RESEARCH ETHICS COMMITTEE (REC) INVESTIGATOR TRAINING 2024

Dr. Lisa Potts, REC Chair

Esha Khan, REC Graduate Assistant

Contact: rec@spalding.edu

REC PURPOSE

- Faculty Senate committee, Separate from OSPRe
- Graduate Dean helps to ensure that graduate programs are meeting REC requirements and getting necessary training, etc.
- 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.*

Overview

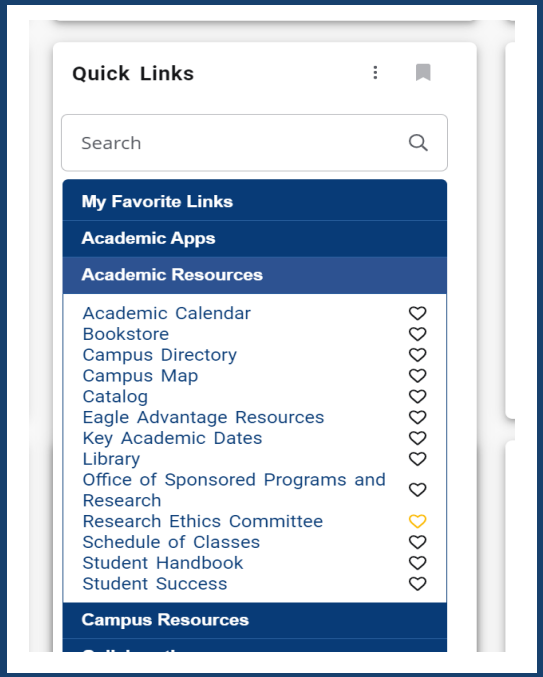
REC WEBSITE

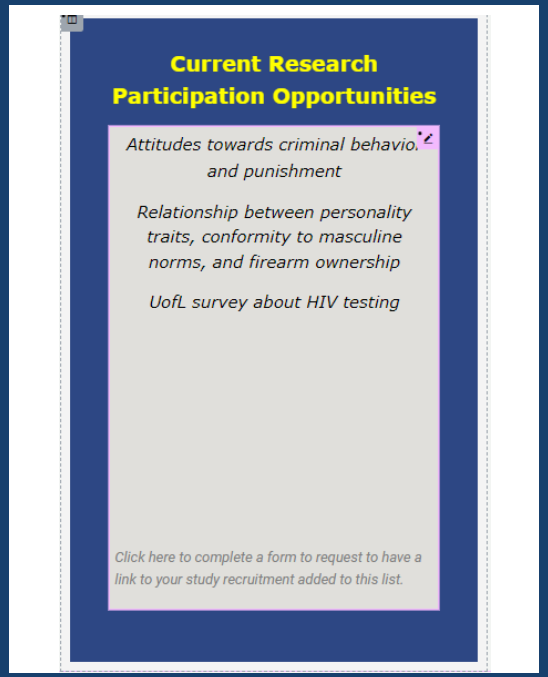
PREPARING YOUR PROPOSAL

- Faculty Responsibilities
- Student Responsibilities

TYPE OF PROJECT / REVIEW

REVIEW PROCESS

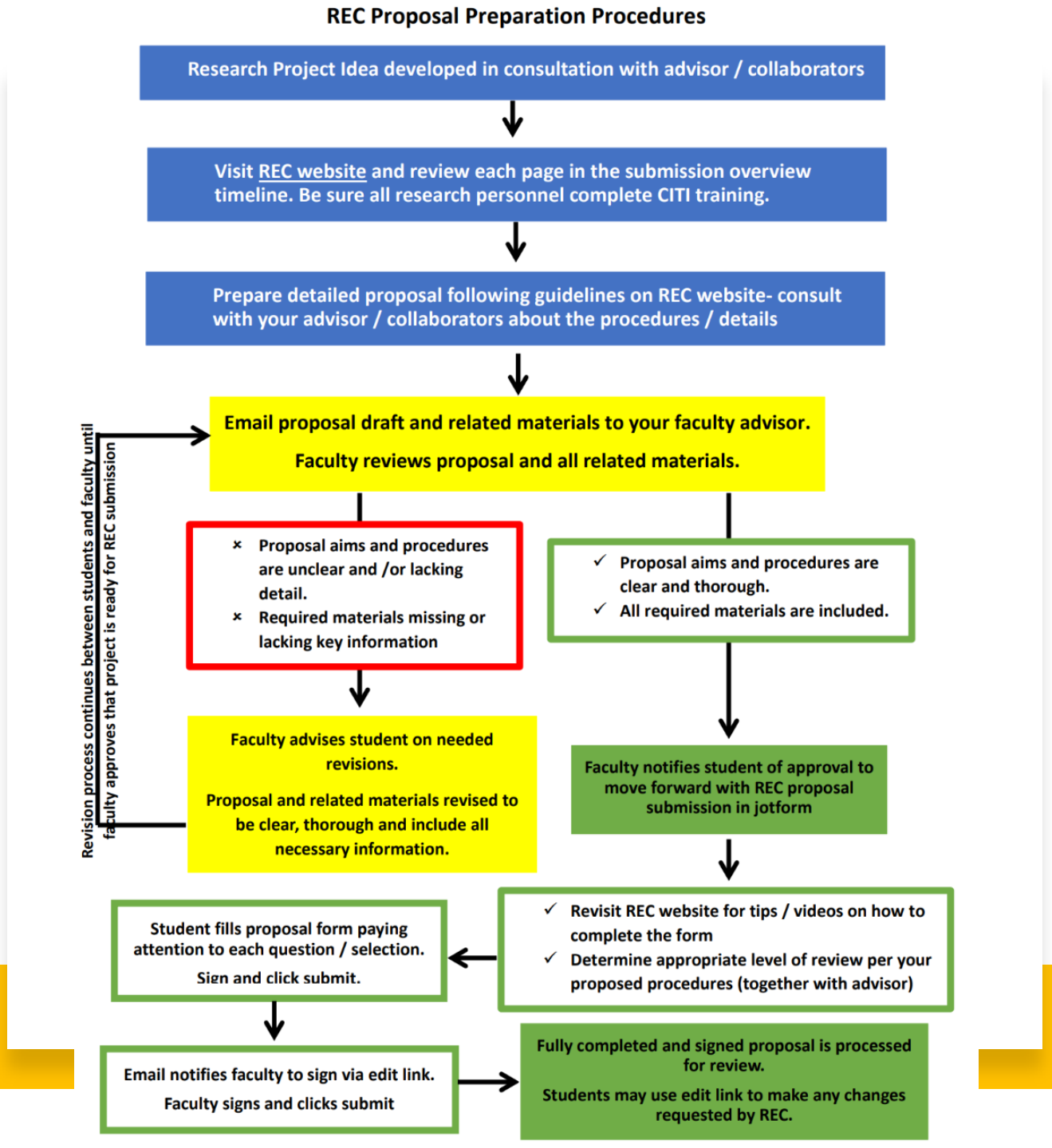




REC WEBSITE

https://rec.spalding.edu/

Proposal Preparation Process



INVESTIGATOR RESPONSIBILITIES

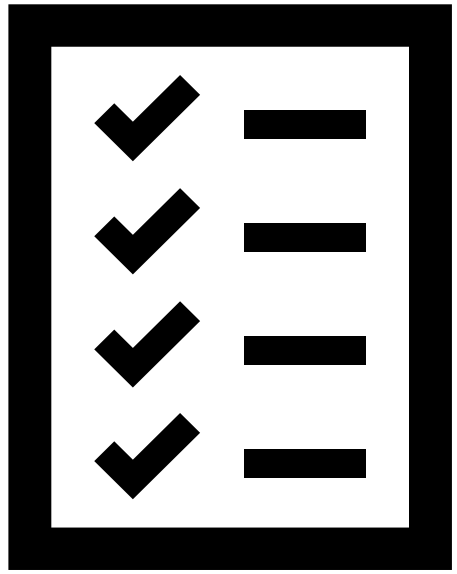
FACULTY ADVISOR (aka Primary Investigator)

1. Complete CITI training
2. Consider project goals / purpose
3. Review / refer to REC website
4. Determine if HSR / Type of Project
5. Review & Recommend revisions
6. Review and Approve for submission
7. Click link to confirm and sign the submission
8. Advise student on any requested revisions

STUDENT (aka Co-Investigator)

1. Complete CITI training
2. Determine research idea
3. Review REC website
4. Develop a plan / type of project
5. Write REC specific proposal
6. Prepare all related appendices
7. Submit proposal AFTER faculty advisor has reviewed and approved ALL materials
8. Revise as needed

Proposal Worksheet



REC Proposal worksheet.docx

DETERMINE THE TYPE OF PROJECT & LEVEL OF REVIEW

Program evaluation / quality improvement

Human Subjects Research

Records-based research

- EXEMPT: Risk is no more than everyday life / routine doctor visit
- EXPEDITED: No more than minimal risk
- FULL: Studies that involve more than minimal risk

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

REC must consider beneficence-weighing benefits against the risks

Purpose / Importance

Purpose:_____

Why is this important?

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

2. Who does it benefit?

What is / are the specific aim(s) of the research?

1. Describe the variables you will consider.

2. Who does it benefit?

IS THIS HUMAN SUBJECTS RESEARCH? [45 CFR 46.102 L (1-4)]: 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

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

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**

NOTE:

- Survey = interaction
- Environmental modification = intervention

PROGRAM EVALUATION / QUALITY IMPROVEMENT PROJECTS

- Is the ONLY goal / purpose to evaluate or improve processes internally?
  - YES→ NOT RESEARCH
  - NO→ Systematic investigation of programs designed to contribute to generalizable knowledge of "best practices" → RESEARCH

- Will you collect private information about individuals ?
  - YES→ HUMAN SUBJECTS
  - NO→ asking questions only about the program / services → NOT HUMAN SUBJECTS

- Program eval / development / improvement PLUS human subjects research
  - Only the research component needs to be detailed in the REC proposal UNLESS the program being implemented is experimental in nature
- See the FAQ on quality improvement projects on the OHRP website for more information

SlideLizard

What type of research is this?

A clinic wants to determine if the services offered are fully meeting the needs of its patients and provides an opportunity for patients to complete a survey that asks about the services provided and does not collect any private, identifiable information about the individuals.

Time left: -

Vote at: **attend.sl/d9kz**

Votes: 0

4 What type of research is this?

Time left: -

Votes: 0

PROGRAM EVALUATION EXAMPLE

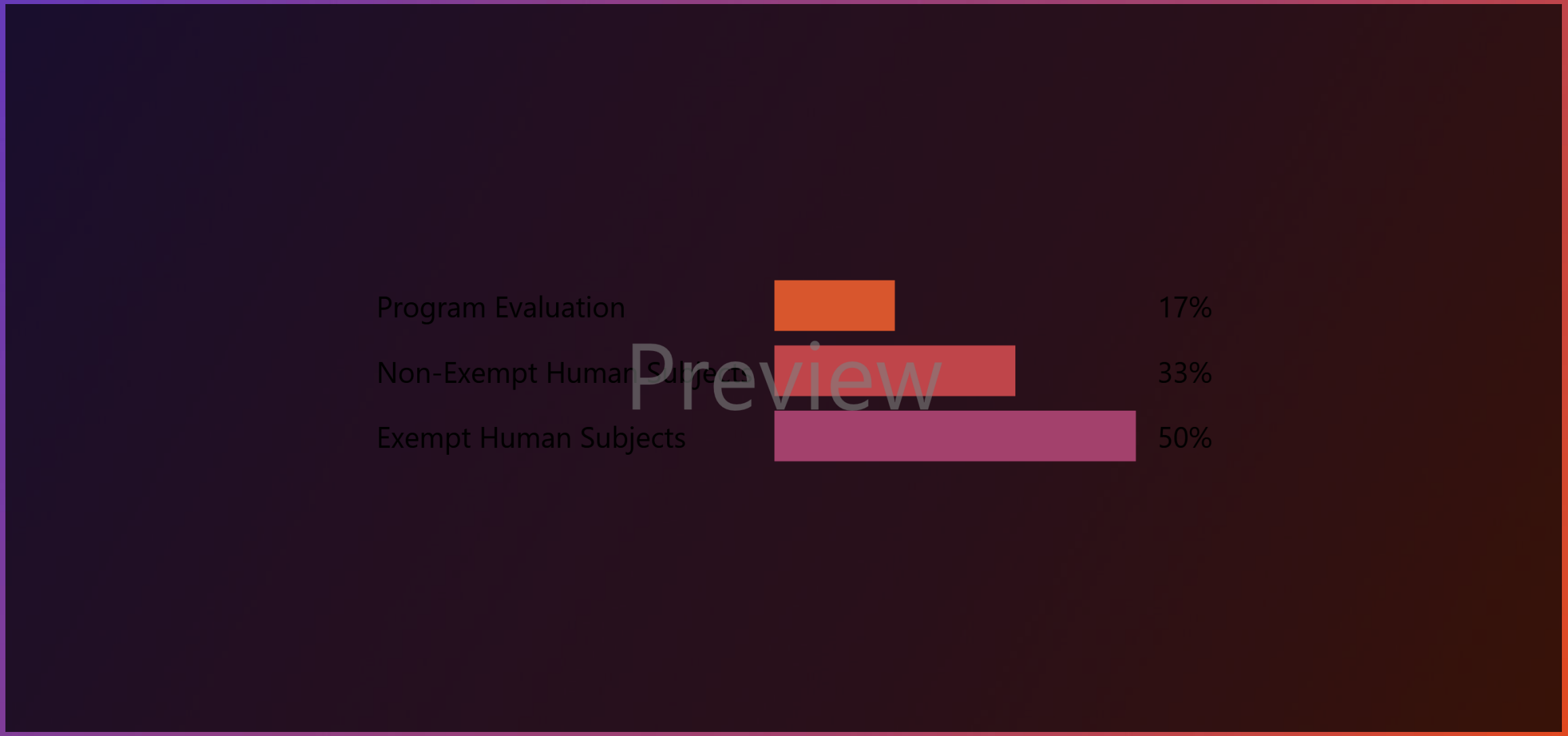
A clinic wants to determine if the services offered are fully meeting the needs of its patients and provides an opportunity for patients to complete a survey that asks about the services provided and does not collect any private, identifiable information about the individuals.

SlideLizard

What type of research is this?

A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

5What type of research is this?



Time left: -

SlideLizard

Votes: 0

QUALITY IMPROVEMENT EXAMPLE

A clinic increasingly utilized by geriatric patients implements a widely accepted capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

RECORDS-BASED RESEARCH

- No direct interaction with human subjects
- Review data from existing records
- Ongoing collection of data from records obtained for other purposes
- Submit records review request form on REC website
- Consider if obtaining consent is feasible and how it will impact the level of risk involved
  - Obtain consent (or documentation of broad consent)

    OR
  - Request waiver of consent

Records based research form

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

SlideLizard

What type of research is this?

An investigator obtains only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients' treating physician. The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances, until the individuals are deceased.

What type of research is this?

Time left: -

Votes: 0

RECORDS REVIEW EXAMPLE 1

An investigator obtains only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients' treating physician. The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances, until the individuals are deceased.

not human subjects research

SlideLizard

2 What type of research is this?

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients.

2 What type of research is this?

Time left: -

Votes: 0

RECORDS REVIEW EXAMPLE 2

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients.

Non-exempt human subjects research

SlideLizard

3 What type of research is this?

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients

3 What type of research is this?

Time left: -

Votes: 0

RECORDS REVIEW EXAMPLE 3

An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients

Exempt human subjects research

LEVELS OF REVIEW

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

See OHRP exemption decision charts

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

Reviewed by REC chair

Must still submit to REC to approve EXEMPT status

Allow 2-4 weeks from submission to final approval

EXPEDITED: No more than minimal risk

See Expedited categories on REC OR OHRP websites

Reviewed by REC chair or committee member

Allow 2-4 weeks from submission to final approval

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

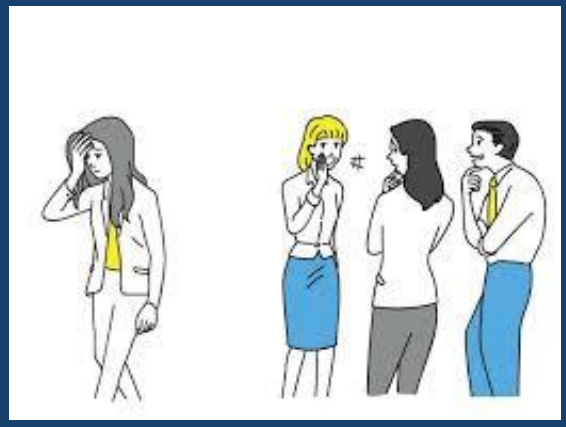
Allow 1-3 months from submission to final approval

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

RISKS TO CONSIDER

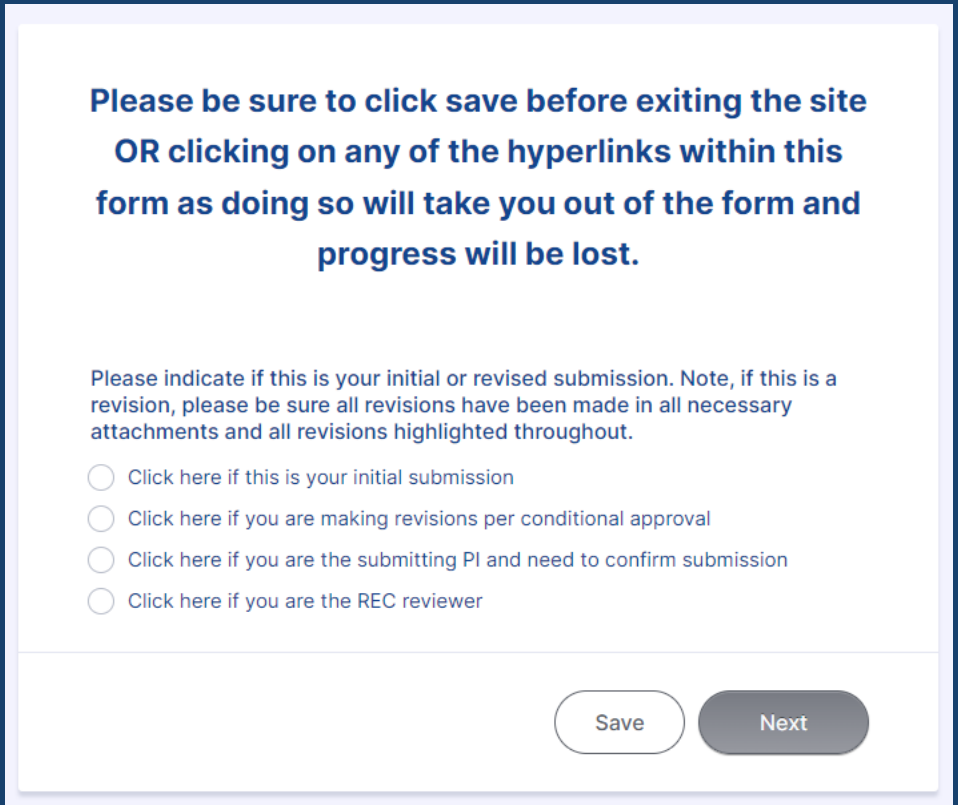
- Physical
- Emotional
- Criminal or civil liability
- Damaging to:
  - Financial standing
  - Employability
  - Insurability
  - Reputation
- Stigmatizing



PROPOSAL COMPONENTS

- Investigator info
- CITI certificate confirmation
  - Best to upload separately
- Site(s) of research
  - Site permission letter(s)
- Target population
  - Readability justification
- Duration
- Funding

JOTFORM COVER PAGE



- Type of project
- Review category
- Question Pro link
- Proposal
- Recruitment
- Consent
- Appendices
- Signature

https://rec.spalding.edu/rec-policies-procedures/

SITE PERMISSION

- On letterhead OR copy of email
- Indicates understanding of procedures
- Signed

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? _____

PROPOSAL COMPONENTS

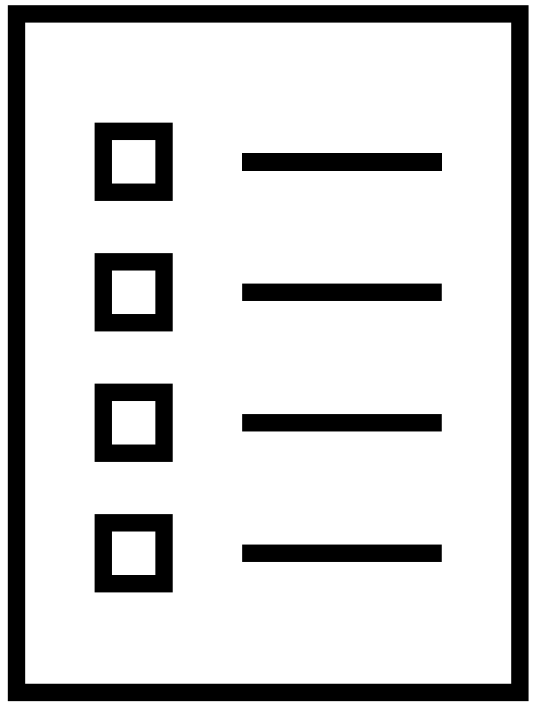
- PROPOSAL DETAILING:
  - Background / purpose of research-*keep it concise*
  - Recruitment process-*be explicit with details*
  - Consent process-*be explicit with details*
  - Data collection / research procedures and methodology
  - Risks and benefits of research-*describe ALL potential risks*
 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

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



RISKS

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? _____

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?

_____

_____

_____

_____

Level of review (circle one):

EXEMPT (no more than expected in daily life or routing psychological evaluation)

EXPEDITED (no more than minimal risk and falls in one of the noted categories-see REC website)

FULL (greater than minimal risk or not eligible for expedited review)

LEVELS OF REVIEW

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

See OHRP exemption decision charts

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

Reviewed by REC chair

Must still submit to REC to approve EXEMPT status

Allow 2-4 weeks from submission to final approval

EXPEDITED: No more than minimal risk

See Expedited categories on REC OR OHRP websites

Reviewed by REC chair or committee member

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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 1-3 months from submission to final approval

PROCEDURES

- Don't just refer to attachments-describe the process of how the attachments will be used

Recruitment:

- How will you initially solicit/ contact potential participants?
- Where will recruitment take place?
- Who will help you with recruitment (and how)?

Consent:

- How will you obtain consent (forms)?
- Where will consent take place?
- Who will be responsible for obtaining consent?

Is the informed consent document consistent with the procedures and information described in your proposal (if not, it should be)?

PROCEDURES

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

- **What** will you and / or the participants do?
- **How** will you collect the information?
- Consider if / what survey or assessment measures or tools may be used.
- Do you have permission to use these assessments?
- Do you have permission from the site to carry out your proposed procedures?

PROCEDURES

- Demonstrate that the intended data collection process and analysis align with the stated project goals

Methodological Design:

- What type of study will you do (e.g qualitative, 2x2 factorial, quasi-experimental, case / control, etc.)?

Data analysis:

- How will the proposed procedures / data collected be used to support your aims?

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?

Data storage:

- How will data be stored and protected?
- Where will it be stored?
- Who will have access (and who will not)?

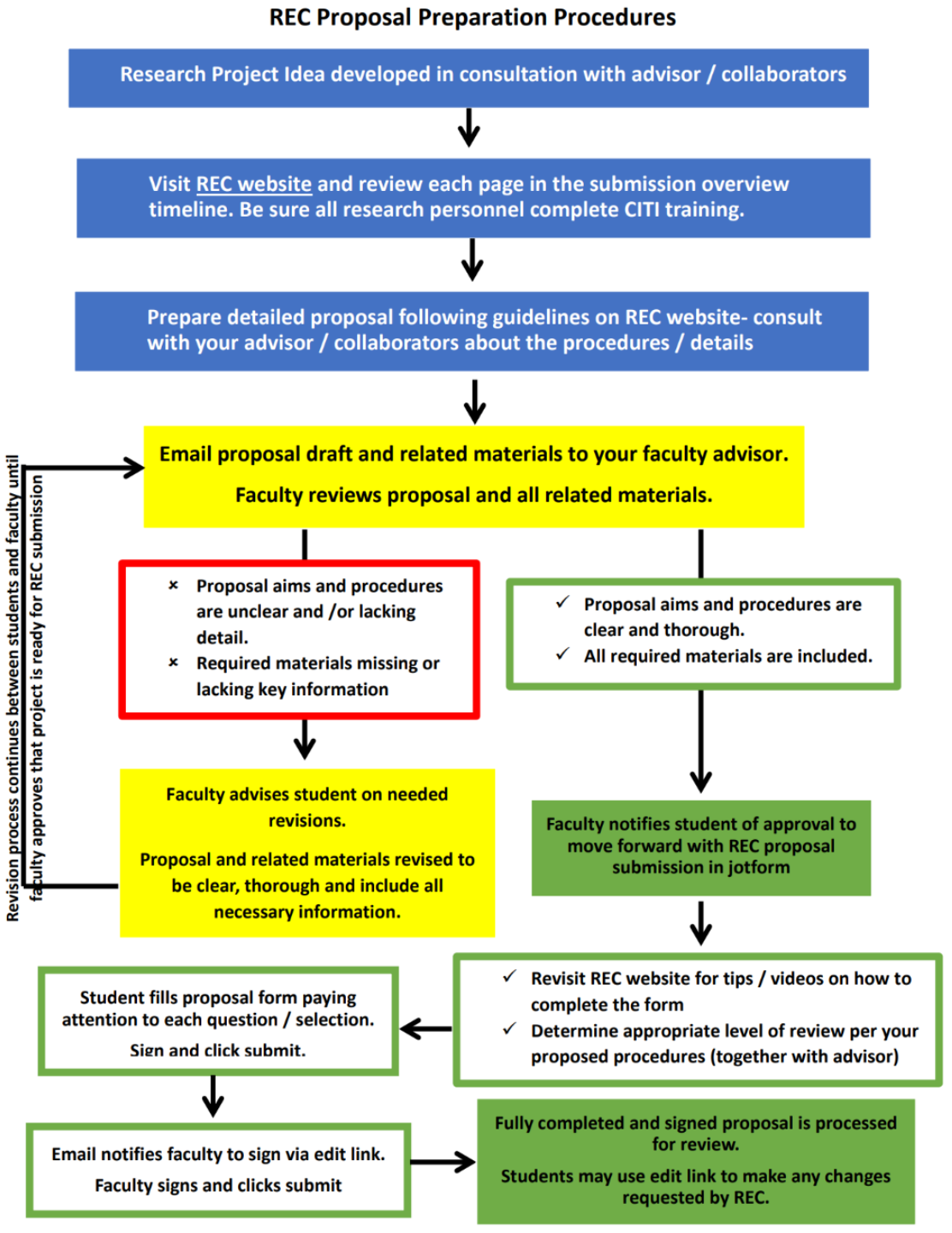
Is there a statement in the consent and proposal noting that data will be stored for a minimum of 3 years after study completion (or longer if needed per your study design) (if not, there should be)?

CRITERIA FOR APPROVAL

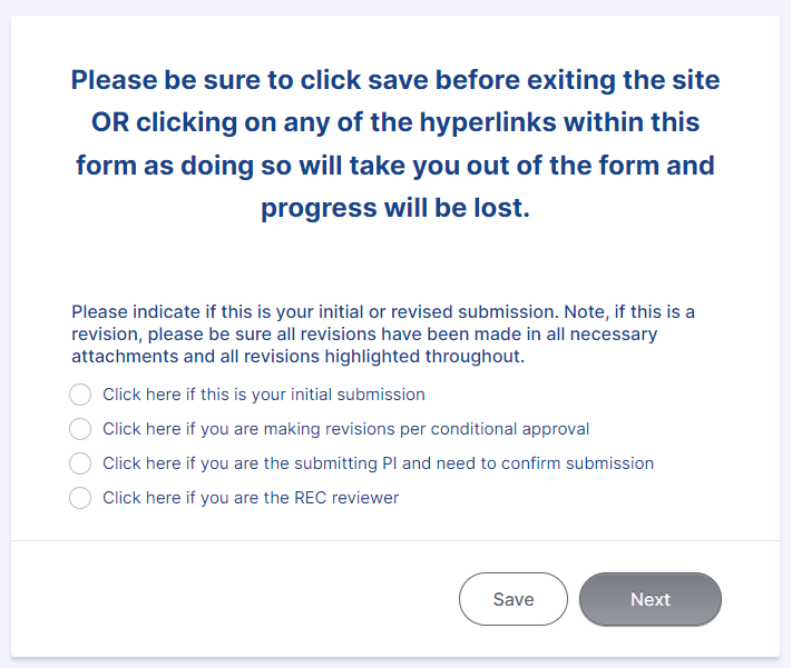
In addition to preparing a detailed proposal per your responses above, have you prepared each of the following required attachments with the above noted considerations in mind?

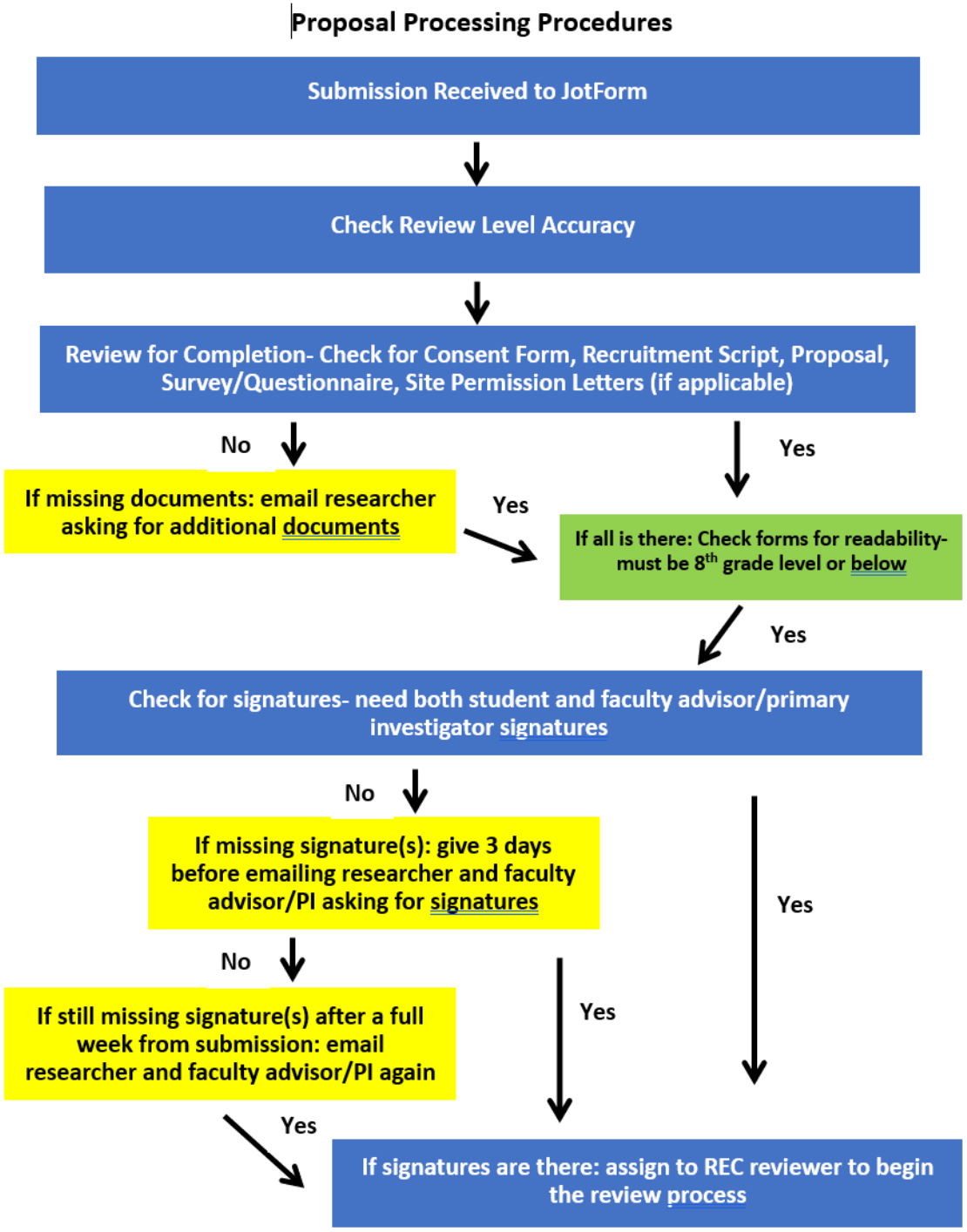
☐Site permission letter
☐ Recruitment script
☐ Consent / permission / assent form(s)
☐ All survey questions as they will be seen by participants (if applicable)
☐ All assessment measures or other tools / protocols to be used on or by participants
☐ Any other required documents such as CoC, data use agreement, etc.

Proposal Preparation Process



Review Process





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

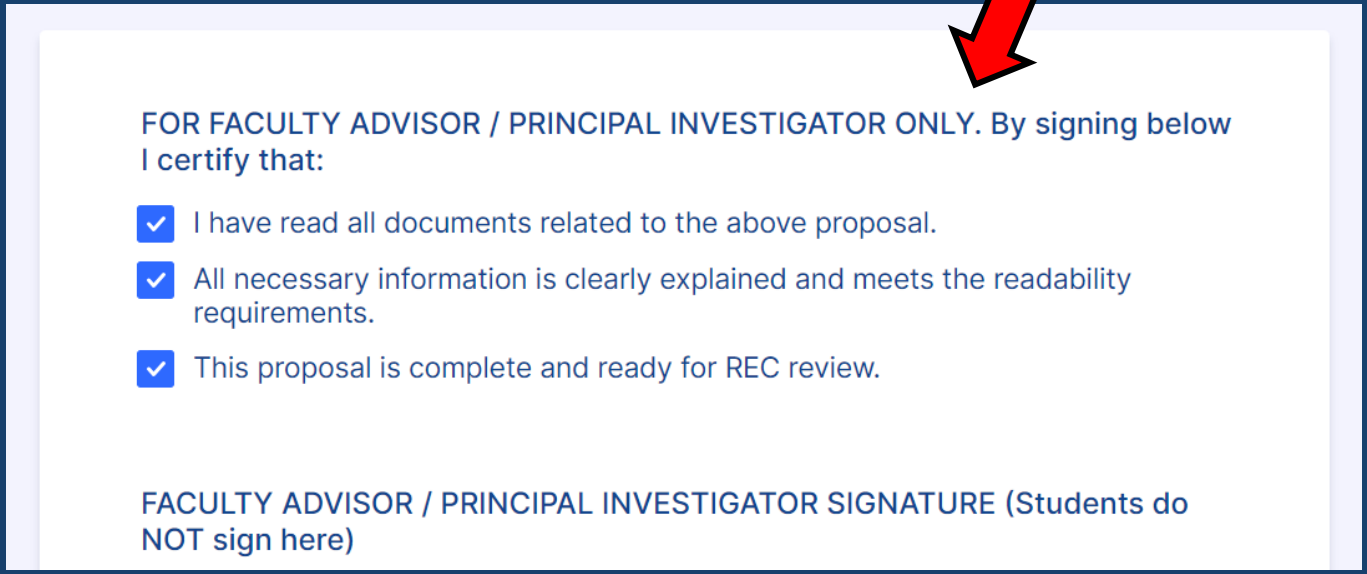
Get Page URL	https://form.jotform.com/221727604977061
	Click here if this is your initial submission
By Checking YES, you verify that ALL listed investigators have completed CITI training and submitted certification of completion.	YES
RESEARCH PROJECT TITLE:	EXAMPLE FOR TRAINING
Please include your abstract 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

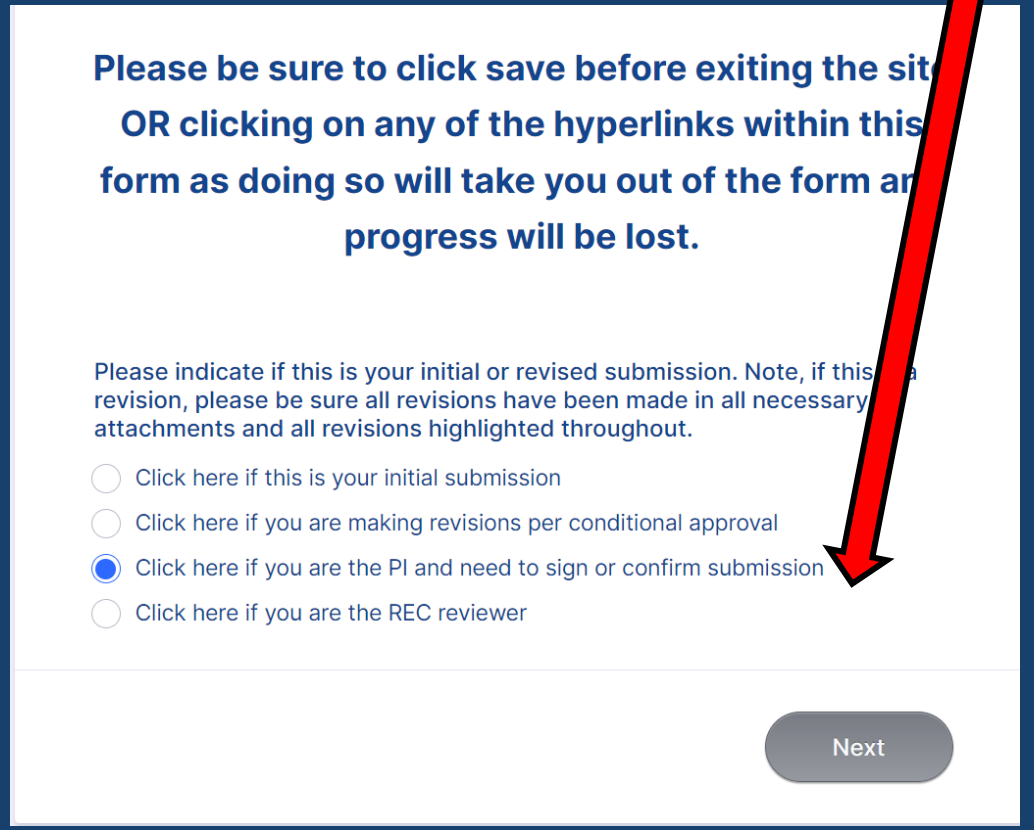
Faculty:

[Edit link example]

1. Check your email to **review the 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*****





Faculty:

1. Check your email to review the conditions.
2. **Discuss with the student how to address the conditions**.
3. **REVIEW their revised materials**-be sure all changes are highlighted and there is a separate document with a response to each condition
4. Instruct the student to click the link in the notification email to make edits / upload revised documents

From: Spalding REC (noreply@jotform.com)
To: Istiml[redacted]
Subject: your request has been conditionally approved
Status: SENT

Details

23-09-06 22:27:51 PDT

Dear Steph[redacted]

Your REC proposal entitled Navi[redacted]been conditionally [illegible]oved pendir are made per the list of conditions noted below. You may also find the completed reviewer guidelines and / or letter of conditions attached near the end of t[illegible]oposal (if app revise your proposal accordingly by updating this form and any attachments as indicated. **Please highlight all changes made per these conditions and [illegible]d the new atta form.** Please also include a document with responses to each of the conditions so the reviewer(s) can clearly understand how you have addressed each [illegible]ition. This can be additional attachment.

You can access and edit your submission using the following link https://www.jotform.com/edit/5692981276412776893

Please contact us at rec@spalding.edu if you have any questions regarding the necessary changes or resubmission process.

Sincerely,

Lisa Potts

Chair

Research Ethics Committee

Conditions to be met / concerns to be addressed for approval:

Remove the following line from the recruitment script: "As part of my capstone project requirements" Please use Spalding letterhead for the consent

https://www.jotform.com/edit/5692981276412776893

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 PI and need to sign or confirm submission
- ○ Click here if you are the REC reviewer

Next

DON'T FORGET!...

- Submit a request for amendment form for any significant changes to the approved procedures
- Remind students to submit a completion report once their study is finished
- Delete / destroy data after required data storage period has lapsed (at least 3 years)

INTEGRATING REC INTO YOUR COURSE / PROGRAM

Complete CITI training—1st assignment

Review REC website – 2nd or 3rd assignment (with a short quiz)

Determine research idea –required meeting with faculty advisor

Develop a plan / type of project – 2nd or 3rd assignment (proposal worksheet)

Submit REC specific proposal to faculty for review—4th assignment

Revise proposal and prepare all related appendices—5th assignment

Submit proposal AFTER faculty advisor has reviewed and approved ALL materials—implement a deadline for submission

Revise as needed

COMMON MISTAKES

- Wrong options selected in jotform coverpage
- 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 or thoroughly revised to fit the study
- Missing appendices
- Missing signatures

REC CONTACT INFO

Email: rec@spalding.edu

Institutional/Signatory Official:

Kurt Jefferson.- Dean of Graduate Studies

Current Chair:

Lisa Potts, PhD

502-873-4442

KCC 159

Current Graduate Assistant:

Esha Khan

Lisa Potts –ASOT (Chair)
Regina Martin – Business (Non-Scientist Member)
Kristen Harris – Education (Non-Scientist Member)
Melba Custer - ASOT
Leslie Cairo - Social Work
Goutam Singh - Natural Sciences
Mike Starling – Psychology
Claire Beaulieu - Psychology
Farrah Thornsberry- Nursing
Brian Martin- Community Representative
Mike Chapman –MSAT (alternate)
Tom Malewitz – Education (Non-Scientist Member-alternate)
Brenda Nash – Prison Representative
Norah Chapman – Prisoner Representative

END

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 CONTACT INFO

Email: rec@spalding.edu

Current Chair:

Lisa Potts, PhD

502-873-4442

KCC 159

Current Graduate Assistant:

Casie Cullinane

About Research Participation

A Library of Resources About Research and Research Participation

ARP
ABOUT RESEARCH PARTICIPATION

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

OHRP has developed the *About Research Participation (ARP)* online collection of resources for you. These materials will help you understand what research is and what is involved in research participation. They will empower you to make your own informed decisions regarding potential participation.

Interested in learning more?

Access using the link *www.hhs.gov/About-Research-Participation* or scan this QR code and have access to our library of resources at your fingertips!

- Watch short informational videos
- Read infographics on the history of human research protections
- Print a list of questions to ask about research participation

All of our ARP materials are available in Spanish!

Additional questions? Email us at *OHRP-EDU@hhs.gov*
or call toll-free *(866) 447-4777*

OASH | Office for Human Research Protections

PREPARING YOUR PROPOSAL

Consider who, what, where, when, why and how for each step

- Example for the recruitment process:
  - 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?
  - Will you recruit via social media / snowball sampling? Provide the drafted social media post.
  - Explain why you might need to use any specific procedures for this process.

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

WHAT ABOUT COLLABORATIONS WITH OTHER INSTITUTIONS?

- Studies with approval from another IRB may not need REC approval.
- You must still notify the REC
- Must submit an IRB Authorization Agreement (IAA) for approval.

SPECIFIC TYPES OF RESEARCH

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

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.*

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 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