Purdue Extension: Field/Discipline Specific Responsible Conduct of Research (RCR)

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New Purdue Training Requirement Announced in 2020

Responsible Conduct of Research (RCR)

- Discipline/Field Specific Training
- 2 Hours of Training
- Deadline is July 1, 2022
- Complete just once

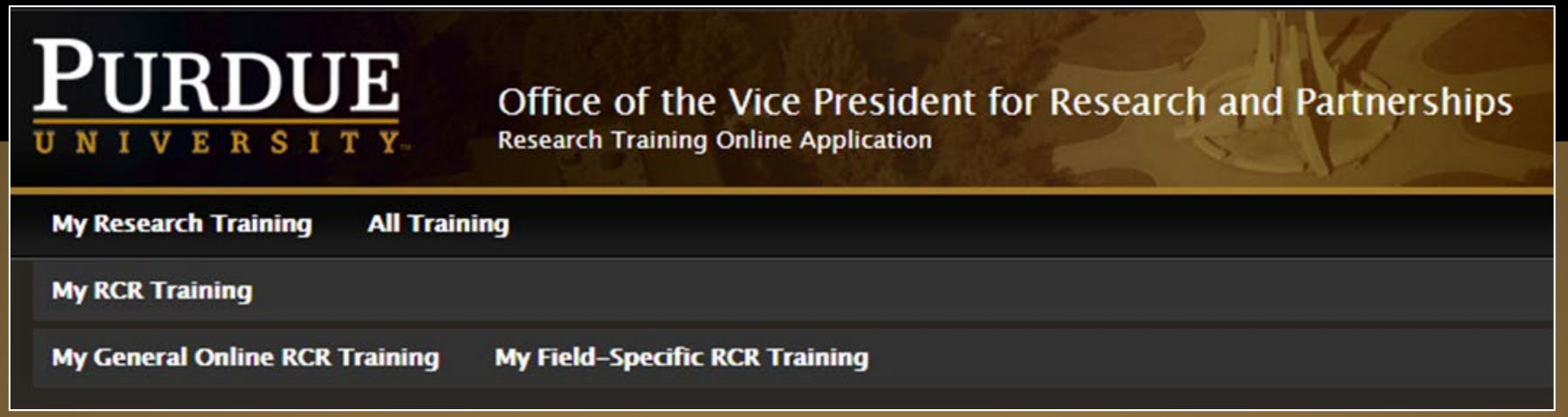
CoA Trainings

Recordings & Workshops Available

- College of Agriculture Field Specific Training (1.5 hours)
  - https://www.youtube.com/watch?v=4YCfEH2M4=Q
- Purdue Pharmacy Field Specific Training (1 hour)
  - https://mediaspace.itap.purdue.edu/media/RCR+2021/1_8i7i2zxo
- Krannert Field Specific Training (2 hours)
  - https://youtu.be/pS6PxMH6hZI
- College of Science (1 hour each)
  - April 8, 2021 (students, staff): https://youtu.be/3zUmVsfm5o4
  - March 12, 2021 (faculty): https://www.youtube.com/watch?v=4xrhy3nwRiE
- Find Workshops:
  - https://www.purdue.edu/gradschool/professionalworkshops/index.php

Self-Report Completion of 2 Hours of Training

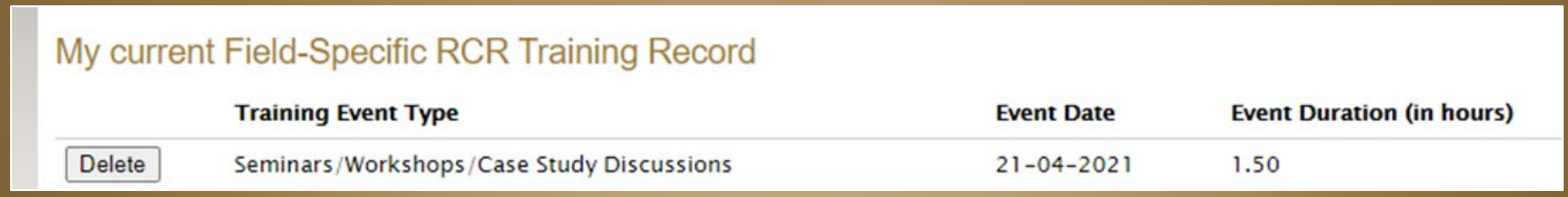
- https://www.purdue.edu/research/integrity/responsible-conduct.php
- Select “Tracking Your RCR Training”
- Log in with username and password (NOT BoilerKey)



My General Online RCR Training – This is the Collaborative Institutional Training Initiative (CITI) course titled "Responsible Conduct of Research (RCR) for Faculty, Postdoctoral, and Graduate Students"

My Field-Specific RCR Training – This is the one you need to self-report

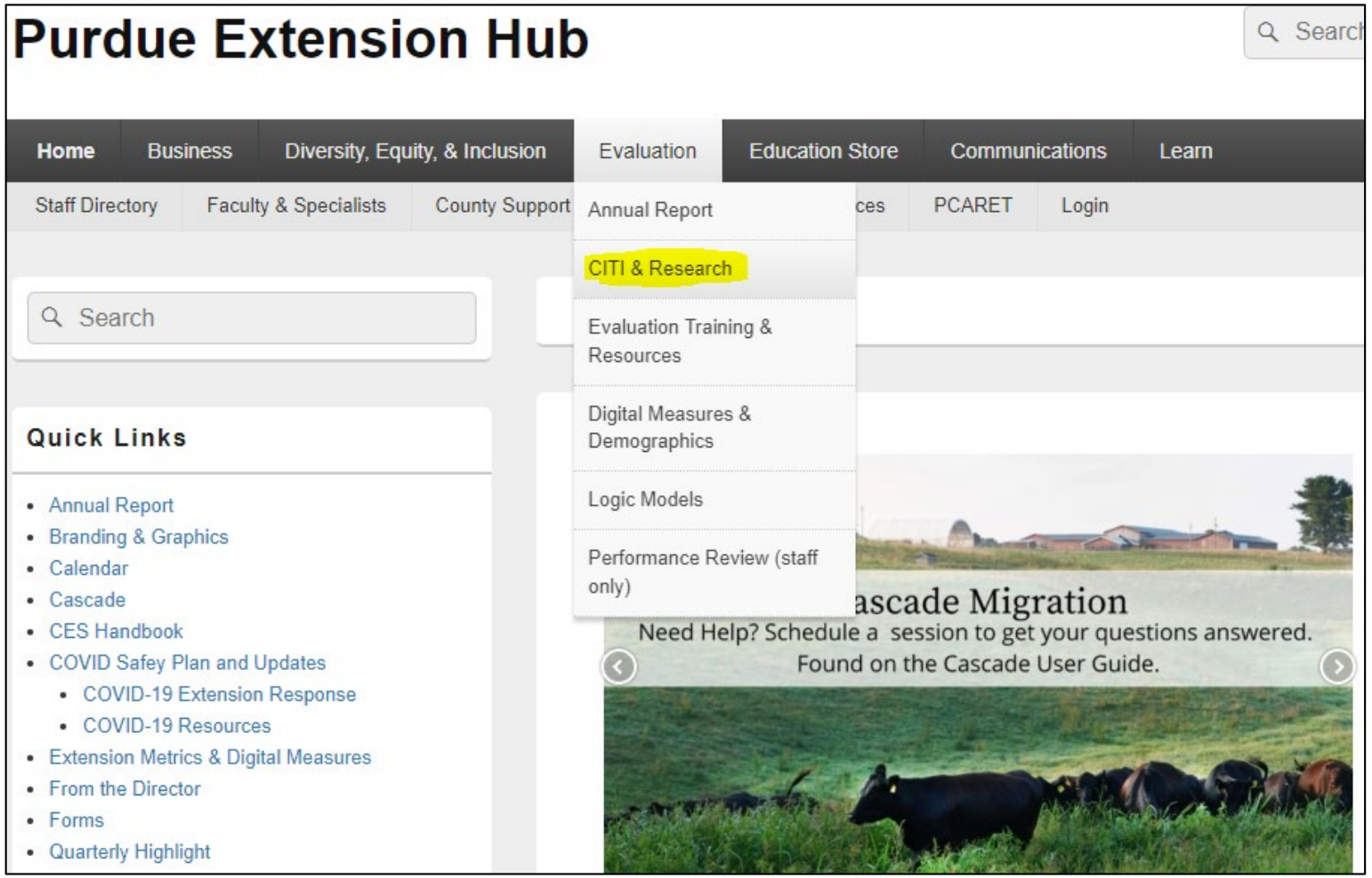
- Select "My Field-Specific RCR Training"
- Document your Researcher Type, as "Research Associate"
- Document the training you completed to reach the required 2 ho



EVPRP

- If you have questions about, or need assistance with, the EVPRP site, email RCRTraining@purdue.edu.
- Executive Vice President for Research and Partnerships
  - Responsible Conduct of Research
  - https://www.purdue.edu/research/integrity/responsible-conduct.php

Human Subjects Research Training Requirements for E



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https://extension.purdue.edu/hub/

3 Requirements

1- CITI* Group 2: Social Behavioral Research Investigators and Key Personnel

- Certification is good for 4 years, then need to do a refresher course to keep

2- CITI* Responsible Conduct of Research (RCR) Training (Faculty, Postdoctoral, and Graduate Students (also referred to as "General" RCR)

- Do once for your role in Extension.

3- EVPRP** Responsible Conduct of Research (RCR) Discipline Specific Training

- Do once for your role in Extension.

*CITI = Collaborative Institutional Training Initiative (CITI Program) https://citiprogram.org/

** EVPRP = Purdue Office of the Executive Vice President for Research and Partnerships https://www.purdue.edu/research/policies/responsible-conduct.php

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Old CITI Courses/Old IRB Protocols

CITI Group 3. Cooperative Extension Service (CES) Extension Educators training is n

- You can still see it on the CITI site, but DO NOT take it anymore.
- The CITI site has not changed and doesn't know that Educators no longer current.
  - If you receive an email from CITI about your Group 3, you need to do G Behavioral Research course instead.
- If you already completed Group 2, it is possible you may still receive CITI e so, you may ignore the email about Group 3.

Are you using old IRB Protocols?

- Often listed with this type of code 5[illegible]X or 1011009953 or 0605003884
- Contact jbuettem@purdue.edu before June 30, 2022 to discuss, then close your prot
- All old protocols will be closed on July 1.

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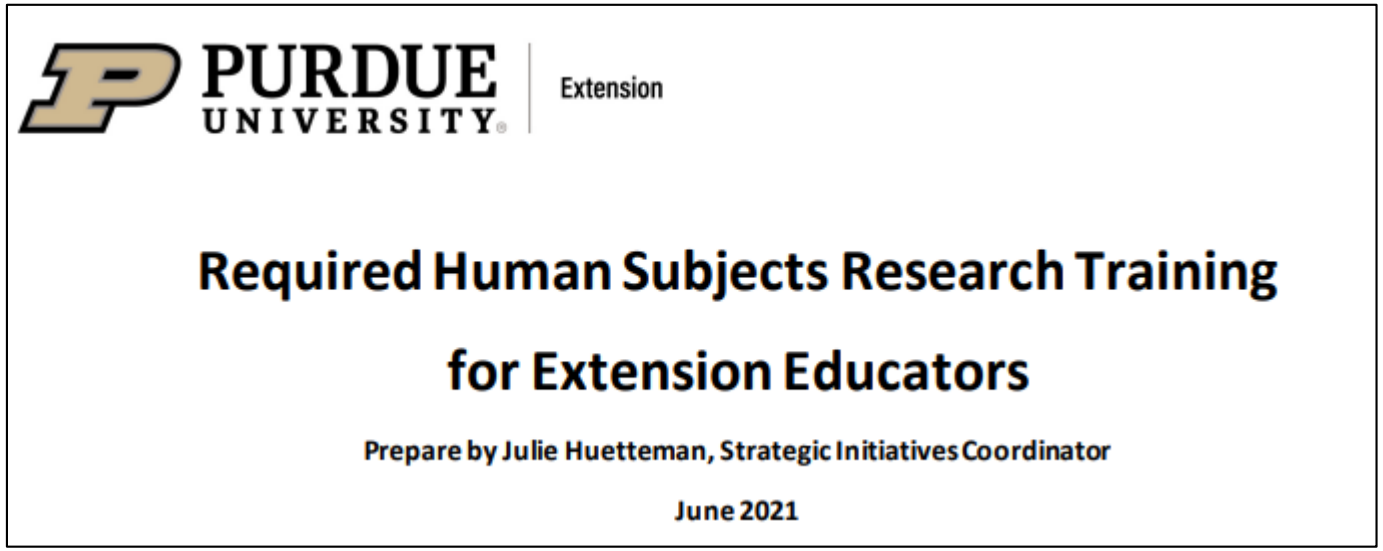
Training Instructions

https://extension.purdue.edu/intdev/wp-content/uploads/2021/06/Extension-Required-Training-for-Human-Subjects-Research-2021.pdf



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Required Human Subjects Research Training

for Extension Educators

Prepare by Julie Huetteman, Strategic Initiatives Coordinator

June 2021

"Exempt" Research Categories

https://www.irb.purdue.edu/guidance/

Most common for Extension Educators:

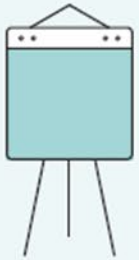
- Category 1 – Educational practices
- Category 2 – Surveys
- Category 4 – Secondary

Preparing the Research Protocol

https://www.irb.purdue.edu/docs/IRB_protocol_application.pdf

Infographic

SUBMITTING AN IRB PROTOCOL APPLICATION



Complete your training.

The research team must have context of the history of human subjects research, responsibilities of a researcher and duties of the IRB. The IRB will not review your proposed study prior to researcher training.

What is your research question?

1. Tell the IRB what specific trait, function or behavior you want to study. Tell us how previous research studies and their results support your study.
2. Give the IRB an example of potential discoveries you hope to make. For example, ple, outline a disease state or behavior that might benefit from the study results. This is required to assess the risk/benefit ratio.

Who will be in your study?

1. Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study as inclusion criteria.
2. In contrast, there might be individuals who should not participate in your study because it could be too risky or interfere with a condition. List these as exclusion criteria.

How will people find out about your study?

1. It's common for studies to be advertised on fliers, ads or social media. The IRB must know how people find out about the study.
2. It's also important to consider the privacy concerns associated with recruitment. If the study topic may bring up sensitive or potentially embarrassing topics, outline the way that potential participants will contact the research team.

How long will you need to keep study records?

1. When the original research question is answered, you will need to close the study with the IRB. You will need to keep the study records for a minimum of **three** years following the final closure.
2. If your study is sponsored, you should keep the study records for a minimum of **three** years after the closure of the sponsored financial account.
3. If your study involved Protected Health Information (PHI) you will need to keep study records for a minimum of **six** years following the closure of your study or grant.

How will you affirm and document that someone wants to be in your study?

1. Research is voluntary, so consider the investment of time that a participant commits and be certain that they are made aware of any risks, costs, benefits, and procedures. Everyone should know how to contact the principal investigator and the IRB. Informed consent is more than a form; it's a process and a responsibility!
2. If your study involves a vulnerable population (recall the definition from your training!), you will need to have some additional protections in place.

How will you keep the data and records private, anonymous and/or confidential?

1. When you are collecting data, consider the questions and the environment in which you are working. This is a consideration of privacy.
2. If there is a risk of discomfort (either physical or emotional) to the participant, explain the way you will minimize these discomforts. Outline how you will monitor participant safety. Review the IRB requirements to report any recordkeeping concerns (e.g. loss of study records) or unanticipated events.
3. Tell the IRB how you will store hard copy and electronic data. Limit record sharing to only project personnel. Use university-approved, password-protected systems. Store files in locked cabinets in limited access areas. These measures contribute to the confidentiality of a study.

What will you do if something unexpected happens?

1. You need to amend your protocol with the IRB if any of the research procedures change or if there are changes to project personnel.
2. Consider how you would handle and report any unexpected events that may occur. Outline this in the application. If there is a risk of discomfort (either physical or emotional) to the participant, explain the way that you will minimize discomforts. Know how and when to report problems with the research to the IRB.

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EA/EOU

When is an IRB review needed?

https://www.irb.purdue.edu/getting_started/

Purdue Extension practices

- Program evaluation
- Measuring outcomes, sharing impact
- Results to share documenting in DM for USDA required reporting, or communicating with County Advisory Committee, others

IRB involvement

- Vulnerable populations – children, pregnant women, prisoners, etc.
- Data collected to inform curriculum development intended for distribution/sale
- Presentation at professional conference
- Publication in journal article, Extension publication, book, etc.

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Protocol Research

Examples of Extension Language for IRB Protocols for Exempt Research

Structure	Examples
Research Question	• Effectiveness of training • Impact of program on participants • Increased knowledge, attitude, skills, aspirations about… • Adoption of practices or changes in behavior learned in training
Research Subjects	• Youth in grades 6-8 • Parents of preschool age children • Large scale - Row crop farmers in Indiana • Community volunteers from non-profit agencies
Recruitment of Research Subjects	• Email invitations • Flyers posted on social media • Attach example
Voluntary Participation	• Instructions on top of survey = participation is voluntary, responses are anonymous • Verbally read instructions when introducing/distributing survey • Youth – there are no right or wrong answers…if you don't want to fill out the survey, you don't have to or if there is a question you don't want to answer, you can leave it blank

Data - Anonymous	• Survey includes questions about:
	  ○ Demographic information - race/ethnicity, gender, grade
	  ○ 4-H experience
	  ○ Interest in science and engineering, and jobs in science and engineering
	  ○ Science process skills
	• Storage of data – locked drawer/cabinet; limited-access Purdue Extension server
	• Attach a copy of the survey

Protocol Research

The Extension Context

Structure	Examples
Extension Program	• A 3-month program providing instruction, demonstration, small group activities… about _____ • Delivered as a hybrid program with collaborative activities in person and online study between sessions… about _____ • Program will be held in the County office training room… via ZOOM, etc.
What you will do with the results	• Present at a professional conference • Publish a curriculum and sell to other institutions • Create an Extension article or publish a journal article

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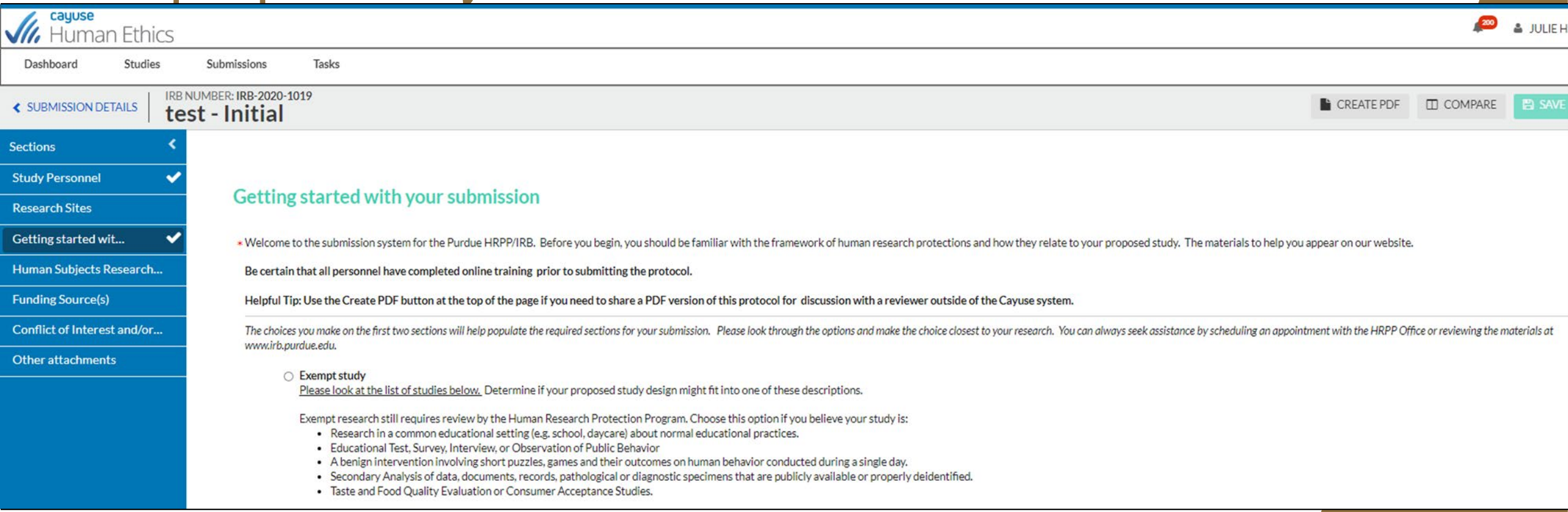
Submit Exempt Protocol via Cayuse IRB

https://purdue.cayuse424.com/rs/irb



Quick Reference Guide https://www.irb.purdue.edu/docs/QRC%20For%20N

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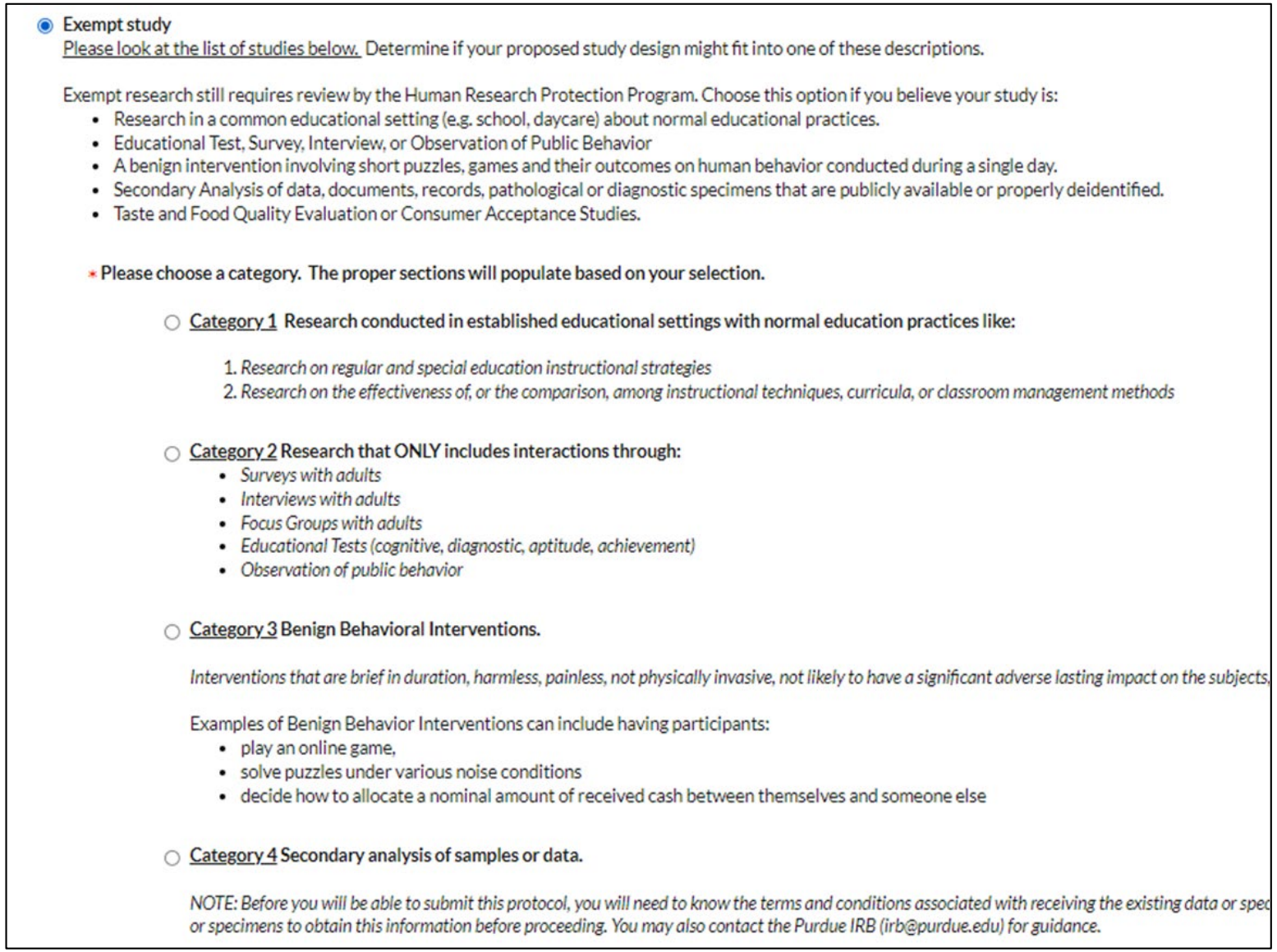
Submit Protocol via Cayuse IRB



◉ **Exempt study**

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

* **Please choose a category. The proper sections will populate based on your selection.**

○ **Category 1 Research conducted in established educational settings with normal education practices like:**

1. *Research on regular and special education instructional strategies*
2. *Research on the effectiveness of, or the comparison, among instructional techniques, curricula, or classroom management methods*

○ **Category 2 Research that ONLY includes interactions through:**

- *Surveys with adults*
- *Interviews with adults*
- *Focus Groups with adults*
- *Educational Tests (cognitive, diagnostic, aptitude, achievement)*
- *Observation of public behavior*

○ **Category 3 Benign Behavioral Interventions.**

Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects,

Examples of Benign Behavior Interventions can include having participants:

- play an online game,
- solve puzzles under various noise conditions
- decide how to allocate a nominal amount of received cash between themselves and someone else

○ **Category 4 Secondary analysis of samples or data.**

NOTE: Before you will be able to submit this protocol, you will need to know the terms and conditions associated with receiving the existing data or spec
or specimens to obtain this information before proceeding. You may also contact the Purdue IRB (irb@purdue.edu) for guidance.

Submit Protocol for Consideration

○ **Exempt study**

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
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○ **Non-exempt study**

Research that does not fit into an exempt category typically involves the collection of new data from a participant.

○ **Just-in-time**

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors s

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

○ **Quality Improvement**

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

◉ **I need to know if my project is considered "Human Subjects Research"**

○ **I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).**

After Approval Modifications

https://www.irb.purdue.edu/after/

If anything in your protocol changes after approval, you will need to amend your IRB protocol.

Changing Personnel and/or Study Procedures

The Cayuse IRB system is now used for all study modifications. Modifications must be approved by the IRB prior to changing the study. Common reasons to modify a study include:

- When key personnel are added to or removed from a project.
- When researchers update the techniques, recruitment, survey questions, assessments, compensation, or other methodologies in an approved IRB protocol.

Follow these steps to submit a study modification.

Human Research Protection Program (HRPP)

https://www.irb.purdue.edu irb@purdue.edu