Demystifying the REC process

Dr. Lisa Potts, REC Chair

Stephanie Lewis, REC Graduate Assistant

Contact: rec@spalding.edu

OVERVIEW

- Role of REC
- Overview of REC process
  - *understand the timeline from submission to final approval*
- Review key elements of the REC proposal and submission form(s)
- Walk through proposal preparation worksheet
  - *tips for success and mistakes to avoid*
- Q & A

REC PURPOSE

- 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

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.)
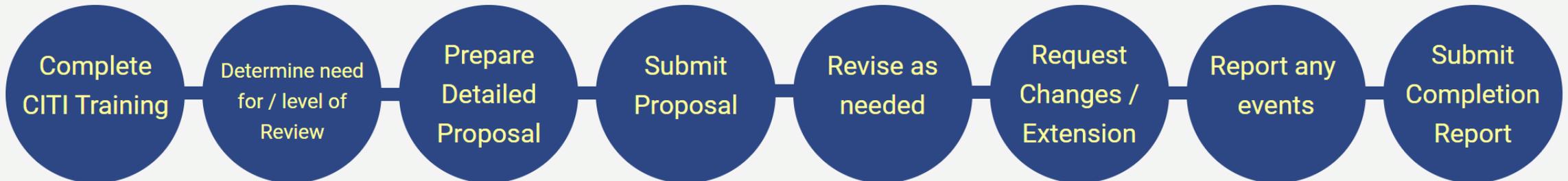- Is there potential for coercion / undue influence?

JUSTICE

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

WHERE DO I START?

WHERE DO I START?

Proposal Submission Overview

(Complete CITI Training) — (Determine need for / level of Review) — (Prepare Detailed Proposal) — (Submit Proposal) — (Revise as needed) — (Request Changes / Extension) — (Report any events) — (Submit Completion Report)
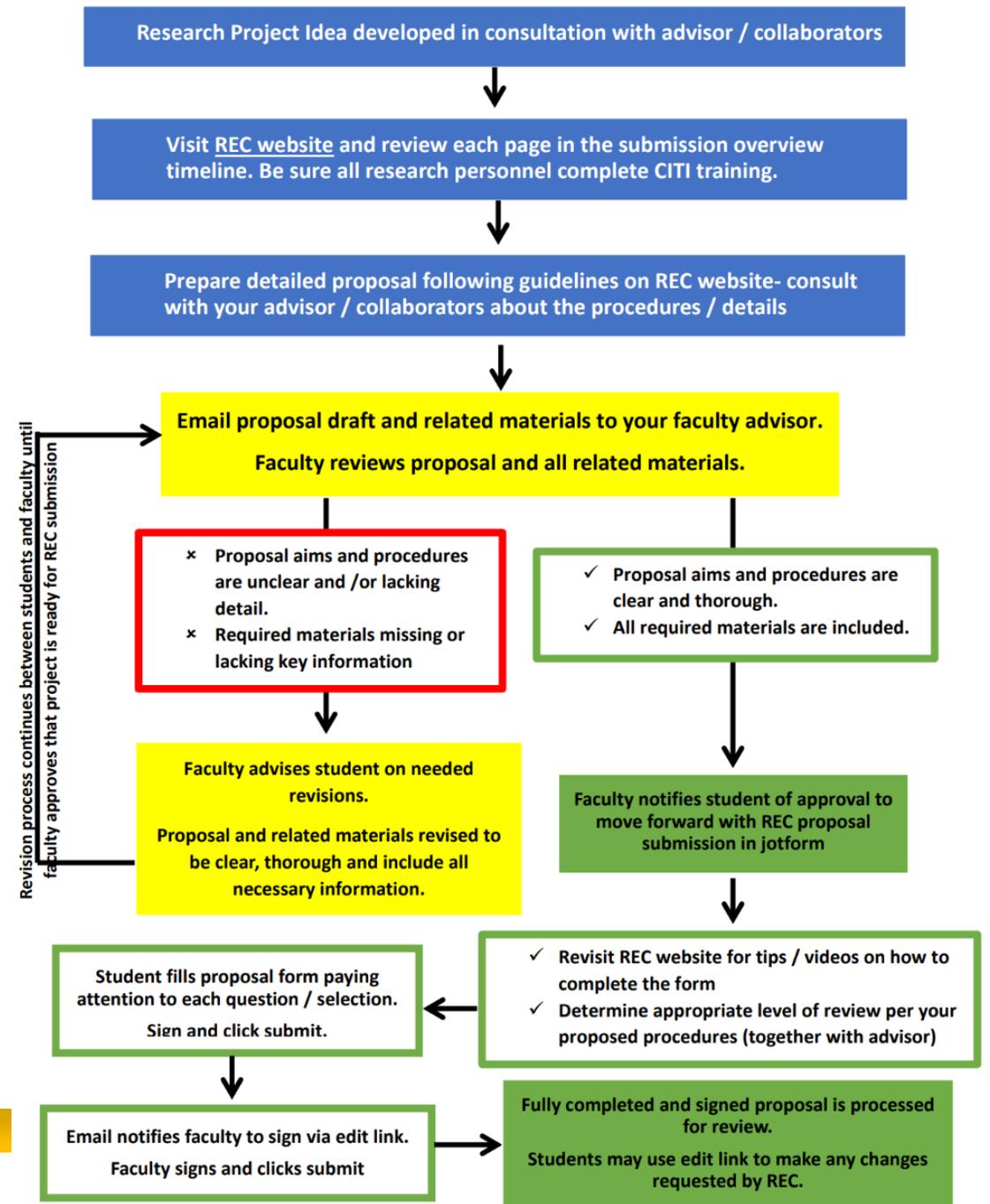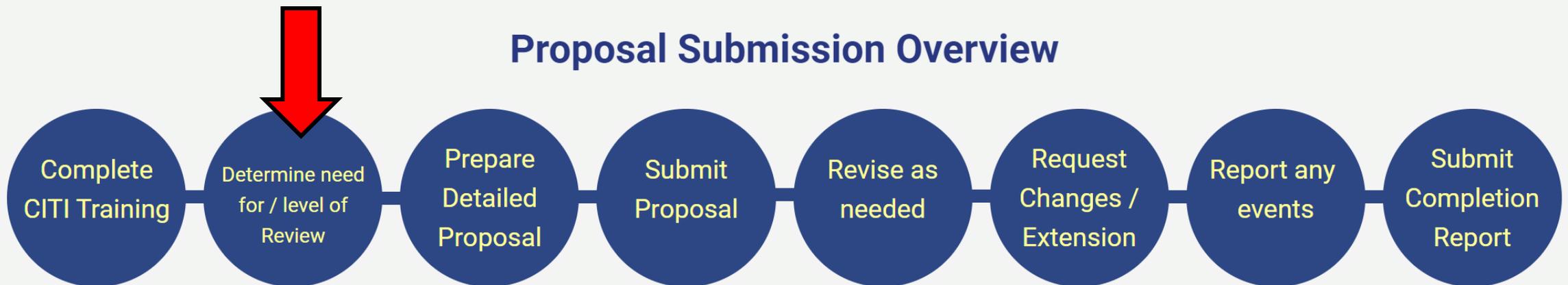
Start here!
- complete CITI training before doing anything else

Proposal Preparation Process

REC Proposal Preparation Procedures

DETERMINE IF YOUR PROJECT QUALIFIES AS HUMAN SUBJECTS RESEARCH

Proposal Submission Overview

Complete CITI Training → Determine need for / level of Review → Prepare Detailed Proposal → Submit Proposal → Revise as needed → Request Changes / Extension → Report any events → Submit Completion Report

- **determine if you are doing HSR and what level of review you need**

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

1) **What is the purpose of the project?**
   - <u>Systematic</u> investigation designed to contribute to <u>generalizable</u> knowledge → RESEARCH
   - <u>Solely</u> to evaluate or improve processes at a specific organization → NOT RESEARCH

2) **How is human subject defined?**
   - living individual <u>about whom</u> an investigator obtains information…
     - through intervention or interaction with the individual
       OR
     - generates or uses **identifiable private information**

DETERMINE THE TYPE OF REVIEW

EXEMPT: Risk is no more than every day life / a routine doctor visit.

- Not bound by the OHRP regulations, though it may still be best practice to follow their guidance
- ~2 weeks

EXPEDITED: No more than minimal risk

- ~4 weeks

FULL COMMITTEE: Studies that involve more than minimal risk

- ~6 weeks – 3 months

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

PROPOSAL COMPONENTS

- PROPOSAL DETAILING:
  - Background / purpose of research-*keep it concise*
  - Recruitment <u>process</u>-*be explicit with details*
  - Consent <u>process</u>-*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:

CONSIDER WHO, WHAT, WHEN, WHERE, WHY AND HOW... FOR EACH STEP

Example for the recruitment process:
- Who will your participants be?
- How will you find and recruit participants?
- Where will your recruitment materials be posted?
  - Do you have permission to post them there?
- What will you /others say to recruit people verbally?
- Is there a specific time and location that recruitment will take place?
- Who will help with the recruitment process?
  - Do those recruiting have any kind of status / power over the potential participants?
- Will you recruit via social media / snowball sampling?
  - **Provide a separate social media post for recruitment.**
- Explain why you might need to use any specific procedures for this process.

FEELING OVERWHELMED?

REC resources can help

- ❖ REC Website
- ❖ Review determination form
- ❖ Proposal worksheet
- ❖ 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
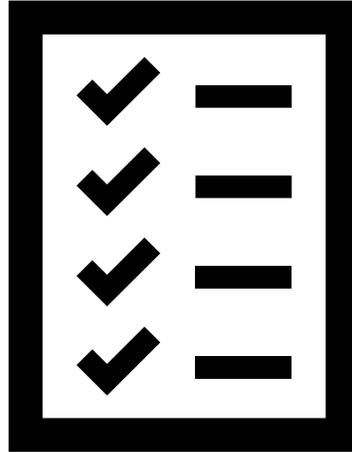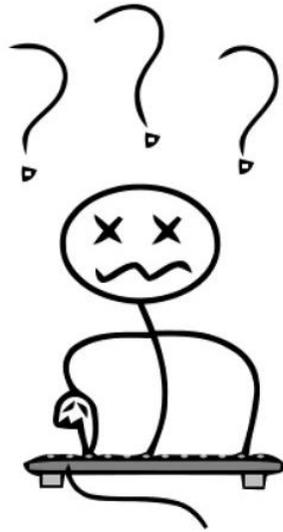
PROPOSAL WORKSHEET

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

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.
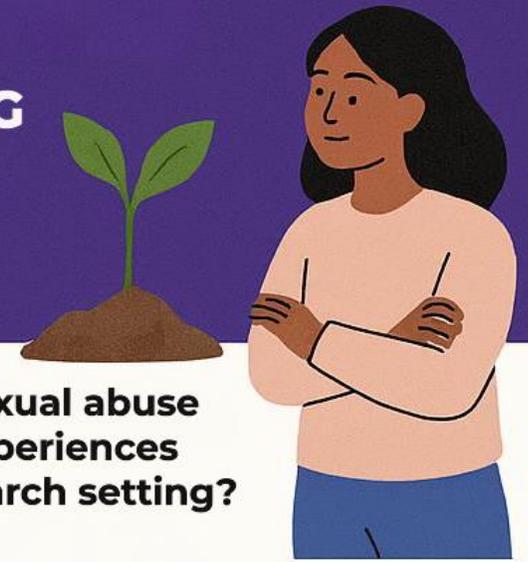
_____

_____

_____

_____

How will you minimize these risks?

_____

_____

_____

_____

Risk level→ type of review

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

How / where could this recruitment flyer be used?

Seeking participants for research study on COPING MECHANISMS AMONG SURVIVORS OF SEXUAL ABUSE

Are you an adult survivor of sexual abuse who is willing to share your experiences in a safe and confidential research setting?

We are conducting a study to better understand the coping strategies . survivors use to navigate healing and daily life. Your insights can helpar inform future support services, mental-health interventions, and survivor-centered programs.

ABOUT THE STUDY

· Purpose: To learn about coping mechanisms used by adult survivors of sexual abuse.
. Participation: You will be. assked to take part in an interview, survey, or both (depending on your pret.).
· Time Commitment: Approx, 60-90 minutes.
. Location: Virtual or in-person options available.

YOU MAY BBE ELIGIBLE IF:

· You are 18 years or older
· You identify as a survivor of sexual ebuse
· Allability to participate inin an
interview or survey in English

WHY YOUR VOICE MATTERS

Your experiences and perspectives can help improve care, resources, and support systems for survivors. Sharing your story is power-ful-and may help others in the future,

YOUR SAFETY AND PRIVACY

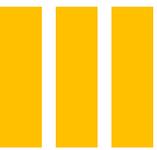. Participation is completely voluntary,

RISKS TO CONSIDER

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

Participants
Do inclusion criteria align with study aims?

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? _____

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.

SITE PERMISSION

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

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

READY TO SUBMIT?

AFTER you / your student has compiled all the required documents and prepared the proposal:

- **REVIEW IT FOR COMPLETENESS** – Are all the forms there and signed?
  incomplete proposals will NOT be reviewed until ALL required materials are submitted

- **READ THE PROPOSAL** and associated forms to check for accuracy, clarity and thoroughness
  - Are all components of the research described in a way that someone unfamiliar with your profession or project could understand the procedures you will use?
  - It is more than just providing the forms / scripts
  - **—DESCRIBE THE PROCESSES TO BE USED—**

Ready to submit to REC?

REVIEW IT FOR COMPLETENESS – Are all the forms there and signed?

incomplete proposals will NOT be reviewed until ALL required materials are submitted

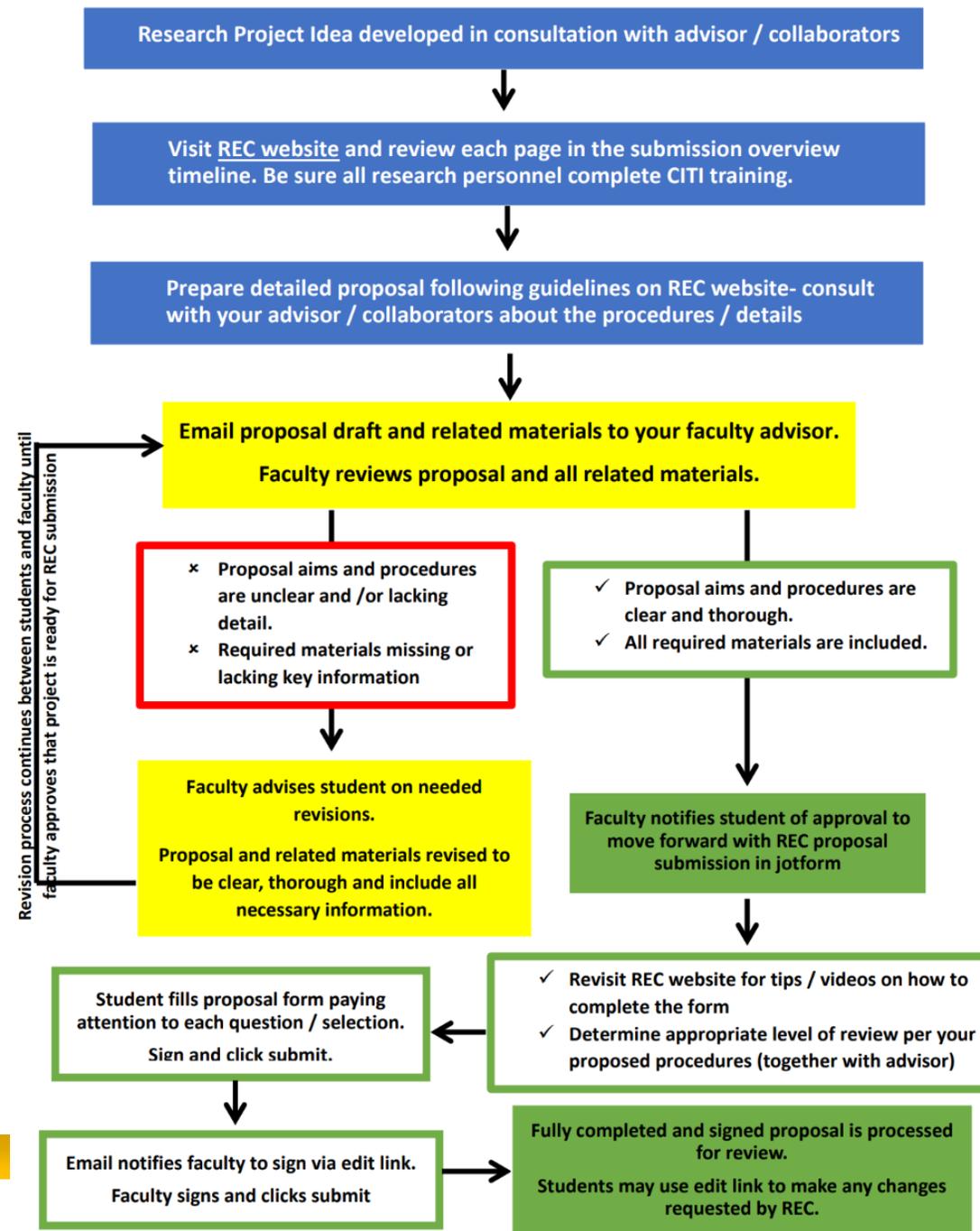**READ THE PROPOSAL** and associated forms to check for accuracy, clarity and thoroughness

Are all components of the research described in a way that someone unfamiliar with your profession or project could understand the procedures you will use?

It is more than just providing the forms / scripts

—DESCRIBE THE PROCESSES TO BE USED—

CONFIRM WITH FACULTY advisor you have the OK to submit the proposal

REC Proposal Preparation Procedures

Research Project Idea developed in consultation with advisor / collaborators

↓

Visit REC website and review each page in the submission overview timeline. Be sure all research personnel complete CITI training.

↓

Prepare detailed proposal following guidelines on REC website- consult with your advisor / collaborators about the procedures / details

↓

Email proposal draft and related materials to your faculty advisor. Faculty reviews proposal and all related materials.

× Proposal aims and procedures are unclear and /or lacking detail.
× Required materials missing or lacking key information

✓ Proposal aims and procedures are clear and thorough.
✓ All required materials are included.

Faculty advises student on needed revisions.
Proposal and related materials revised to be clear, thorough and include all necessary information.

Faculty notifies student of approval to move forward with REC proposal submission in jotform

Revision process continues between students and faculty until faculty approves that project is ready for REC submission

✓ Revisit REC website for tips / videos on how to complete the form
✓ Determine appropriate level of review per your proposed procedures (together with advisor)

Student fills proposal form paying attention to each question / selection. Sign and click submit.

Email notifies faculty to sign via edit link. Faculty signs and clicks submit

Fully completed and signed proposal is processed for review.
Students may use edit link to make any changes requested by REC.

SUBMIT PROPOSAL VIA THE REC WEBSITE

PROPOSAL SUBMISSION

Faculty advisor / chair = Principal Investigator

Student = Co-Investigator

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

Please be sure to click save before exiting the site OR clicking on any of the hyperlinks within this form as doing so will take you out of the form and progress will be lost.

Please indicate if this is your initial or revised submission. Note, if this is a revision, please be sure all revisions have been made in all necessary attachments and all revisions highlighted throughout.

- ○ Click here if this is your initial submission
- ○ Click here if you are making revisions per conditional approval
- ○ Click here if you are the submitting PI and need to confirm submission
- ○ Click here if you are the REC reviewer

Save   Next

SR

Spalding REC
To: Research Ethics Committee

📄 5704721796579066736.pdf
126 KB

You can edit this submission using the following link Edit Submission

Research Ethics Committee (REC) Proposal submission form

Get Page URL	https://form.jotform.com/221727604977061
	Click here if this is your initial submission
By Checking YES, you verify that ALL listed investigators have completed CITI training and submitted certification of completion.	YES
RESEARCH PROJECT TITLE:	EXAMPLE FOR TRAINING
Please include your abstract here. Briefly describe the purpose, rationale, major procedures and methodology of your research project.	The purpose of this project is to provide an example of how the proposal submission system works.
Some projects involve multiple components. Please select all that apply to the proposed research.	other data collection
Name of Faculty Advisor / Primary Investigator	Lisa Potts

Faculty Advisor /PI, please click this link to sign.

Edit Submission

Research Ethics Committee (REC) Proposal submission form

Get Page URL   https://form.jotform.com/221727604977061

                      Click here if this is your initial submission

By Checking YES, you   YES
verify that ALL listed
investigators have
completed CITI training and
submitted certification of
completion.

RESEARCH PROJECT   EXAMPLE FOR TRAINING
TITLE:

Students – be sure your advisor knows to:
1. Check their email to **review and sign your submission**
2. Click the edit link to sign the proposal
3. Select the option to **sign / confirm the submission**
4. Confirm you have read and approve the proposal
5. Sign, date, submit
*proposals will not be reviewed until the faculty signature OR confirmation is received*

Please be sure to click save before exiting the sit **OR clicking on any of the hyperlinks within this** **form as doing so will take you out of the form an** **progress will be lost.**

Please indicate if this is your initial or revised submission. Note, if this revision, please be sure all revisions have been made in all necessary attachments and all revisions highlighted throughout.
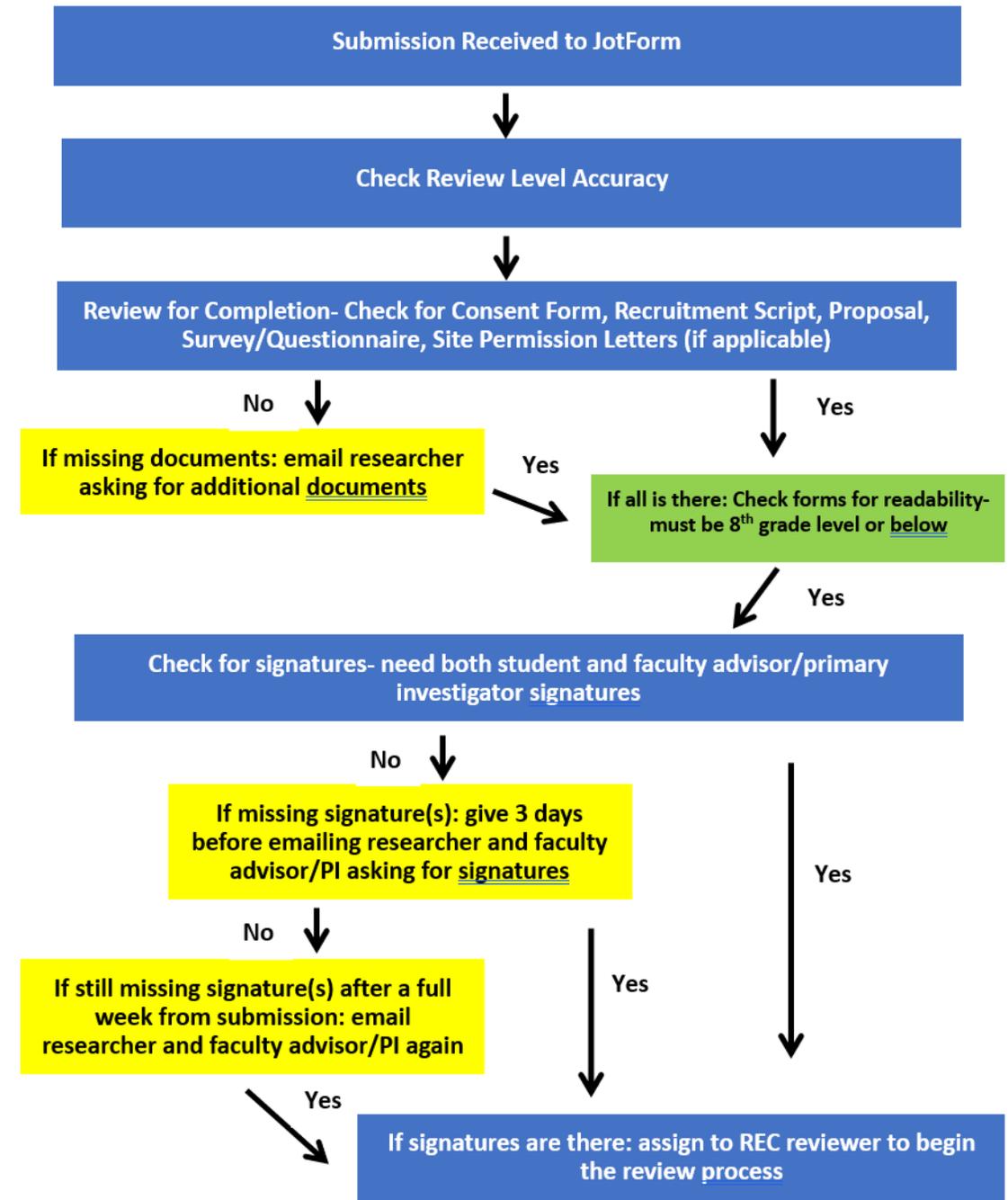
○ Click here if this is your initial submission
○ Click here if you are making revisions per conditional approval
● Click here if you are the PI and need to sign or confirm submission
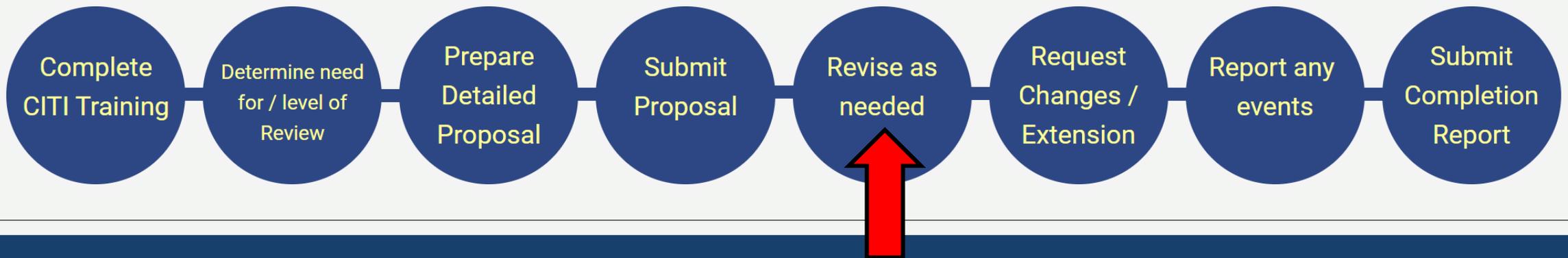○ Click here if you are the REC reviewer

Next

FOR FACULTY ADVISOR / PRINCIPAL INVESTIGATOR ONLY. By signing below I certify that:

☑ I have read all documents related to the above proposal.

☑ All necessary information is clearly explained and meets the readability requirements.

☑ This proposal is complete and ready for REC review.

FACULTY ADVISOR / PRINCIPAL INVESTIGATOR SIGNATURE (Students do NOT sign here)

Edit link example

Review Process

Proposal Processing Procedures

Submission Received to JotForm

↓

Check Review Level Accuracy

↓

Review for Completion- Check for Consent Form, Recruitment Script, Proposal, Survey/Questionnaire, Site Permission Letters (if applicable)

No ↓   **Yes** ↓

If missing documents: email researcher asking for additional documents   **Yes** →

If all is there: Check forms for readability- must be 8th grade level or below

Yes ↓

Check for signatures- need both student and faculty advisor/primary investigator signatures

No ↓

If missing signature(s): give 3 days before emailing researcher and faculty advisor/PI asking for signatures

No ↓   **Yes** ↓

If still missing signature(s) after a full week from submission: email researcher and faculty advisor/PI again

Yes ↓   **Yes** ↓

If signatures are there: assign to REC reviewer to begin the review process

HOW DO I MAKE REVISIONS?

Proposal Submission Overview

Complete CITI Training — Determine need for / level of Review — Prepare Detailed Proposal — Submit Proposal — Revise as needed — Request Changes / Extension — Report any events — Submit Completion Report

Students:
- Consult with your advisor on how to address the conditions
- Submit revised materials directly back into your **original** submission via the edit link
  —please do NOT create a new submission—

1. Check your email to review the conditions.
2. **Discuss with your advisor how to address the conditions**.
3. **Have your advisor REVIEW the revised materials**-be sure all changes are ==highlighted== and there is a separate document with a response to each condition
4. Once your advisor approves the revisions, click the edit link in the notification email to upload revised documents

WHEN CAN I START COLLECTING DATA?

- After all requirements of the REC have been fulfilled

  AND

- **An approval letter from the REC has been received**

  - Any data collected prior to that date is not valid.

  - If the study involves a sponsored project, no funds can be expended until study is approved by REC

WHAT'S NEXT?

Proposal Submission Overview

Complete CITI Training → Determine need for / level of Review → Prepare Detailed Proposal → Submit Proposal → Revise as needed → Request Changes / Extension → Report any events → Submit Completion Report
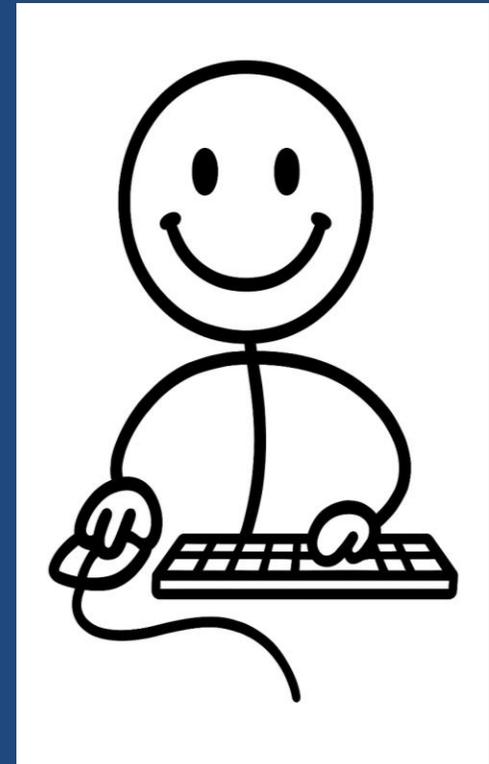
- You must submit a request for approval of any desired changes to the approved procedures (amendment form)
- Submit a completion report once the study is finished
- Delete / destroy data after required data storage period has lapsed (at least 3 years)

TIPS FOR A SUCCESSFUL PROPOSAL

CHECK IN WITH YOUR FACULTY OFTEN
&
USE REC RESOURCES

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 following the REC template

❑Data monitoring plan (if needed)

❑Adequate plans to protect privacy and maintain confidentiality

❑Additional safeguards to protect vulnerable populations
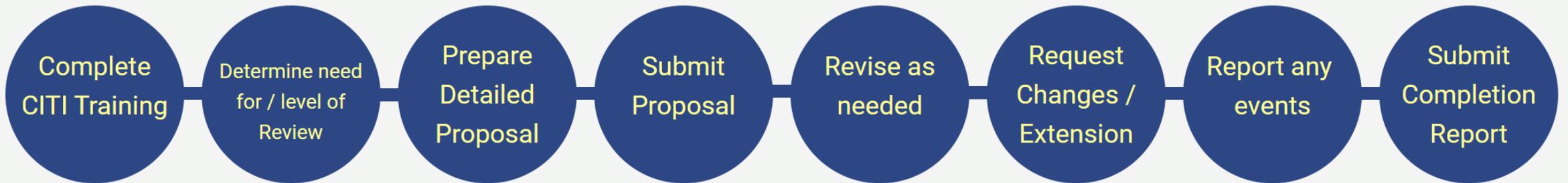
COMMON MISTAKES

- Recruitment and consent process are not clearly explained
- Methods / intervention / data collection processes not clearly explained
- Unclear timeline of events
- Discrepancies between proposal and consent or other documents
- Readability too high
- Templates not followed
- Missing appendices
- Missing signatures
- Question pro link differs from proposal / appendices

REC WEBSITE

- Research Ethics Committee – Human Subjects Research at Spalding University

Proposal Submission Overview

Complete CITI Training → Determine need for / level of Review → Prepare Detailed Proposal → Submit Proposal → Revise as needed → Request Changes / Extension → Report any events → Submit Completion Report

REC MEMBERS – THANK YOU!!

Email: rec@spalding.edu

Current Chair:

Lisa Potts, PhD

lpotts01@spalding.edu

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

EXTRA INFO

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 <u>not</u> 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 <u>must be submitted and approved in advance</u>

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

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

REC POLICIES

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

STUDENTS IN RESEARCH
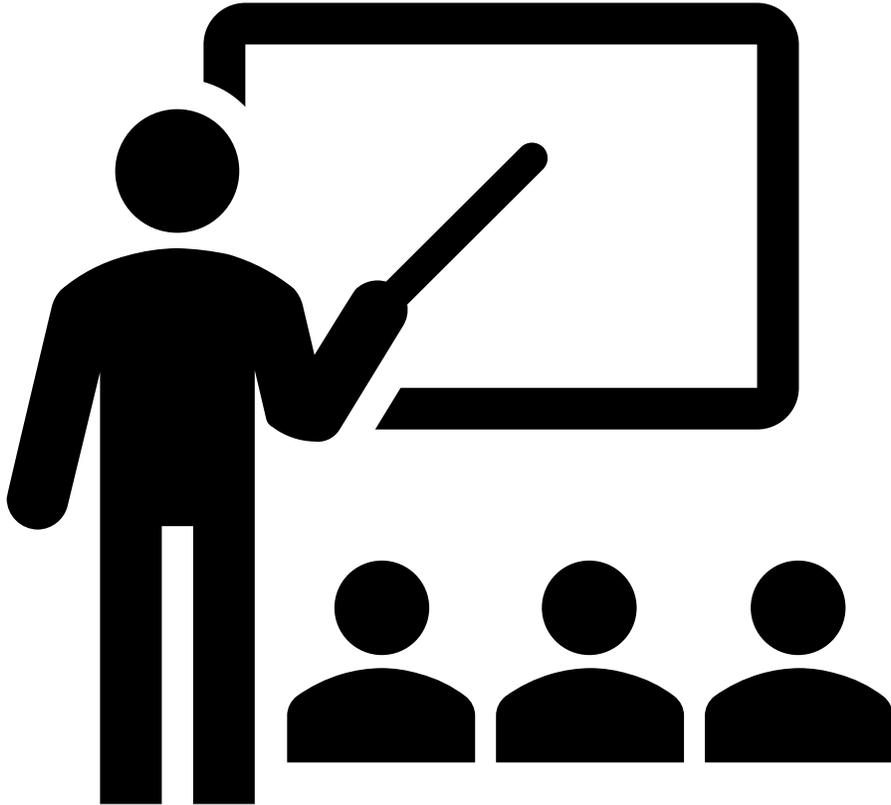
- *The REC will not approve studies requesting to specifically target Spalding students who are currently enrolled in a course taught by faculty involved in the recruitment, consent or data collection processes of the study.*

- 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

Approval Flow for Distributing Research Participation Requests to Spalding Community Members