



**Human Subjects**

*Office of Research*

**UNIVERSITY OF GEORGIA**

# Identifying Student Research in the Portal and Consent Documents

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# Importance of Identifying Student Research in the Portal and Consent Document

- Graduate students are not eligible to be the PI. It should be the Faculty Advisor (or other eligible faculty member) who is primary responsible for the preparation, conduct, and administration (management) of human subjects research
  - Exceptions:
    - 1) Post-Graduate Professional Trainees
    - 2) Projects that do not meet the definition of human subjects research
    - 3) Where UGA IRB will rely on the review of an External IRB
- It helps the reviewer in providing correct guidance
- To protect the student who is working hard for the project when/if the PI leaves UGA or otherwise can no longer oversee the project

# Identifying Student Research in the Portal

PROJECT00007288

Study Team Members

## Study Team Members

1. Identify each UGA faculty, staff, or student who will be engaged in the conduct of human research. Do not select the PI again

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone	Is Student Project
<a href="#">View</a> Alyssa Guadagni	CO- INVESTIGATOR DATA ANALYST RESEARCH COORDINATOR	no	yes	ajg14350@uga.edu		true

The submission will say "TRUE" if this is a student project.

2. Identify non-UGA collaborators\* who will be engaged in the conduct of human research. ?

Name	Email	Organization	Training Document	Investigator Agreement
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There are no items to display

\*Submit an Individual Investigator Agreement for all study personnel with an institution that does not have an assurance with the Office for Human Research Protections or OHRP (typically, local schools, private doctors, clinics).

\*For study personnel who are affiliated with an institution that has an assurance (has its own IRB), do not submit an Individual Investigator Agreement. Instead indicate that you have an External Site on the Study Scope page.

\*If the submission is for reliance on an External IRB, do not list study team personnel at non-UGA sites.



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# Project Funding

1. \* Is the work described in this protocol, or the work described in the overarching project, funded by an external source:  
 Yes  No

2. Compare the scope of the Human Subjects Activities included in the overall project to the activities described in this protocol submission:

*They are the SAME:*

All human subjects activities in the overall project are included in this protocol submission:  
 Yes  No

*They are DIFFERENT:*

Human subjects activities included in the overall project but not part of this protocol submission have already been included in a separate pending or approved protocol submission:  
 Yes  No

Identify the UGA IRB project number for any related pending submissions with ID like 'PROJECTxxxxxx':

ID	Name	Principal Investigator	Project State
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There are no items to display

Identify the UGA IRB project number for any related pending submissions with ID like 'STUDYxxxxxx':

ID	Name	PI Last Name	Project State
STUDY00003632	Emotional perception	Sabatinelli	Approved

Human Subjects Activities included in the overall project but not in this IRB Submission are intended to be included in a future UGA IRB Submission:  
 Yes  No

Human Subjects Activities included in the overall project but not in this IRB Submission have already been included in a separate pending or approved IRB Submission to an external institution/entity:  
 Yes  No

Human Subjects Activities included in the overall project but not in this IRB Submission are intended to be included in a future IRB Submission to an external institution/entity:  
 Yes  No

Student research may also be identified on how they answer **PROJECT FUNDING, Q2.**

# Identifying Student Research in the Consent Form

UNIVERSITY OF GEORGIA  
PARENTAL PERMISSION FORM  
[TITLE OF THE STUDY]

You are being asked to allow your child take part in a research study. The information in this form will help you decide if you want your child to be in the study. Please ask the researcher(s) below if there is anything that is not clear or if you need more information.

<b>Principal Investigator:</b>	<i>Name</i>	<b>Co-Investigator:</b>	<i>Name</i>
	<i>Department</i>		<i>Department</i>
	<i>Contact Information</i>		<i>Contact Information</i>

← The student is usually the Co-investigator

Your child is invited to be in this research study because he/she is in a class where the teacher will be evaluating methods to improve reading comprehension. We want to learn more about how different group activities affect reading comprehension. We are very interested in how groups with equal numbers of girls and boys work together and how groups with students at different reading levels may affect comprehension as well.

← Sometimes they mention here that they are under the supervision of the FA

If you have any questions about the study, contact *[name and contact information.]* If you have any complaints or questions about your rights as a research volunteer, contact the Institutional Review Board (IRB) at IRB@uga.edu or 706-542-3199.

← Student's contact info is found on the latter part of the consent form.



# Portal Correspondence




**Institutional Review Board**  
**UNIVERSITY OF GEORGIA**




Date: Friday, March 24, 2023 4:44:40 PM

**Print** **Close**

PROJECT00007288 Project Basics

## Project Basics

- \* Title of Study:  
Dose Response Effects of Pecan Consumption
- \* Principal Investigator:  
Jamie Cooper
- \* Does the Principal Investigator have a financial interest related to this research?   
 Yes  No
- \* The Principal Investigator will receive all communications related to this project. Select one or more persons to receive the same communications or to have read access to the project even if they are not study team members (e.g., a project coordinator):  

Name	Organization
Alyssa Guadagni	FACS-Nutritional Sciences
- \* Are you requesting determination if your project meets the definition of human subjects research?   
 Yes  No
- \* Are you requesting determination if your project meets the criteria for developmental review?   
 Yes  No
- \* Will an external IRB act as the IRB of record for this study?   
 Yes  No

It would be best for the student to be added in **Q4 of PROJECT BASICS** so the student will receive the correspondence directly from the Portal.



# Primary vs. Secondary Research

It is ***not*** secondary research when investigators interact or intervene with living individuals to obtain data or biospecimens ***specifically for the proposed research***

US DHHS, Regulatory Options for Secondary Research with Private Info and Biospecimens Pt. 1  
<https://www.youtube.com/watch?v=tQPEqnawZ04>



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# Secondary Research

Research use of information or biospecimens originally collected for:

- **Non-research purposes**

- Examples:
1. Blood left over from routine clinical tests
  2. Health information for clinical care
  3. Educational records
  4. Quality assurance or evaluation data

Or

- **Research studies other than the initially proposed one**

- Original study: Blood samples left over from a study evaluating the impact of stress on cortisol levels
- New study: Evaluating the prevalence of pre-diabetes in the population





# Example

- The purpose of this study is to explore what participating teachers understand regarding the root principles undergirding the Instructional Conversation pedagogy and how they use and think about the pedagogy after the training. A secondary goal is to evaluate the delivery of professional development to identify best practices for effective, transformative, and sustainable teacher learning.
  - **Student's secondary research:** The aim of this study is to add to the existing literature on teacher attitudes, by specifically exploring differences in attitudes between special education and general education teachers working in the state of Georgia based on characteristics such as district, training program, amount of years teaching, education level, experience teaching ELLs, certification area, teacher first language, and grade levels taught.

# Options for IRB Review

- **Not human research determination**
  - If all data are de-identified and the student research does not have access to code-keys or other methods to re-identify
- **Human research eligible for Exemption**
  - If data are identifiable when provided to student but student will immediately de-identify and will not be allowed to recontact participants or access way to re-identify
- **Human research eligible for Expedited review**
  - If data are identifiable and student will need to re-identify or the use of the data is otherwise not eligible for exemption

OR

- **Modification to ongoing primary study**

# What do we look for?

- Does the study team page identify the student who is doing the secondary research?
- How does the student reference the primary research in the submission? (***Funding details page***)
- Should the student reach out and re-consent the previous participants to use their data for this new research? (***It depends on what the primary research consent said and the state – identifiability – of the data.***)
- Does de-identifying the data prior to providing it to the student obviate the need for the “re-consent” process? (***Not necessarily. But it might mean that the new purpose is not approvable. See previous item re: primary consent.***)
- Additional concerns regarding data sharing? (***NIH CoC, Funding, Data leaving UGA***)
  - *Email from PI of approved primary research*

# Helpful Links/Resources:

- [Principal Investigator Eligibility](#)
- [Consent requirement for future use/sharing: 45 CF 46.116\(b\)\(9\)](#)
- [NIH Certificate of Confidentiality](#)



# Thank you!



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