RESEARCH ETHICS COMMITTEE (REC) INVESTIGATOR TRAINING 2025

Dr. Lisa Potts, REC Chair

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OVERVIEW

- REC Purpose & Applying the Common Rule
- Types of Research & Review Categories
- REC Policies
- Proposal Components
- Faculty Advisor Responsibilities
- Integrating REC into research courses
- Q & A

REC PURPOSE

- Faculty Senate committee, separate from OSPRe
- To protect the safety and privacy of human subjects research participants.
  - Charged with reviewing all research projects involving human subjects
    - *Assure research is conducted in accordance with the Department of Health and Human Services, Office for Human Research Protections (OHRP) policy for protection of human research subjects as written in the code of federal regulations (CFR)Title 45 Part 46.*

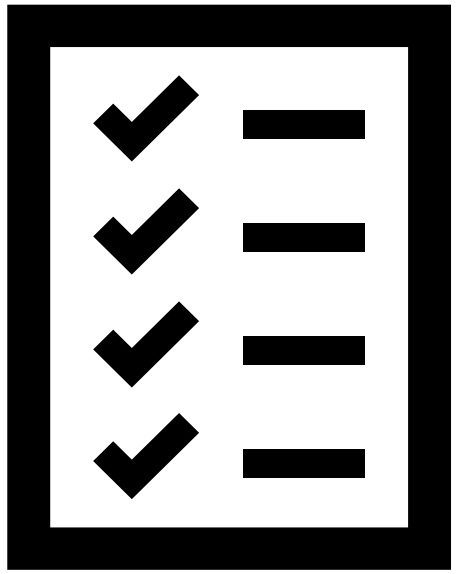
Duties & Responsibilities
1. communicate the regulations of the United States Health and Human Services regarding the use of human subjects in research to the University
2. evaluate the protection of human subjects in research projects proposed by faculty and students
3. catalog all research proposals submitted to the Research Ethics Committee in the Office of the Provost, along with the recommendations made regarding those proposals
4. promote research and share research reports completed in the University community, and to recommend (via the Faculty Senate/or appropriate administrative channels) University-wide research policies and procedures
5. submit summary reports via the chair to the Faculty Senate
6. review and maintain the REC website
7. provide training to University programs involved in human-subject research at least once during each academic year

PROJECT DEVELOPMENT, PROPOSAL PREPARATION & SUBMISSION

Faculty advisor / chair = Principal Investigator

Student = Co-Investigator

Proposal Worksheet



REC Proposal worksheet

WHAT IS HUMAN SUBJECTS RESEARCH?

IS THIS HUMAN SUBJECTS RESEARCH? [45 CFR 46.102 E (1-6)]: 2 QUESTIONS TO ASK

1) What is the purpose of the project?

- Systematic investigation designed to contribute to generalizable knowledge → RESEARCH
- Solely to evaluate or improve processes at a specific organization → NOT RESEARCH

2) How is human subject defined?

- living individual about whom an investigator obtains information…
  - through intervention or interaction with the individual

    OR
  - generates or uses **identifiable private information**

APPLYING THE COMMON RULE

BENEFICENCE

RESPECT FOR PERSONS

JUSTICE

RESOURCES

- Belmont Report
- HHS Regulations – 45 CFR part 46
- Office of human research protections (OHRP)
- Privacy Rule – 45 CFR parts 160 and 164
- CITI training
- REC policies and procedures

APPLYING THE COMMON RULE

BENEFICENCE

- Risk / benefit assessment

Purpose / Importance

What are the specific aims of the research?

Why is this important?

1. How does it contribute to knowledge in the field?

2. Who does it benefit?

REC must consider beneficence→ weighing benefits against the risks

WHAT QUALIFIES AS RISK?

RISKS TO CONSIDER

- Physical
- Emotional
- Criminal or civil liability
- Damaging to:
  - Financial standing
  - Employability
  - Insurability
  - Reputation
- Stigmatizing

RISKS

Consider risks-what's the worst that could happen (during the study and/or if the data were disclosed)? Note that risk includes potential risk to physical, psychological / emotional, social (reputation / stigma) well-being as well as economic, legal and employability implications.

How will you minimize these risks?

Risk level→ type of review

LEVELS / TYPE OF REVIEW

EXEMPT: Risk is no more than everyday life / a routine doctor visit or psychological assessment.

See OHRP exemption decision charts

Not bound by the OHRP regulations (but still good to follow)

Reviewed by REC chair or co-chair

Must still submit to REC to approve EXEMPT status

Allow ~4 weeks from submission to final approval (~2wks for review)

EXPEDITED: No more than minimal risk

See Expedited categories on REC OR OHRP websites

Reviewed by REC chair or committee member

Allow ~4 weeks from submission to final approval (~2 wks for review)

FULL: Studies that involve more than minimal risk

Reviewed by all REC committee members and discussed at a convened meeting

Requires quorum of REC members and majority voting for approval

Allow ~6 weeks - 3 months from submission to final approval

APPLYING THE COMMON RULE

RESPECT FOR PERSONS

- Individual autonomy
- Considerations for reduced autonomy

HOW CAN INDIVIDUAL AUTONOMY BE RESPECTED?

APPLYING THE COMMON RULE

JUSTICE

- Fair distribution of benefits and burdens of research

INCLUSION / EXCLUSION CRITERIA

Does it align with the study aims?

Participants

https://rec.spalding.edu/research-ethics-committee/review-categories/

Who will be the participants? _____

Consider:

1. **Who** will you be getting information **from**?

_____

2. **Who** (or what) will you be getting information **about**?

_____

Are they a vulnerable population? _____

If prisoners are involved have you considered:

1. The 7 additional components required for prisoner research (see REC website)?
2. Whether or not a CoC will be needed to protect against potentially incriminating information?
3. Explaining that disclosure of certain information requires reporting to the appropriate authorities?

If children are involved have you considered:

1. How you will obtain parental permission?
2. If / how you will obtain assent?

Will any part of the recruitment, consent or research process give the **perception** of coercion or undue influence to participate (e.g. faculty soliciting students to participate, etc.)?

_____

How will you reduce the potential for coercion?

_____

Are there any potential or perceived conflicts of interest for any of the investigators that need to be disclosed? _____

APPLYING THE COMMON RULE

BENEFICENCE

- Risk / benefit assessment
- Maximize benefits / minimize harms
  - Confidentiality

RESPECT FOR PERSONS

- Individual autonomy→ informed, voluntary participation
- Considerations for reduced autonomy (children, impaired, etc.)
- Is there potential for coercion / undue influence?

JUSTICE

- Fair distribution of benefits and burdens of research
- Inclusion criteria→ who are you recruiting and why?
- Recruitment strategy

TYPES OF RESEARCH & LEVEL OF REVIEW

Complete the review determination form for feedback to help you determine how to classify your project.

Latent class analysis for development of a new diagnostic tool

Latent class analysis for development of a new diagnostic tool

Development of educational materials for improving patient compliance with home exercise program

DETERMINE THE TYPE OF PROJECT & LEVEL OF REVIEW

Survey Research

Program evaluation / quality improvement

Records-based research

Vulnerable Populations

SURVEY RESEARCH: DECISION CHART 4

See the America Association for Public opinion research website for a list of FAQ regarding survey research.

- May be asked to use "information sheet" as consent (i.e. name / signature not included)
- Online survey research must be conducted through the University's QuestionPro account.
  - Disable collection of IP addresses when possible
- Survey research may be exempt if:
  - The information cannot be linked to or used to ascertain the identity of the subject.*

OR

  - The subjects' responses were disclosed it would not place them at risk of criminal or civil liability or affect their financial, educational, occupational or social status.*

OR

  - It has been determined that confidentiality of identifiable information will be maintained.

**If your research involves children, these criteria only apply if the research involves educational tests or is strictly observational.*

PROGRAM EVALUATION / QUALITY IMPROVEMENT PROJECTS

Is the ONLY goal / purpose to evaluate or improve processes internally?

YES→ NOT RESEARCH

NO→ HSR

Will you collect <u>private</u> information <u>about individuals</u> ?

YES→ HSR

NO→ questions only about the → NOT HSR

Program eval / development / improvement PLUS human subjects research

CAN BE BOTH!→ distinguish program from research

See <u>the FAQ on quality improvement</u> projects on the OHRP website for more information

RECORDS-BASED RESEARCH

- Data completely stripped of identifiers & not coded → NOT human subjects
- Coded data: if ALL 3 are met → NOT human subjects research:
  1. Coded data is the only thing being used
  2. Data were not collected for the proposed research via interaction or intervention with a living individual
  3. Investigator(s) cannot readily ascertain participants identity due to

     (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances OR

     (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances OR

     (c) there are other legal requirements prohibiting the release of the key to the investigators

OHRP info on secondary use and consent requirements for coded data
https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/cdebiol.pdf
https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html

CONSIDERATIONS FOR WAIVER OF CONSENT

- No more than minimal risk
  - Confidentiality plan
  - Plan to destroy the identifiers at the earliest opportunity, unless there is a health, research or legal justification for retaining the identifiers
  - Written assurances that the PHI will not be reused or disclosed
- Research could not practicably be carried out without the waiver
- Research could not practicably be carried out without using private information or identifiable biospecimens
- The waiver will not adversely affect the subjects
- When appropriate, subjects will be provided with additional pertinent information after participation

VULNERABLE POPULATIONS

RESEARCH WITH PRISONERS (SUBPART C)

- Exemptions do not apply unless the research only incidentally includes prisoners
- Un-incarcerated persons are the reference for risk

Four categories of research involving prisoners:

1. Cause, effects, processes of incarceration and criminal behavior
   - No more than minimal risk and inconvenience
2. Prison institutions or prisoners as incarcerated persons
   - No more than minimal risk and inconvenience
3. Conditions specifically affecting prisoners*
4. Practices that may improve the health or well-being of the subject*

**require HHS secretary approval*

RESEARCH WITH PRISONERS (SUBPART C)

Must provide documentation of additional considerations:

1. Falls into one of the permissible categories under § 46.306(a)(2).
2. Any benefits offered by participation must not be so large as to impair a prisoner's ability to weigh risks and advantages in a constrained environment.
3. Risks in the research must be no greater than those acceptable to non-prisoner volunteers in similar studies.
4. Subject selection methods must be fair and free from arbitrary influence; absent justification to the contrary, control subjects must be chosen by random selection among eligible prisoners.
5. The information presented to prisoner subjects must be in language understandable to them.
6. Adequate assurance that participation will NOT affect parole decisions, and prisoners must be informed in advance of this assurance.
7. Adequate provision for follow-up care or examination post-study as needed, considering varying sentence lengths—inform participants accordingly.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html#46.305

RESEARCH WITH CHILDREN: 45 CFR 46 SUBPART D

- Only certain exemptions apply to children
  - Observation with no researcher participation
  - Educational tests
  - Identity can not be ascertained
  - Disclosure of information would not put at criminal or civil risk or be damaging
- Must be no more than minimal risk to be considered for expedited review
- Will need parental permission and child assent, if applicable

LEVEL OF REVIEW

EXEMPT REVIEW (~4 WEEKS)

- Research involves no more than minimal risk / every day life
- Exempt research does not require ongoing (annual) review
- However, REC application for human subjects research must be submitted and approved in advance

REC determines and approves exempt status

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

1) Established **educational setting involving normal education practices**
   - Will not impact student learning opportunities
   - Assessment of educators

   **applies to children*

2) Only includes **educational tests, surveys, interviews or observation AND:**
   - Identity cannot be ascertained or linked to subject **OR**
   - Disclosure of information would not put subject at any kind of risk **OR**
   - Confidentiality of identifiable information is maintained

   ***does NOT apply to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

3) Research involving **benign behavioral interventions*** and collection of information from adults with their agreement **AND:**
   - Identity cannot be ascertained or linked to subject **OR**
   - Disclosure of information would not put subject at any kind of risk **OR**
   - Confidentiality of identifiable information is maintained

**benign behavioral interventions are brief, harmless, painless, non-invasive, will not have significant adverse lasting impact, and no reason to believe they would be offensive or embarrassing*

***does NOT apply to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

4) Secondary research for which consent is not required if one of the following criteria is met:
   - Identifiable info or specimens are publicly available
   - Identity of info or specimens cannot be ascertained or linked to subject
   - Research is for health care operations or public health activities per 45 CFR 164.512(b)
   - Research is conducted on behalf of a federal department or agency using government generated or collected information
     - Must be in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501

**applies to children*

CATEGORIES OF EXEMPTION
45 CFR 46.104(d)

5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads….
   - The research or demonstration project must be published on the supporting department /agencies website list prior to commencing the research involving human subjects.

   **applies to children*

6) Taste and food quality evaluation if using wholesome foods without additives or with additives at the level approved by the FDA

   **applies to children*

7-8) Secondary research on information or specimens utilizing broad consent that meets additional requirements per CFR 46.111, .116 or .117

   **applies to children*

SUMMARY OF EXEMPTIONS

- Normal educational setting / practices
- Educational tests, surveys, interviews or observation
- Benign behavioral interventions
- Secondary research for which consent is not required or broad consent may be utilized
- See the full list here
- **REC determines approval of EXEMPTION**

RESEARCH THAT IS NOT ELIGIBLE FOR EXEMPTION:

- Research involving prisoners
- Surveying or interviewing of children
- Observation of children when researcher is participating in the activities being observed

EXPEDITED REVIEW (~4 WEEKS)

- Research with no more than minimal risk
  - Identifiers linked to personal / sensitive responses
  - Personal or sensitive information
  - Risk minimal, but beyond everyday life

- Approval can be given by REC reviewers without convened meeting

- No continuing review is required

See the full list of expedited categories here.

EXPEDITED REVIEW CATEGORIES

- 1. Certain drug and device studies.
- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under certain conditions.
- 3. Collection of biological specimens for research purposes by noninvasive means (e.g. saliva, hair and nail clippings, etc.)
- 4. Collection of data through noninvasive procedures routinely employed in clinical practice (e.g. EEG, MRI, sensors, etc.)
- **5. Materials / data collected solely for non-research purposes (i.e. secondary use / records review)**
- **6. Voice, video, digital, or image recordings made for research purposes**
- **7. Research on individual or group characteristics or behavior or research utilizing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**
- 8-9. Certain continuing reviews

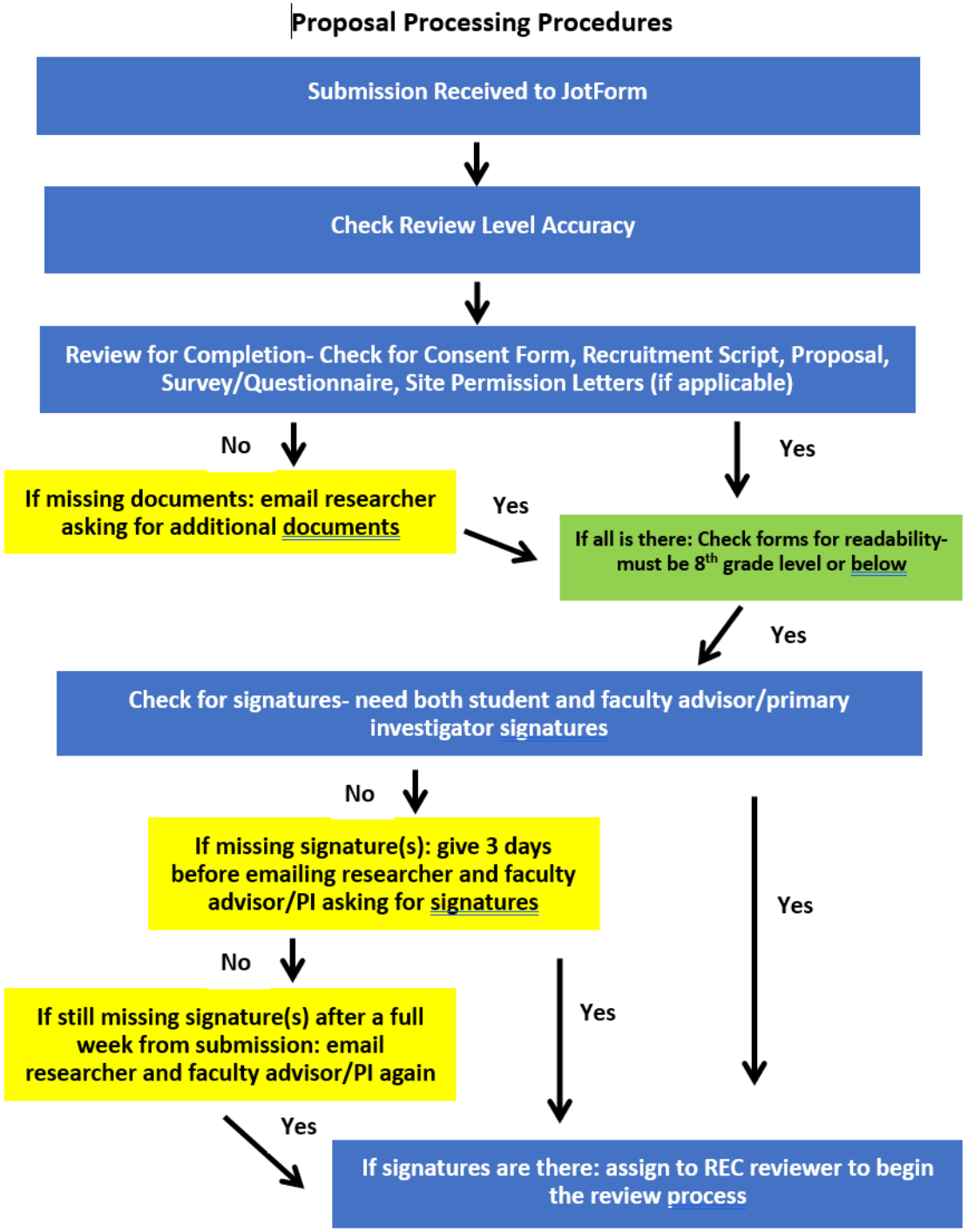
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

FULL COMMITTEE REVIEW (6 WEEKS – 3 MONTHS)

- Research that involves more than minimal risk
  - Minors if data are sensitive
  - Vulnerable populations (prisoners, individuals with impaired decision making abilities, pregnant women, etc.)
  - Increased physical discomfort, risk of injury or invasion of privacy

  - Requires a quorum of REC members present at convened meeting with a majority voting to approve

Review Process



REC POLICIES

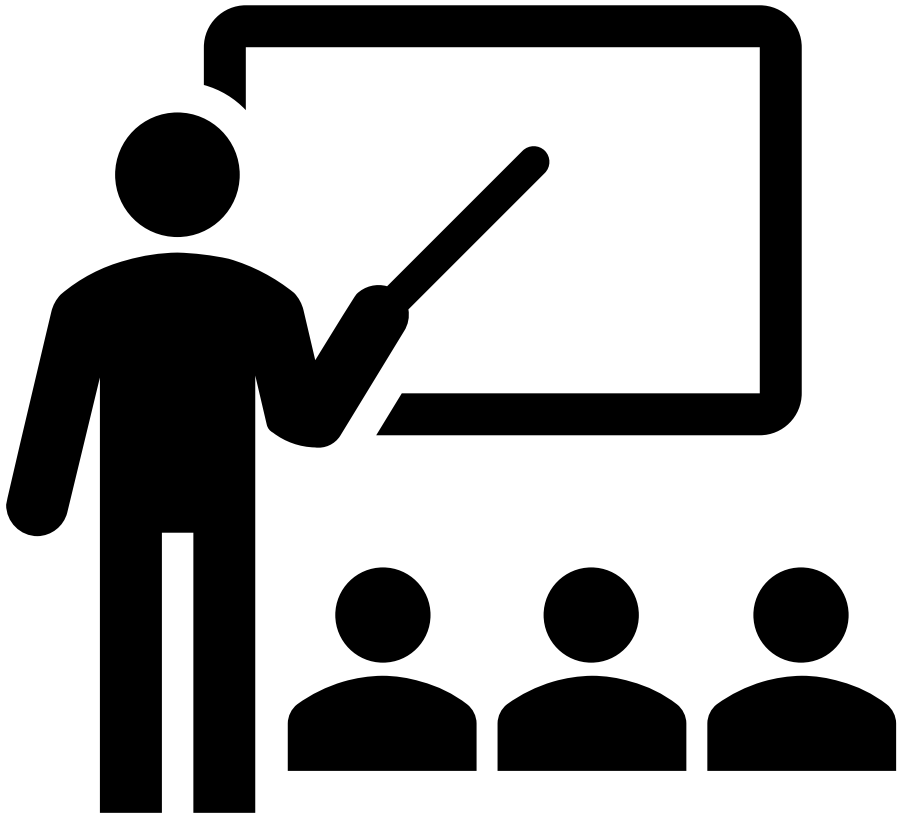
https://rec.spalding.edu/research-ethics-committee/rec-policies-procedures/

Ask students to complete a survey about the resources they used to determine which resources contributed to student su your course.

Ask colleagues to provide a list of low performing students so you can recruit them for your study on factors influencing use of the student success center

Ask colleagues to provide a list of low performing students so you can recruit them for your study on factors influencing use of the student success center

Ask students in your class to participate in your survey research on college student lifestyle habits and stress.

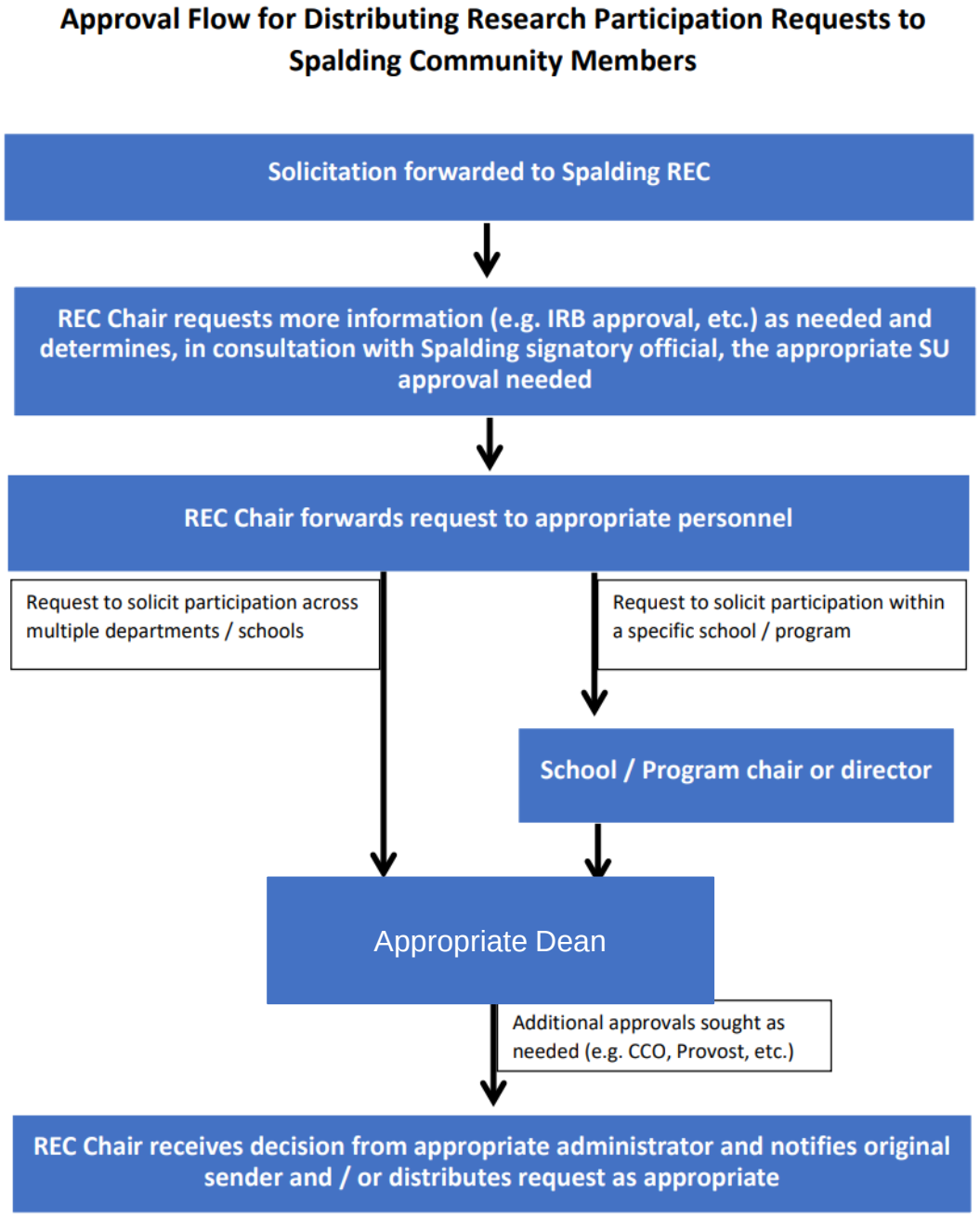


STUDENTS IN RESEARCH

- *The REC will not approve studies requesting to specifically target Spalding students who are currently enrolled in a course taught by faculty involved in the recruitment, consent or data collection processes of the study.*
- Extra credit should be considered an exception rather than the norm for encouraging student research participation
  - Additional considerations must be made
  - See best practices document

DISTRIBUTING REQUESTS FOR RESEARCH PARTICIPATION

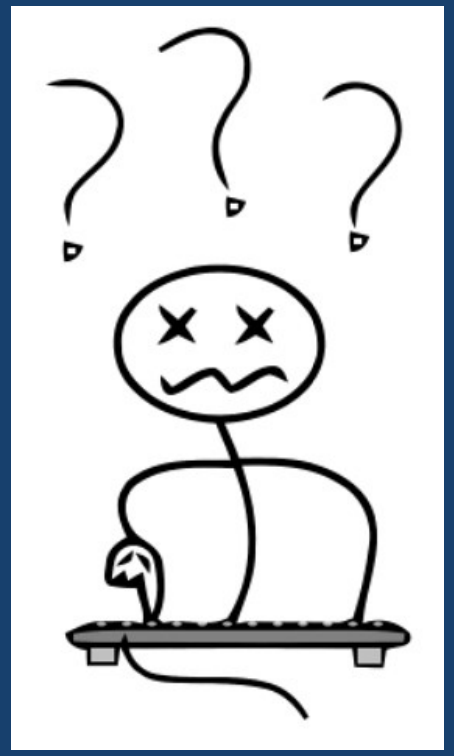
- Must follow approval process
- Do NOT give out student or employee contact information



INVESTIGATOR ROLES & RESPONSIBILITIES

ROLE OF FACULTY ADVISOR

Students need your help with ALL aspects of their research



ROLE OF FACULTY ADVISOR

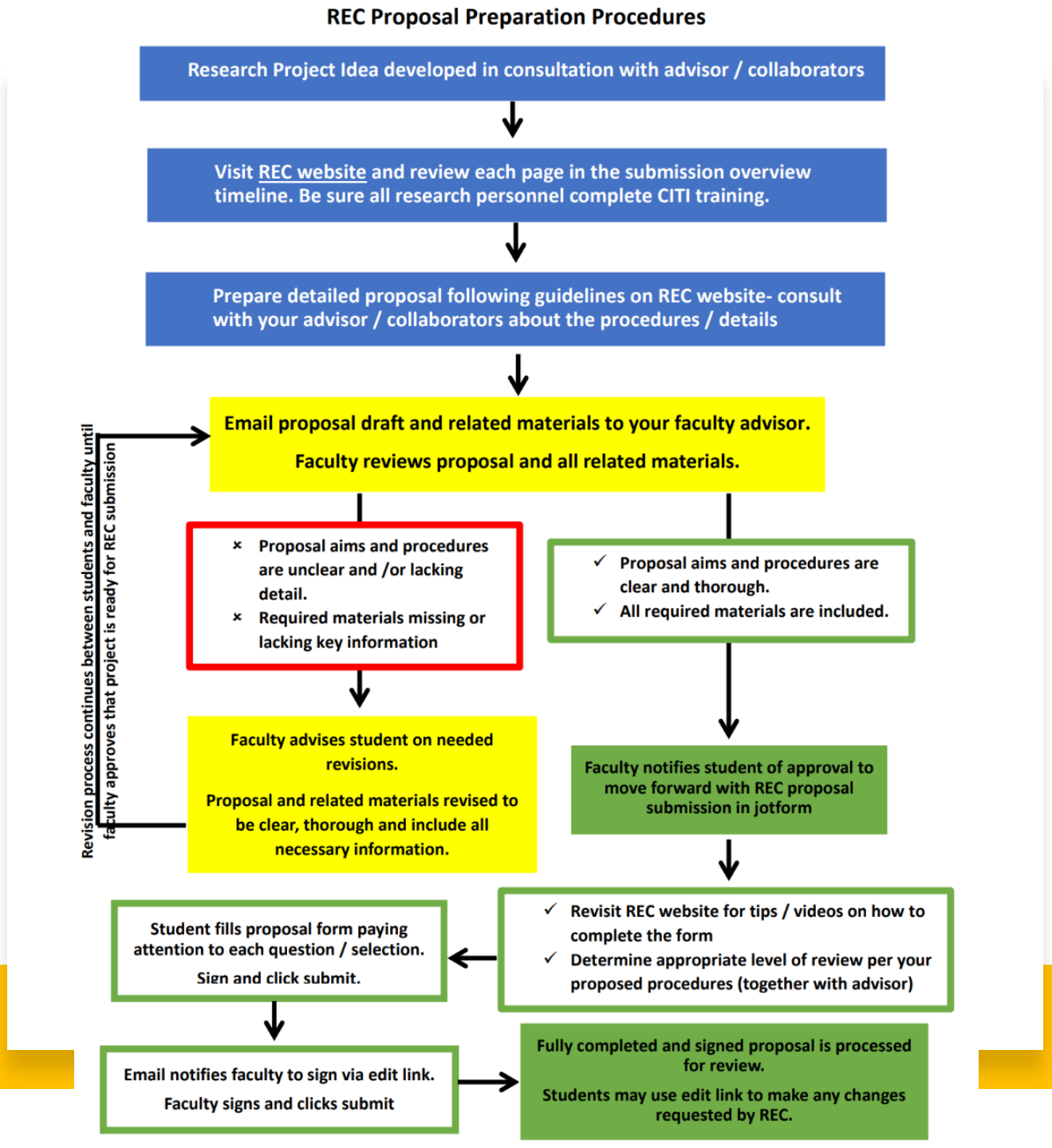
Faculty advisor is the principal / primary investigator & responsible for ensuring that all investigators:

- follow University policies
- comply ethical regulations / guidelines
- adhere to approved research procedures

Help student with:

- Developing clear aims & questions
- Determining the type of research / methods best for addressing these aims
- Designing procedures & to answer these questions
- Determining procedural details needed to thoroughly address REC proposal components
- **REVIEW ALL PROPOSAL MATERIALS BEFORE THEY START THE REC SUBMISSION**

Proposal Preparation Process



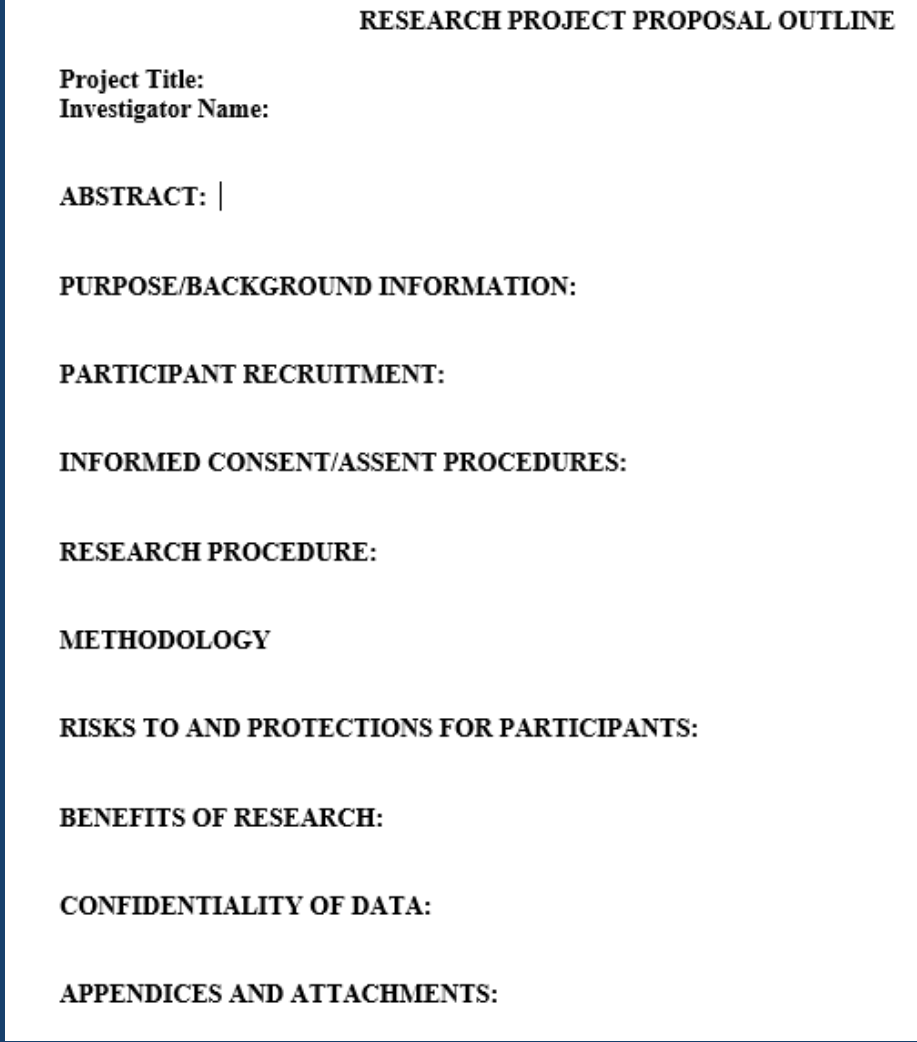
TIPS FOR A SUCCESSFUL PROPOSAL

PROPOSAL COMPONENTS

- PROPOSAL DETAILING:
  - Background / purpose of research-*keep it concise*
  - Recruitment process-*be explicit with details*
  - Consent process-*be explicit with details*
  - Data collection / research procedures and methodology
  - Risks and benefits of research-*describe ALL potential risks*
  - Data storage and confidentiality-*be explicit with details*
  - Appendices and attachments

DO NOT SUBMIT AN ENTIRE CAPSTONE / DISSERTATION PROPOSAL. Only submit the REC required information. *

https://rec.spalding.edu/research-ethics-committee/tips-for-submitting/



RESEARCH PROJECT PROPOSAL OUTLINE

Project Title:
Investigator Name:

ABSTRACT:

PURPOSE/BACKGROUND INFORMATION:

PARTICIPANT RECRUITMENT:

INFORMED CONSENT/ASSENT PROCEDURES:

RESEARCH PROCEDURE:

METHODOLOGY

RISKS TO AND PROTECTIONS FOR PARTICIPANTS:

BENEFITS OF RESEARCH:

CONFIDENTIALITY OF DATA:

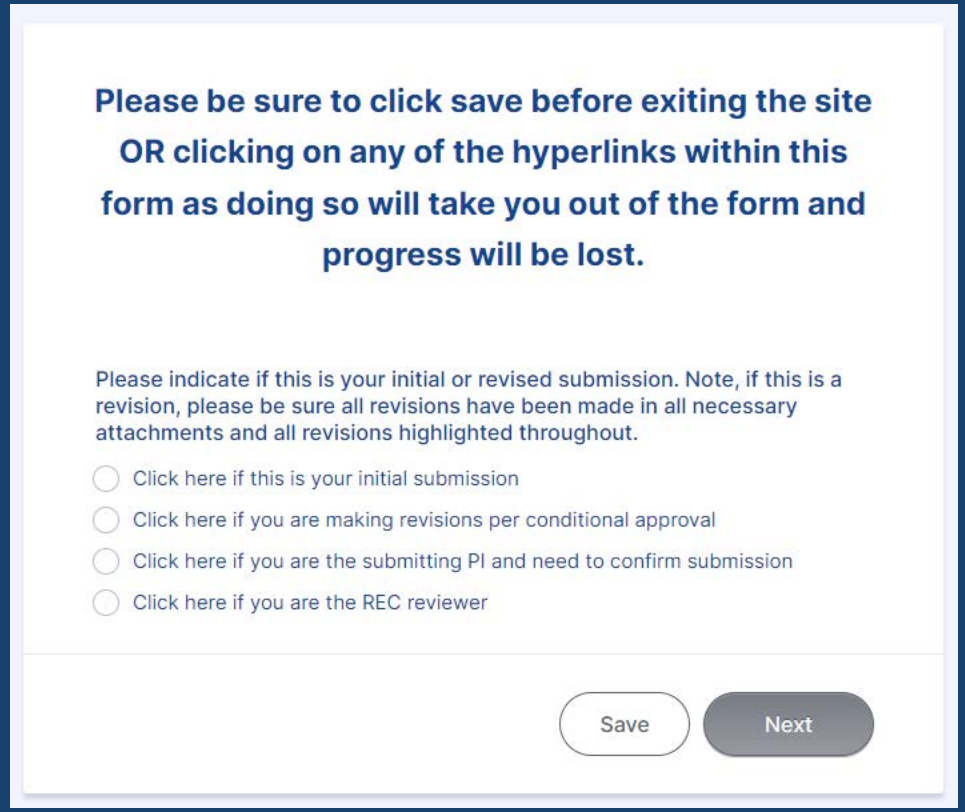
APPENDICES AND ATTACHMENTS:

PROPOSAL COMPONENTS

Prepare this information BEFORE starting jotform submission

- Investigator info
- CITI certificate confirmation
  - Best to upload separately
- Site(s) of research
  - Site permission letter(s)
- Target population
  - Readability justification
- Duration
- Funding
- Type of project
- Review category
- Question Pro link
- Proposal
- Recruitment
- Consent
- Appendices
- Signature

JOTFORM COVER PAGE



SITE PERMISSION

- Required for research:
  - Taking place at an organization
  - Requesting access to recruit specific individuals

- On letterhead OR copy of email
- Indicates understanding of procedures
- Signed by authorized individual

PROCEDURES

- Provide enough **detail** that someone outside your field could understand what will happen in your project, step by step.

Confidentiality:

- Will /can confidentiality be maintained?
- How will you protect confidentiality (or reduce likelihood of disclosure) throughout recruitment, informed consent and data collection procedures?
- What might happen if there is a breach of confidentiality?
- Could recruitment procedures violate privacy?

Data storage:

- How will data be stored and protected?
- Where will it be stored (Spalding or personal device)?
- Who will have access (and who will not)?
- Must maintain records for 3 years AFTER study is completed
- Audio / video recordings should be deleted as soon as possible after transcription / verification.

Acknowledgement of confidentiality risks, precautions and data storage details in the consent form.

INTEGRATING REC INTO YOUR COURSE / PROGRAM

Submit CITI training certificate

Quiz over REC website

Meet with faculty advisor to determine research idea

Proposal Worksheet

Outline / draft of research procedures

Review determination form (if needed)

Submit revised proposal and appendices to faculty advisor for approval

Review REC website / jotform to confirm review type and form selections

Meet with faculty as needed to ensure everything is ready to submit

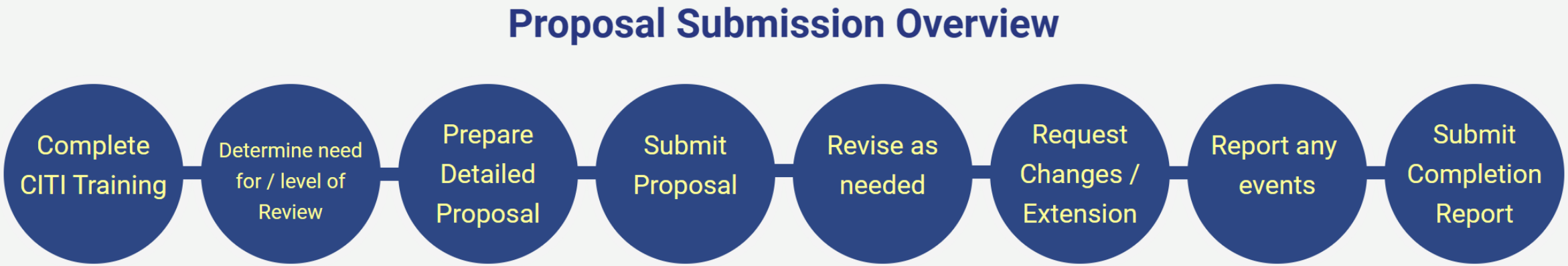
Submit proposal in jotform

CRITERIA FOR APPROVAL

- ❑ All necessary components / appendices have been submitted
- ❑ Risks are minimized
- ❑ Risks are reasonable in relation to proposed benefit
- ❑ Equitable selection of subjects
- ❑ Informed consent sought and documented
- ❑ Data monitoring plan (if needed)
- ❑ Adequate plans to protect privacy and maintain confidentiality
- ❑ Additional safeguards to protect vulnerable populations

REC WEBSITE

- Research Ethics Committee – Human Subjects Research at Spalding University



REC MEMBERS – THANK YOU!!

Email: rec@spalding.edu

Current Chair:

Lisa Potts, PhD

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502-873-4442

KCC 159

Current Graduate Assistant:

Stephanie Lewis

Lisa Potts –ASOT (Chair)
Goutam Singh – Physical Therapy (Co-Chair)
Regina Martin – Business (non-scientist member)
Kristen Harris – Education
Melba Custer – ASOT
Kevin Borders- Social Work
Mike Starling – Psychology
Claire Beaulieu - Psychology
Farrah Thornsberry- Nursing (non-scientist member)
Amanda Roberts – Criminal Justice (Prison Representative)
George Armitage – Clinical mental health counseling (non-scientist member)
Lacy McNary - Community Representative (non-scientist member)
Mike Bassi – Community Representative (non-scientist member)
Betty Goodell – Community representative (non-scientist member, alternate)
Jason Jordan – Clinical mental health counseling (alternate)
Tom Malewitz – Education (alternate)
Norah Chapman – Psychology (Prisoner Representative –alternate)

WE VALUE YOUR FEEDBACK!

Scan the QR code or click the link below to share your feedback about this training and ideas for additional REC workshops for students / faculty

Powered By QuestionPro

https://spalding.questionpro.com/t/ASjxGZ7M35