for this instruction to take place within the school.

* I will follow the school’s procedure or requirements for this to instruction to occur.
* If I have more questions about this topic, I will reach out to NC State University [General Counsel](https://generalcounsel.ncsu.edu/).

☒ **I have reviewed and understand the NC State University IRB guidance for the** [**use of images and recording of participants in research studies**](https://docs.google.com/document/d/1SNbPGc2sXzmvxyARkAXtCLVYiRd3V148/edit#heading=h.gjdgxs)**.**

**Surveys**

**13. Are you implementing a survey for data collection?**

☐ No

☒ Yes. If yes, below, check all that apply:

☐ The survey will be administered online using NC State licensed Qualtrics.

☐ The survey will be administered online using NC State’s REDCap.

☐ The survey will be administered online using UNC-Ch licensed REDCap (with an agreement of some kind in place for use of their license).

☒ The survey will be administered online using NC State licensed Google Forms.

☐ The survey will be administered online using the following survey platform:

☐ The researchers will utilize the following online survey panels to reach participants:

☐ The survey will be completed by participants using an NC State University owned device.

☐ The survey will be completed by participants using the researcher’s personal device.

☒ The survey will be completed by participants using their own personal device.

☐ Researchers are telling participants to take the survey in a private location, on a private internet. connection and device, using a web browser set to private or incognito mode.

☐ The survey will be completed by participants using physical paper and writing utensils. Describe how the physical surveys are turned in to the research team:

☐ The survey will be completed verbally with the research team asking participants the questions.

☐ The survey will be implemented in a K-3 classroom in a public NC school and it addresses student **well-being or serves as a health screening** as described it the [NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights”](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf).

* I understand that because of the NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights” that a copy of the blank survey may be required to be available to school officials or parents.
* For exempt research, this law makes it a requirement to seek parental/guardian consent for implementation of student well-being or health screening surveys in K-3 classrooms in NC schools.
* If I have more questions about this topic, I will reach out to the school where the research will take place or if appropriate, to NC State University [General Counsel](https://generalcounsel.ncsu.edu/).

☐ The survey will be implemented in a K-12 classroom in a public NC school. I understand that parental/guardian permission must be sought in order for a for a “Protected Information Survey,” as described in the [NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights”](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf) section 115C-76.65(a)(2), to be implemented.

* For exempt research, this law makes it a requirement to seek parental/guardian consent for implementation of surveys in NC schools that contain content described in 115C-76.65(a)(2). I will follow the K-12 school’s procedure or requirements that address this.
* I understand that because of the NC Session Law 2023-106, Senate Bill 49 “Parent’s Bill of Rights” that a copy of the blank survey may be required to be available to school officials or parents at least 10 days before administration. I will follow the school’s procedure or requirements for this to occur.
* If I have more questions about this topic, I will reach out to the school where the research will take place or if appropriate, to NC State University [General Counsel](https://generalcounsel.ncsu.edu/).

**Taste Tests and Food Quality Evaluation**

**14. Are you implementing a taste test, food quality evaluation, or consumer acceptance study of a food?**

☒ No

☐ Yes. If yes, please answer the following:

**14a. Is the food being tasted or evaluated:**

☐ A wholesome food without additives.

☐ A food that contains a food ingredient at or below the level and for a use found to be safe by the U.S. Food and Drug Administration.

☐ A food that contains an agricultural chemical or environmental contaminant tested is at or below the approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ Commercially available.

**14b. How is the food prepared? Please check all that apply:**

☐ The item is prepackaged.

☐ The item is prepared in a commercial kitchen that follows good manufacturing practices.

☐ The item is handled in accordance with FDA standards.

☐ Other. Please describe:

**14c. How is the food served? Please describe:**

**Benign Behavioral Interventions or Data Collection Using Sensors**

**15. Does this study involve** [**benign behavioral intervention**](https://docs.google.com/document/d/1xGzMpDN79SUQaL0TQU3yBnRVj6advBiV/edit#heading=h.gjdgxs)**?** *A benign behavioral intervention is related to human behavior, is brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the researcher has no reason to think the participants will find the interventions offensive or embarrassing.*

☒ No

☐ Yes, Describe the benign behavioral intervention(s) that are a part of the study:

**16. Will this study use Augmented Reality (AR) or Virtual Reality (VR)?**

☒ No

☐ Yes, the AR/VR used in this study does not take any recordings from the human body.

☐ Yes, the contraindication for the use of the AR/VR used in the study is communicated in the consent.

☐ Yes, based on the contraindication of the AR/VR used in the study, participants will be appropriately screened out and deemed ineligible.

☐ Yes, the AR/VR will be cleaned between participants’ uses.

☐ Yes, Describe Use:

**17. Will this study ask participants to view or interact with media materials (photos, audio, video, gaming, other,**

☒ No

☐ Yes, describe the content of the materials used:

☐ Yes, describe the maturity rating ex: G, PG, PG-13, R, NC-17)of the materials used:

**18. Will any recordings be taken of or from the human body?** *This can include physical sensors, scanning, eye tracking, etc. An exemption for this project is only allowable under the NC State University FLEX special exemption category for unfunded (and never to be funded) work.*

☒ No

☐ Yes, describe what recordings will be taken, how they will be collected, and with what device(s). If data collection tools are placed on the body (e.g., sensors, headset, eye tracking glasses, etc.) discuss how this equipment is donned and doffed by participants with respect to bodily autonomy, consent, and personal privacy.

**19. Does this study involve** [**deception or incomplete disclosure?**](https://docs.google.com/document/d/14olPHJTWxRQUZY6RERk1Qu5gjrCiaAse/edit?usp=sharing&ouid=111628324854172758765&rtpof=true&sd=true)*Incomplete disclosure applies when information about the real purpose or nature of the research is withheld from participants. Deception in the context of human research refers to providing false information to prospective participants. If you don’t want to disclose the deception/incomplete disclosure to participants, the project cannot be exempted.*

☒ No

☐ Yes. If yes:

**19a. Describe the deception or incomplete disclosure**:

**19b. Describe why the deception or incomplete disclosure is necessary**:

**19c. Describe the debriefing process (and upload debriefing material)**:

**19d. Is a statement about deception or incomplete disclosure present in the consent information**?

☐ No

☐ Yes

**Images & Recordings for Research Purposes**

*Answer N/A to all questions in this section related to images and recordings if they are occurring in a classroom as this information is addressed in section 12 above.*

**13. Are you collecting images or recordings for research purposes?**

☐ No.

☒ Yes. If yes, provide the following details regarding content and privacy of images and recordings:

**13a. The recordings or images are of**: graduate student instructor discussions

**13b. The recordings or images will be taken via**: voice recorder

**13c. The identifiable video or photos will be stored (where and how)**:

**13d. The recordings or images will be transferred via**: SD card and google drive

**13e. The recordings or images will be destroyed when**: the study is completed

**14. Image & Recording Privacy Practices,** check all that apply**:**

☐ N/A

☐ Participants must agree to be recorded/photographed to be in the research.

☒ Participants do not have to agree to be recorded/photographed to be in the research.

☒ Audio recordings of primary or third-party participants (below, check what applies):

☒ Audio recordings will only be used for transcription purposes.

☒ Audio recordings will be deleted and not shared with others (beyond transcription services).

☐ Audio recordings may be shared with others, in accordance with participant consent.

☐ Transcripts of audio recordings will not be shared with others.

☐ De-identified transcripts of audio recordings may be shared with others, in accordance with participant consent.

☐ Identifiable or re-identifiable transcripts of audio recordings may be shared with others, in accordance with participant consent.

☐ Other:

☐ Video recordings of primary or third-party participants (below, check what applies):

☐ Video recordings will only be used for transcription purposes.

☐ Video recordings will be deleted and not shared with others (beyond transcription services).

☐ Video recordings may be shared with others, in accordance with participant consent.

☐ Individuals will be blurred/masked during data analysis.

☐ Individuals will blurred/masked when images are published or presented publicly.

☐ Transcripts of video recordings will not be shared with others.

☐ De-identified transcripts of video recordings may be shared with others, in accordance with participant consent.

☐ Identifiable or re-identifiable transcripts of video recordings may be shared with others, in accordance with participant consent.

☐ Other:

☐ Still photos of humans (primary or third party participants).

☐ [Photovoice](https://drive.google.com/open?id=15Cu9IIt3IunQ9d_I7Uac0nbTx5Mvx08d) is a mode of data collection in this research and I will teach participants how to engage in this mode of data collection ethically, including the boundaries around image capture and consent from third party participants.

☐ Other photo/video recordings. Please describe:

**15. Affirm Understanding of Researcher Expectations for Images and Recordings.**

☐ N/A

☒ I understand that if using Zoom to record human subjects data, I must comply with the [NC State University required settings for use of Zoom in human subjects research](https://docs.google.com/document/u/2/d/e/2PACX-1vS2_q6sITeONul76lLzoUP9Qe0WVQ6xgHhWk6CfwsTDTiNs9kQFnnaqL7eqUk_bq5vZMR5az1x1soZ4/pub?urp=gmail_link).

☒ I have reviewed and understand the NC State University IRB guidance for the [use of images and recording of participants in research studies](https://docs.google.com/document/d/1SNbPGc2sXzmvxyARkAXtCLVYiRd3V148/edit#heading=h.gjdgxs).

**16. Compensation and Incentives:**

☒ There is no [compensation or incentive](https://drive.google.com/open?id=1Lwn4v6N3rP8H0JUK4SvLAYZvYEqGwaSO) for participation in this study.

☐ Course credit will be offered for participation in this study via SONA:

☐ Course credit determined and offered by individual instructor where an alternative option (that takes the same amount of time and effort) is also offered.

☐ Participants will be monetarily compensated for participation in this study:

*Note: Collecting compensation information directly on an instrument with responses, changes the identifiable nature of that data. Make sure compensation information is congruent with your description of identifiability in this application and supplemental documents.*

**16a. Describe amount of compensation:**

**16b. Describe mode of compensation:**

**16c. Describe how compensation is distributed:**

**16d. Describe if information used for compensation is connected to the research data**:

**16e. Describe what information is needed for compensation:**

**16f. Describe what information is shared with HR/Accounting for compensation and if it is given directly to HR/Accounting by the participant or if the researchers handle the information at any time.** *Note, if the researchers handle the compensation information, it must be treated in accordance with NC State’s* [*data sensitivity requirements*](https://oit.ncsu.edu/it-security/data-framework/):

**16g. Describe if there is a difference in compensation among participant groups in the study**:

☐ No difference.

☐ Describe:

☐ Other Compensation or Incentive:

**17. Does this research qualify for NC State University FLEX special exemption category?** *Research that is eligible for the FLEX exemption is research that is not funded nor will it ever be funded, nor is it contractually obligated to adhere to the Federal regulations at 45 CFR 46. Additionally it is no more than minimal risk to participants, participants can be adults and/or minors.* *See the* [*IRB exemption request unit standard*](https://docs.google.com/document/d/1vVbB4aGlK_elrRioTIR9aNj3ps7cbYRb/edit?usp=share_link&ouid=111628324854172758765&rtpof=true&sd=true)*.*

☐ No

☒ Yes. If yes, which of the following FLEX exemption categories apply to this study?

☐ Collection of body measurements using a scale, a tape measure, or eye tracking. Detail measurements and mode of measurement collection**:**

☒ Minimal risk surveys, interviews, observations, focus groups, or benign behavioral interventions that involve minors.

☐ Request to use secondary private identifiable/indirectly identifiable information as data for research where no contract or agreement is required (upload a data access and security plan for all red/purple data). If the secondary data includes identifiable video, photo, or voice recordings of primary or third-party participants, please detail what is captured in the recordings, will individuals be blurred/masked during analysis, where the identifiable video, photos or voice recordings will be stored if and how they will be transferred, how long they will be retained/when they will be destroyed:

**Secondary Data or Biospecimens**

*See* [*IRB guidance on secondary data*](https://docs.google.com/document/d/1ytvLEFsIgAcZhLtvnFcNNAUyJ72IlJwP/edit?usp=share_link&ouid=111628324854172758765&rtpof=true&sd=true) *for reference. Secondary data/biospecimens is information or specimens that were generated for another research study OR for non-research purposes (e.g., student records, medical procedures, social media, assessment efforts) that you wish to re-use for research purposes.*

**18. Is this study seeking to access secondary information or biospecimens to use as data for research?**

☒ No

☐ Yes. If yes, answer the following:

**18a. Can the identifiable data be considered “red” highly-sensitive data, or “purple” ultra-sensitive data in accordance with** [**NC State OIT Sensitivity Framework**](https://oit.ncsu.edu/it-security/data-framework/)**?**

☐ N/A.

☐ No.

☐ Yes, please explain:

☐ If yes, a [data access and security plan](https://drive.google.com/file/d/17vi6gPC1f_34eSW7X7_miLyh0VHIdJX5/view) has been completed with OIT is uploaded with this IRB application.

**18b. Describe the public/private nature of the data or biospecimens:**

☐ N/A

☐ The data are public and have always been public and no permission is needed to access it.

☐ The data are public but were once private and no permission is needed to access it.

☐ The data are private and permission from individuals or gatekeepers is needed or must be considered (this includes release from an organization, another researcher, or an individual, etc.).

☐ Use this space to provide details you find necessary (if not already addressed):

**18c. If permission to access the secondary data or biospecimens is needed, who will provide you permission?**

☐ N/A

☐ Individuals whose data/specimens as accessed will provide permission.

☐ The data/specimens are subject to HIPAA and I am seeking [HIPAA Authorization](https://drive.google.com/file/d/11LLm-8LNKVU1phWPO3bvW6W0jn-g5dHO/view) from individuals.

☐ The data are subject to FERPA and I am seeking permission under FERPA from individuals.

☐ Record holders will release the data (*IRB approval is not permission for records release*).

☐ The data/specimens are subject to HIPAA and I am seeking a [waiver of HIPAA Authorization](https://drive.google.com/file/d/1LBUDrTm9D0_qbqODqXJ6-2bT9Ja_GKSz/view) from individuals. Instead, I am seeking the records be released from an appropriate HIPAA records holder.

☐ The data are subject to FERPA and I am seeking waiver of permission under FERPA from individuals. Instead, I am seeking the records be released from an appropriate FERPA records holder.

☐ Other. Please describe:

**18d. Are the secondary data or biospecimens identifiable?**

☐ No, the data is anonymous to the research team.

☐ Yes, the data/specimen is indirectly identifiable to the research team through triangulation of data information.

☐ Yes, the data/specimen is indirectly identifiable to the research team through researcher access, role, expertise, or quality of the data (such as qualitative data or student artifacts).

☐ Yes, the data/specimen is directly identifiable to the research team because identifiers are directly on the dataset or specimen.

☐ Yes, the data/specimen is directly identifiable to the research team because the researchers have access to a master list that directly links to codes on the dataset or specimens.

**18e. Describe the content of the secondary data/biospecimens:**

**18f. This study requests receipt or access to** [**FERPA data**](https://docs.google.com/document/d/181Bc0Q-PFhhG8nIEMgASj_8kt-68Ys-n/edit?usp=drive_link&ouid=111628324854172758765&rtpof=true&sd=true) **only**

☐ N/A

☐ The FERPA data accessed/received is completely anonymous.

☐ The researcher is accessing/receiving identifiable FERPA data only and the researcher is doing the project on or behalf of an institution (Note: the study will be reviewed via [45 CFR 46.d.1](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104)).

☐ The researcher is accessing/receiving identifiable FERPA data only and research is intended to develop, validate, or administer predictive tests, administer student aid programs, or improve instruction (Note: the study will be reviewed via [45 CFR 46.d.1](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104)).

☐ The researcher is accessing/receiving identifiable FERPA data only and the project:

* Is not being done on or behalf of the institution or an educational agency from which the data is sought.
* Is not intended to develop, validate, or administer predictive tests, administer student aid programs, or improve instruction.
* Does not qualify for the NC State University special FLEX exemption category.
* *If all three points directly above are true, the study will be reviewed via* [*expedited category 5*](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html) *and a full eIRB application must be completed instead of this form.*

☐ The researcher is requesting access/receipt of identifiable FERPA data where FERPA consent will ***not***be sought from participants and this study does not qualify for the NC State University special FLEX exemption category.

* *This study will be reviewed and approved by the IRB under expedited category 5.*
* *The study must qualify for a waiver of consent under 45 CFR 46 and a FERPA exception*
* *A full eIRB application must be completed instead of this form.*

**18g. Are the data/specimens subject to HIPAA?**

☐ No

☐ Yes, describe permission to access the data (direct [HIPAA Authorization](https://drive.google.com/file/d/11LLm-8LNKVU1phWPO3bvW6W0jn-g5dHO/view) or [HIPAA Waiver Request](https://drive.google.com/file/d/1LBUDrTm9D0_qbqODqXJ6-2bT9Ja_GKSz/view)):

☐ Yes, the data are considered a “Limited Dataset.”

☐ Yes, the data have the HIPAA identifiers on the dataset and is considered a directly identifiable HIPAA dataset.

**18h. Do the data/specimen provider(s) require an agreement be signed (e.g., a** [**Data Use Agreement or Materials Transfer Agreement**](https://research.ncsu.edu/administration/data-use-agreements/)**) in order to release the data/specimens?**

☐ No

☐ Yes, Describe:

**18i. For the access and use of the private identifiable secondary data/specimens that you want to use, at the time of original data collection, was “broad consent” sought?**

☐ No

☐ Yes, Describe the procedure for how broad consent was sought:

**18j. Are you accessing information that is identifiable to you, but recording that information in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects?**

☐ No

☐ Yes

☐ If yes, check the box to attest that none of the researchers will contact the participants.

☐ If yes, check the box to attest that none of the researchers will attempt to re-identify participants.

**Data Access & Security**

**19. What direct IDs will you be collecting/accessing/receiving in the dataset?**

☐ None

☐ Digital Identifiers (ex: E-Mail, Usernames, Profile Names, Personal Web Address. If from minors, treat as “red data”)

☐ Government/Organization Identifier (ex: Campus ID, Badge Number, Licensure ID, Conference ID)

☐ Immigration ID (“red data”)

☐ License Plate

☒ Name

☐ Name of Parent/Guardians

☐ NC State Unity ID

☐ Phone/Fax number (If from minors, treat as “red data”)

☐ Physical Address (If from minors, treat as “red data”)

☐ Precise geographic location

☐ Social Security Number (“purple data”)

☐ Other, Describe:

**20. What indirect IDs will you be collecting/accessing/receiving in the dataset?**

☒ None

☐ Account Numbers (bank accounts, treat as “red data”)

☐ Admission/Discharge Date

☐ Biometrics (ex: iris scans, fingerprint, treat as “purple data”)

☐ Biospecimens

☐ Device IDs/Serial Numbers

☐ Enrollment Date

☐ Genomic Data (or genomic sequencing) where an individual can be readily re-identified (treat as “red data”)

☐ Health Plan IDs (if from covered entity, treat as “red data”)

☐ IP Address and some URLs

☐ Medical Record Number (if from covered entity, treat as “red data”)

☐ Mother’s Maiden Name (“red data”)

☐ MTurk IDs

☐ Online Panel IDs

☐ Photos containing screenshots, personal items, tattoos, birthmarks, skin patterns

☐ Precinct

☐ Rank/Title

☐ SONA ID

☐ Unique Content of Information Shared, such as unique stories

☐ Zip Code

☐ Other, Describe:

**21:** **What demographic data or unique information will you be collecting, accessing, or receiving?**

☐ None

☐ Ability or Disability Status (“red” data - if subject to FERPA or identifiable)

☐ Age

☐ Date of Birth (If from minors, treat as “red data” if identifiable)

☐ Education

☐ Employment

☐ Ethnicity

☐ Gender/Gender Identity

☐ Income

☐ National Origin

☒ Personal Experiences

☐ Political Preferences

☐ Race

☐ Relationship Orientation

☐ Relationship Status

☐ Religion

☐ Sex

☐ Sex Designated at Birth

☐ Sexual Orientation

☐ Veteran Status

☐ Years of Service

☐ Other, Describe:

**22: Does this study require a data access and security plan?** *Note: This plan is required if this project accesses or generates red (highly-sensitive) or purple (ultra-sensitive) data.*

☐ Yes, the completed [data access and security plan](https://drive.google.com/file/d/17vi6gPC1f_34eSW7X7_miLyh0VHIdJX5/view) form is uploaded.

☒ No. No data access and security plan is needed. As a result, the following data protection tools will be implemented. Check all that apply:

**22a. Digital Protection**

☐ Suggestion of using private device and internet connection.

☐ Suggestion of completing research in private location.

☐ Suggestion of using web browser in private/incognito mode.

☐ Suggestion of deleting cookies or browser history when activities are completed.

☐ Research team use of password protection.

☐ Research team use of file/drive encryption.

☐ Research team use of VPN when transferring or accessing data.

☒ Research team use of NC State Google Drive.

☒ Research team use of NC State Google email where the email is not forwarded to private email addresses.

☒ Research team restriction of access to files/drives via NC State Google Drive.

☒ Research team will ensure all software, hardware, and malware protection remains up to date.

☐ Research team will use NC State University owned devices only.

☐ Research team will be stored on a non-networked computer (only necessary for purple data).

☒ Research team will use 2-Factor Authentication.

☐ Research team will remove IDs directly from data and create a master list that will be protected with encryption.

☐ Research team will ensure that their private device is not connected to the internet while data is on said device, except for when transferring data to NC State Google Drive using VPN.

**22b. Physical Protection**

☐ Locked Building.

☐ Locked office.

☐ Locked cabinet/desk.

☐ Removal of direct IDs on hardcopy data.

☐ Physical master list kept separate from physical data.

☐ Data submitted to researcher by participant in a private manner such as a sealed envelope. Describe:

**23: After three years (minimum required for records retention), what will you do with the raw data? Check all that apply:**

☐ De-identify and keep it for your own future work.

☐ De-identify and keep it to share with others.

☐ De-identify it and put it in a repository.

☐ Keep the raw data in an identifiable/re-identifiable format in accordance with the approved IRB protocol and the informed consent.

☐ Keep the raw data in an identifiable/re-identifiable format in accordance with the approved IRB protocol and use it for future unspecified work in accordance with broad consent that was given by participants whose data you are keeping.

☒ Securely destroy the raw data.

☐ Other, Describe:

**24: What privacy and confidentiality protections do you have in place? Check all that apply:**

☐ Participants are told to complete the virtual research activities in a private location.

☐ Participants complete the face-to-face activities in a private location.

☒ Only the research team members and other professional associates (such as transcription services or data analysts) will have access to the research data.

☒ The researcher will not disclose the participants’ information outside of the research context.

☒ Participants are notified as to how data will be reported, and the data will be reported in accordance with the consent.

☐ No demographic subgroups smaller than groups of      will be reported in publications.

☐ No individual quotes will be used.

☒ Individual quotes will be used, but demographic data describing the participant will not lead to participant re-identification.

☒ Individual quotes will be used, and participant identities may be directly or indirectly identifiable, but participants will provide consent for their information to be shared in this way.

☐ Additional privacy and confidentiality protections of note:

**Informed Consent, Minor Assent, and Parental Permission**

**25. Describe the informed consent, assent, or parental/guardian permission process** *Please use the IRB* [*exemption consent templates*](https://docs.google.com/document/d/1b-5-3XPkwTfPJoXagCe7ye3EzUGB7uur/edit?usp=share_link&ouid=111628324854172758765&rtpof=true&sd=true) *to create your consent. Make sure to address FERPA, HIPAA, the GDPR, and the* [NC Session Law 2023-106, Senate Bill 49](https://www.ncleg.gov/Sessions/2023/Bills/Senate/PDF/S49v5.pdf) *requirements as applicable:* Graduate instructors for the course will be presented with information about the study, the possible identifiability of their data due to the small group size, and an option to participate in the study.

**26. Will you be seeking** [**broad consent**](https://drive.google.com/open?id=1R0fkGq4KUCydAe0y9Wft_6YGup1qAfSB) **for the use, storage, and maintenance of identifiable data for unspecified future research?**

☒ No

☐ Yes. If yes, describe how you plan to track which individuals provide broad consent:

**27. Attestation of study amendment guidelines for exempt studies: I understand that I must submit an amendment to this protocol for the following changes:**

☒ Change in faculty point of contact. You do not need to submit research team member changes for exemption, but you do need to keep track for your own records (or in case of an audit). Tracking should include training, overview of activities completed, and timeframe of working on the project.

☒ Addition of funding and/or subsequent changes from said funding.

☒ Addition of participant groups. For example, the addition of minors, pregnant people, incarcerated people, or people contextually vulnerable, or people not initially described in the approved protocol.

☒ Addition of data collection procedures such as new surveys, new observations. For example, adding an interview where there was not one before. Addition of questions for surveys, interviews, questionnaires, and focus groups.

☒ Addition of a dataset that requires a data use agreement, material transfer agreement, or addition of any identifiable or indirectly identifiable data that is not publicly available. Please see [secondary data guidance](https://docs.google.com/document/d/1ytvLEFsIgAcZhLtvnFcNNAUyJ72IlJwP/edit#heading=h.opku75vve966).

☒ Addition of any information that will be collected that directly links the participant to the study or the study data. For example, adding an email address directly on the survey where data are collected to provide compensation.

☒ Addition of audio or video recording of participants, use of photography, screen recording, or motion tracking.

☒ Addition of multimedia such as videos images that participants are exposed to or will view.

☒ Addition of compensation.

☒ Addition of any procedures that are physical in nature.

☒ Correction of documents beyond spelling, grammar, or one-word replacements that do not affect the meaning of the sentence.

**Appendix A**

Defining Exempt Research and Participant Eligibility

If it has been determined that the project is [research](https://docs.google.com/document/d/1jgmeWpFSJhkFyawppbB3BGo44rm_FYSv_aha4cazW44/edit#heading=h.ieaatb7t50yr) as defined by the regulations, involves [human subjects](https://docs.google.com/document/d/1WVDuyi5_t_oblhiffsucf7V0liwUBtNXSTIFMV_kYVs/edit?usp=sharing) as defined by the regulations, and NC State faculty, staff, students, or other stakeholders are on the research team, then the study requires IRB review/approval through NC State in some way.

To receive an “exempt” determination means that a project qualifies as human subjects research, and the research can be categorized into an exemption category as defined in the [IRB regulations at 45 CFR 46.104](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.104) or NC State’s [special FLEX exemption category](https://docs.google.com/document/d/1vVbB4aGlK_elrRioTIR9aNj3ps7cbYRb/edit?rtpof=true&sd=true#heading=h.gjdgxs).

Due to the [NC State University Human Subjects Regulations 10.10.03](https://policies.ncsu.edu/regulation/reg-10-10-03/) regardless of funding, the researchers must request an exemption determination from the NC State IRB office. Researchers cannot make the determination on their own. The NC State University IRB office will make the official exemption determination.

The NC State University IRB office can approve studies as “exempt” or “exempt with a limited review” if they are considered minimal risk, exclude certain populations, and they fit into the one of the [8 exemption categories](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104) as defined by the IRB regulations at [45 CFR 46 section d.104](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html) OR the NC State University [special FLEX exemption category](https://docs.google.com/document/d/1vVbB4aGlK_elrRioTIR9aNj3ps7cbYRb/edit?rtpof=true&sd=true#heading=h.gjdgxs).

**Participant Group Eligibility for Exempt Research**

* People who are pregnant can be involved in all research categories eligible for exemption under both the [45 CFR 46 section d.104](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html) and the NC State FLEX special exemption category
* People who are incarcerated can only be involved in research categories that are exempt if the research is aimed at involving a broader subject population that only incidentally includes people who are incarcerated.
  + NC State FLEX special exemption category: People who are incarcerated cannot be involved in the NC State University FLEX special exemption category unless they are incidentally included where the general population is the main targeted group.
* People who are under the age of 18 years of age (or are legally considered a minor) may have restrictions regarding involvement in research categories that qualify for exemption
  + d.1: Normal educational practices in educational settings
    - Minors may be involved in this type of exempt research under [45 CFR 46 section d.104](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)
  + d.2: Surveys, interviews, focus groups, and observations of public behavior
    - Minors CANNOT be involved in this type of exempt research unless it is only observation of public behavior when the investigator(s) do not participate in the activities being observed
  + d.3: Benign behavioral interventions
    - Minors CANNOT be involved in this type of exempt research.
  + d.4: Use of some secondary information as research data
    - Minors may be involved in this type of exempt research under [45 CFR 46 section d.104](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)
  + d.6: Taste and food quality evaluation and consumer acceptance
    - Minors may be involved in this type of exempt research under [45 CFR 46 section d.104](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)
  + d.7 and d.8: Storage, maintenance, and use of secondary research data when broad consent was initially sought and given by participants
    - Minors may be involved in this type of exempt research under [45 CFR 46 section d.104](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104)
  + NC State FLEX special exemption category for research that is not federally funded and never will be federally funded.
    - Minors involved in the following may qualify for the NC State University FLEX special exemption category if the research involves:
      * Minimal risk surveys, interviews, observations, or focus groups that involve minors.
      * Request to use secondary private identifiable/indirectly identifiable information as data for research where all contractual obligations are met.

**Minimal Risk Research**

[Minimal risk](https://drive.google.com/file/d/16t1P4PxSeC6ACROx9Gf2-PaFUNcDoLbr/view) is when “the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.”

**IRB Standards for Data Sensitivity and Classification**

* **Purple**: Ultra-sensitive data includes data where unauthorized disclosure or loss poses the highest risk or impact to the human subjects, university, or its affiliates or where specific data categories require special privileged access management.  Examples include social security numbers, passwords, encryption keys, and biometrics (such as fingerprints and iris scans), admitted behavior that could be considered a felony. Other examples of qualitative data that should be treated as “purple” data include data that will likely lead to arrest, detention, incarceration, deportation, physical injury, or death of both primary and third-party participants. Additional access and handling requirements are required for Ultra-sensitive data because it may be impossible to repair damage caused by its unauthorized disclosure.
* **Red**: Highly sensitive data includes data where unauthorized disclosure or loss poses a high risk or impact to the university, or its affiliates. Examples include driver’s license, mother’s maiden name, passport, and immigration number, admitted unlawful behavior that is not considered purple. Other examples of qualitative data that should be treated as “red” data include information that could lead to persecution, harassment or retaliation, information that may or likely will irreparably harm relationships, information that will likely lead to stigmatization where physical or psychological harm may occur as a result of both primary and third-party participants, or any data where unauthorized disclosure or loss poses a high risk or impact to all human subjects.
* Review the [OIT Data Classification Table](https://docs.google.com/spreadsheets/d/1cHJnpD7ObV3a48AIKcCe2AMRZ0MmN4GHkuZMAm1kljg/edit#gid=1639595516) for “All Data Elements and Categories” and their corresponding sensitivity level for appropriate data protection.

**Additional Factors Affecting Eligibility for Exemption (aside from procedures and participants)**

* If the activity can be considered “minimal risk” with confidentiality protections in place
* Contractual obligations
* Funding and sponsorship
* N Size and indirect identifiers collected
* Federal/International laws and reporting obligations of research team members
* Nature of the data as directly identifiable, indirectly Identifiable, or anonymous
* The researcher(s) role, access, expertise, and type of analysis
* Breadth of participant pool N (International, United States of America, a specific state, county, school, club, or class)
* Researcher knowledge of participants (if the researcher knows who the people participating in the research are)
* Additional modes of data collection, aside from survey or pairing survey data with other data.

**Appendix B**

**Categories of Research Eligible for Exemption**

**Category d.1** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

* The research procedures must take place in an established or commonly accepted educational setting AND involve normal educational practices.
* Researchers can justify how the proposed research setting qualifies as an “established” or “commonly accepted” educational setting and how the research activity is a “normal educational practice”.
  + Example Settings: school, after school clubs, distance and online learning environments, conferences, study abroad programs, any place where formal training or learning occurs, other settings deemed culturally appropriate for education and training to occur.
  + Example Activities: classroom observation, use of assessment/evaluation information, most action research, access to some FERPA data, professional development workshops, MOOCs, experiments with instructional design (as long as they are not radically innovative)
* Please refer to the [IRB guidance on Images and Recordings](https://docs.google.com/document/d/1SNbPGc2sXzmvxyARkAXtCLVYiRd3V148/edit#heading=h.gjdgxs) (Word document) as appropriate to this work.
* Please refer to the [IRB’s FERPA standard](https://docs.google.com/document/d/181Bc0Q-PFhhG8nIEMgASj_8kt-68Ys-n/edit?rtpof=true&sd=true#heading=h.xt57fy26bngl) (Word document) as to how FERPA and research activities overlap.

**Category d.2** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

* d.2.i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
  + Readily Ascertainable: if the data are directly identifiable, linked to a master list that the researcher(s) can access, indirectly identifiable to anyone on the research team where an individual can be identified from the data due to researcher(s) access, role, or expertise, or participant can be identified from the content of data, triangulation of data content, pairing with other data, or N size.
* d.2.ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
* d.2.iii.The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.
  + A limited review involves IRB staff reviewing the research for data security measures and required consent information.
  + Data collected that are considered “red, highly sensitive” or “purple, ultra-sensitive” can be exempted under this category if a data access and security plan is completed and uploaded to the IRB application’s supporting documentation section.

**Category d.3** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
  + Readily ascertainable: if the data are directly identifiable, linked to a master list that the researcher(s) can access, indirectly identifiable to anyone on the research team where an individual can be identified from the data due to researcher(s) access, role, or expertise, or participant can be identified from the content of data, triangulation of data content, pairing with other data, or N size.
* Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
* The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.
  + A Limited Review involves IRB staff reviewing the research for data security measures and some required consent information.
  + Data collected that are considered “red, highly sensitive” or “purple, ultra-sensitive” can be exempted under this category if a data access and security plan is completed.
* [Benign behavioral interventions](https://docs.google.com/document/d/1xGzMpDN79SUQaL0TQU3yBnRVj6advBiV/edit?usp=sharing&ouid=111628324854172758765&rtpof=true&sd=true) (Word document) are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.
* [Deception and Incomplete Disclosure](https://docs.google.com/document/d/14olPHJTWxRQUZY6RERk1Qu5gjrCiaAse/edit?usp=sharing&ouid=111628324854172758765&rtpof=true&sd=true) (Word document) If the research involves deceiving the subjects (including leaving out pertinent information) regarding the nature or purposes of the research, for the study to be eligible for exemption, the participant must prospectively agree (via consent) to participate in research where they will be unaware of or misled regarding the nature or purposes of the research.

**Category d.4** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

* d.4.i. The identifiable private information/biospecimens are publicly available.
* d.4.ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
  + Readily ascertainable: if the data are directly identifiable, linked to a master list that the researcher(s) can access, indirectly identifiable to anyone on the research team where an individual can be identified from the data due to researcher(s) access, role, or expertise, or participant can be identified from the content of data, triangulation of data content, pairing with other data, or N size.
* d.4.iii.The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA.
  + This identifiable private data will be considered highly sensitive data (“red”) and a data access and security plan must be submitted with the exemption application.
  + If the data are considered a limited data set under HIPAA, a [data use agreement (DUA)](https://research.ncsu.edu/administration/data-use-agreements/) (opens in a new window) is likely required by the data provider and it must be uploaded to the exemption application.

**Category d.6** Taste and food quality evaluation and consumer acceptance studies:

* If wholesome foods without additives are consumed or
* If a food is consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

**Category d.7** This exemption category is used to review and approve research activities that involve storing secondary private data or biospecimens when broad consent for the future unspecified use of identifiable data or biospecimens was sought and obtained. This allows for the storage and maintenance of the private identifiable data or biospecimens. A limited review must be completed by the IRB for this category to be used.

**Category d.8** This exemption category is used to review and approve research activities that involve using secondary private data or biospecimens when consent for the future use of identifiable data or biospecimens was sought and obtained.

* This is useable when broad consent was sought at initial collection and the researcher wants to use the identifiable data for any type of research.
* This is useable when informed consent was sought and obtained or waived at initial collection and the exemption request is in scope with the original proposal.
* The researcher cannot return individual research results to participants as part of the study plan. This does not prevent a researcher from abiding by any legal requirements to return individual research results.
* A limited review must be completed by the IRB for this category to be used.

**NC State University FLEX special exemption category** This category is an NC State University made exemption category. Only research that is not funded and research that will never be funded is eligible for this exemption. Research procedures that are eligible for the NC State University FLEX special exemption Category are:

* Minimal risk collection of body measurements using a scale or a tape measure.
* Minimal risk surveys, interviews, observations, focus groups, or benign behavioral interventions that involve minors.
* The request to use secondary private identifiable/indirectly identifiable information as data for research where no contract or agreement is required, and an IRB data access and security plan is submitted to the IRB where applicable.
* Research in the FLEX category may involve a limited review (noted below) as needed.

**What is Exempt with a Limited Review?**

This is a part of the federal regulations that allows an IRB to exempt a research project (allowing more flexibility within the regulations) while ensuring participant protections through transparency, disclosure, and data protections are in place. A limited review is performed by IRB staff and consists of the following elements:

* ensure adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data and
* when applicable informed consent or broad consent for storage, maintenance, and use of secondary research identifiable private information or identifiable biospecimens is/was obtained, documented, or appropriately waived.

The IRB reviewer may require specific information be disclosed to participants through the consent process.

**Appendix C**

**Amendments and Exemptions**

(This guidance does not apply to studies approved via Expedited or Full Board procedures)

If your study was reviewed and approved as exempt by the NC State IRB, you do not need to submit an amendment for the following changes:

* Change in undergraduate student personnel (unless it’s the student’s project).
  + For any undergraduate student additional personnel, the PI is responsible for ensuring and tracking who has joined and left the research team and you are responsible for tracking their proof of human subjects’ research training. The IRB may ask for this information if there is an issue or when you apply for a protocol amendment.
* Removal of questions on surveys, interviews, questionnaires, and focus groups
* Minor editorial changes (such as punctuation, single word changes, or grammar) or re-ordering of questions
* Removal of images or video presented to the participants.
* Removal of audio recording or video recording
* Removal of data collection procedures or modes of data collection
* Removal of recruitment documents or modes of recruitment
* Removal of content from consent language THAT MATCHES the removal of data collection procedures.
* Removal of participant groups or decrease in participant amount unless the change to N size increases re-identifiability of the participant.

*Note: if you make a change later in the study that changes the status of the study from approved as exempt to approved as expedited or Full Board, when you submit an amendment for that change, the study must reflect all procedures and documents that will be used from there on out.*