DELTA IRB Information Sheet

1. **Do I need to apply to the IRB?**

   No, if you want to use student data only to assess, evaluate, or improve your course. Student data can include data that is generated as part of your course or through other University programs or offices (for example, data from DELTA or other DELTA courses, Records and Registration, Institutional Strategy and Analysis, etc.). The work meets the federal definition of human subjects research BUT it does not meet the federal definition of research which requires the work to "contribute to generalizable knowledge."

   Yes, if you want to use student data or interact/intervene with students or their learning process to assess, evaluate, or improve your course AND "contribute to generalizable knowledge" by using and/or sharing the student data or what you learned in the quality assessment and improvement process with others. This might take the form of presentations (even if that presentation is at an NC State University research symposium), publications, sharing data or findings with colleagues for research purposes, etc.

   For more information, please review the following IRB resources:
   - What is research and contributing to generalizable knowledge (Word document)
   - What is human subjects research (Word document)
   - Assessment, evaluation, quality assurance, quality improvement, and the IRB (PDF file)

2. **Can you better define what "contributing to generalizable knowledge" means? What's the line between using the data internally where we don't need IRB approval and when we would need IRB approval?**

   "Contributing to generalizable knowledge" is when the findings gained through a systematic investigation can be applied beyond the specific context in which they were discovered. Sometimes that means that the research findings are replicable and scalable (common to quantitative research) or that the knowledge gained can be applied to similar or different settings and populations (common in qualitative research).

   In Appendix A of our guidance document "What is research and contributing to generalizable knowledge," we provide examples of where IRB review would and would not be required. Using findings even in newsletters and magazines might be subject to IRB review if that data can apply beyond the specific context in which it is discovered (i.e., it's

generalizable) and the work meets the federal definition of human subjects research.

For more information, please review the following IRB resources:

- What is research and contributing to generalizable knowledge (Word document) – particularly Appendix A
- What is human subjects research (Word document)

3. **If I am completing research, do I need to get consent, parent/guardian permission, and minor assent under the IRB regulations to use student records as data for research purposes?**

It depends on the public/private nature of the data, the identifiability of the data, and what laws and regulations apply to the data.

Public/Private Nature of the Data

Public Data

Public data are data that are openly available to everyone without any restrictions (e.g., log ins, access approvals, etc.) to access it. The IRB does not regulate the use of public data that has always been public even if the data is personally identifiable. This means that use of always public data does not require IRB approval.

If public data had been private at one point (e.g., ended up public due to a data leak or a social media platform's term of service or operations changing, etc.) and the public data are personally identifiable or easily re-identifiable, the IRB does regulate its use and IRB approval is required. These studies typically qualify for exempt review and the IRB may require a form of consent to be sought.

Please note: *Student data subject to FERPA is not considered by the IRB to be "always public" data even if the school is a public school.*

Private Data

Private data is restricted access data that a reasonable person expects will not be made public. If private data is personally identifiable or re-identifiable, IRB review is required and informed consent must be sought unless the research is eligible for exemption (and the data is not subject to FERPA) or qualifies for a waiver of consent.

If the private data are anonymous or have been de-identified by someone outside of the research team and the research team does not have access to original data to re-identify a participant, then IRB approval and informed consent is not required. Please note sometimes a data provider or a data use agreement will require IRB review for de-identified data.

Identifiability of the Data

Use of **identifiable and re-identifiable participant data** requires IRB approval if the data are private and the research team has access to direct identifiers or if anyone on the research team can re-identify someone from the data through triangulation of data points, access to datasets, the research team's own access to systems or own expertise. The NC State IRB will require informed consent unless the research qualifies for a waiver of consent under the IRB regulations.

Anonymous and de-identified participant data does not require IRB approval if none of the researchers on the research team (at any point in time) can re-identify an individual from the data. This means that the data that was de-identified (meaning, the data set has identifiers on it at one time but the identifiers were all removed or aggregated so that identities are not ascertainable) is not re-identifiable to the research team through a master list, codes, or other data triangulation efforts. If a researcher de-identified the data themselves or has access to a code list or can easily re-identify an individual because they have access to the original identifiable data set, IRB approval must be sought.

Applicable Laws

HHS Policy for the Protection of Human Research Subjects (45 CFR 46)

Informed consent is required for all non-exempt research unless it qualifies for a waiver of consent.

For research that qualifies as exempt, the NC State IRB still requires seeking consent but can act more flexibly with how consent is sought or if it is sought at all.

Family Educational Rights and Privacy Act (FERPA)

In most cases, access to FERPA records requires explicit permission from the eligible student or from a minor's guardian unless the access to records is eligible for a FERPA exception where a records holder may "release" the records to the researcher for use. Although the IRB application requires researchers to disclose their proposed

use of FERPA records for research risk assessment and regulatory review, IRB approval is not a FERPA records release determination because the IRB is not the data steward for FERPA records and does not have the power to release FERPA records to researchers.

For more information, please review the following IRB resources:

- FERPA and research with human subjects unit standard (Word document)
- Identifiable data sets (Word document)
- Secondary data guidance (Word document)
- Adult consent, minor assent, and parent/guardian permission unit standard (Word document)
- NC Parents Bill of Rights (Word document)
- Guidance for data stewards (Word document)

4. If I need to apply to the IRB, what review level will my study be?

Research with students and/or their data can be exempted if one of the following is true about the study:

- The research is about "normal educational practices in established educational settings" and consent/parent or guardian permission is sought OR the study qualifies for a FERPA exception. This category can include student data subject to FERPA (exempt category d.1 – opens in a new window);

- The research involves testing, surveying, interviewing, or observing adult students and it's not possible to re-identify participants from the cleaned data set OR it is possible but the re-identification would not harm participants OR if re-identification could minimally harm participants, the IRB conducts a limited review (exempt category d.2 – opens in a new window);

- The research activities involve benign behavioral interventions with adults (e.g., playing Mozart to see if/how that affects student performance and mental health during testing) that are brief, painless, harmless, non-invasive, have no long-term impacts, and no reasonable person would find the research offensive or embarrassing. If deception is a part of the study, it is prospectively disclosed to participants as part of the consent process and participants are debriefed about the deception at the end of the study (exempt category d.3 – opens in a new window);

- The secondary data is personally identifiable but publicly available OR its personally identifiable data that is recorded in such a manner that participant identities cannot be ascertained. This category excludes FERPA data from inclusion (exempt category d.4 – opens in a new window); or

- The study is not funded – now or in the future, the research is minimal risk, the use of the personally identifiable private data is not subject to any data use restrictions or other applicable laws, and consent/parent or guardian permission is sought could undergo a FLEX exempt review.

Studies that are minimal risk but do not seek consent/parent or guardian permission for personally identifiable private student records and/or where the data provider requires a specific level of IRB review are typically reviewed at the expedited level (i.e., categories 5 & 7 – opens in a new window) when they do not qualify for a FLEX exemption. If the student data is particularly sensitive where the use of the data or re-identification of participants would be more than minimal risk, the study will be reviewed at the convened full board level.

For more information, please review the following IRB resources:

- Exemption requests unit standard (Word document)
- Expedited review procedures unit standard (Word document)
- Educational research exempt review category decision tree checklist (Word document)
- Identifiable data sets (Word document)
- Research involving deception (Word document)

5. I didn't apply for IRB approval to use student records for research, but now I want to. Can I get IRB approval?

Federal law prevents retroactive IRB review and approval. If there was an intention to use student data for research, IRB review and approval must have been prospectively sought.

There are few cases where student data is generated solely through normal class activities and an educator decides that they would like to analyze the data for research purposes. In these cases, IRB review might be granted but review level would depend on the nature of the data, if consent/parent or guardian permission would be sought, and how the data will be used.

6. **Can I use artificial intelligence (AI) with student data?**

   AI is a rapidly developing technology. It depends on the nature and identifiability of the student data, whether or not consent was given by the adult student or parent/guardian of a minor to use the student data for research, the nature of the AI tool itself, and how you plan to use AI with the student data.

   For more information, please review the following IRB resource:
   - Use of artificial intelligence in human subjects research (Word document)

7. **What if I have questions about if IRB review and approval is necessary for a specific project that I want to do?**

   You can email the IRB office at IRB-Coordinator-Pre@ncsu.edu or utilize the bimonthly drop-in IRB office hours (opens in a new window – UnityID is required to access). You can also request a "Not Human Subjects" determination on our website (opens in a new window).