RESEARCH ETHICS COMMITTEE (REC) INVESTIGATOR TRAINING

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OVERVIEW

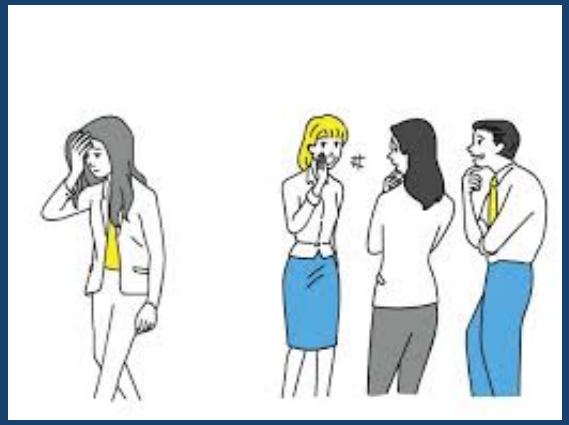
- Purpose
- **Submission & Review Process**
  - Define human subjects research
  - Exemptions
  - Types of Reviews
- **Preparing your proposal**
- Questions

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.*

RISKS TO CONSIDER

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



CONFIDENTIALITY OF DATA

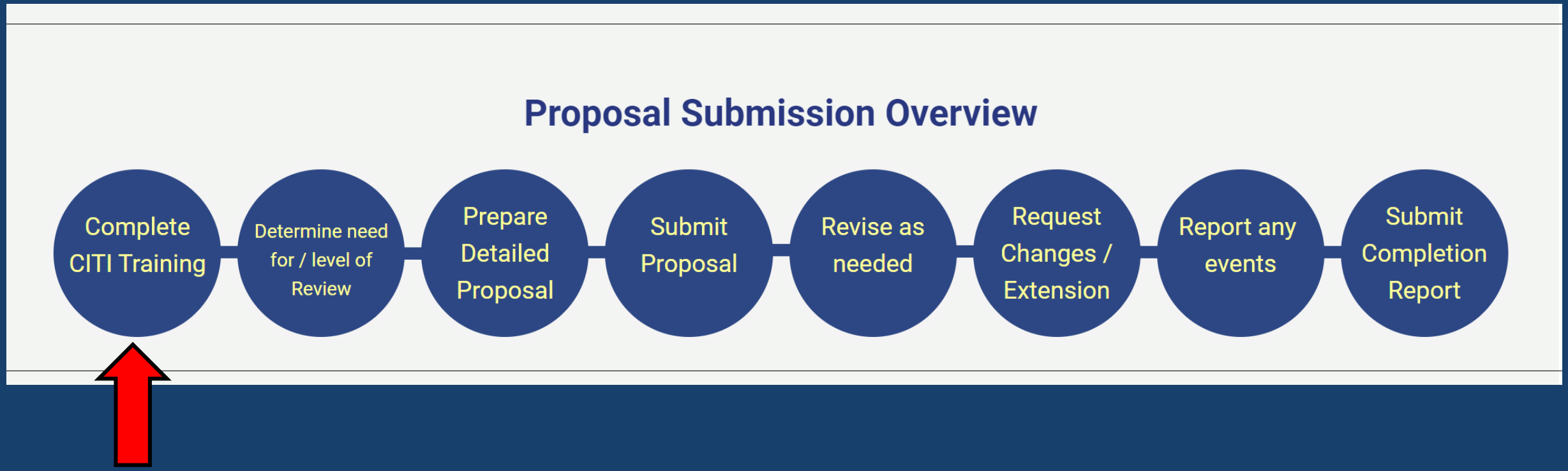
- Respecting a participant's right to be free from unauthorized release of information
  - relationship of trust
  - expectation that data will not be given to others without permission

- Agreement established between investigator and participant, and maintained by handling, management, and dissemination of research data

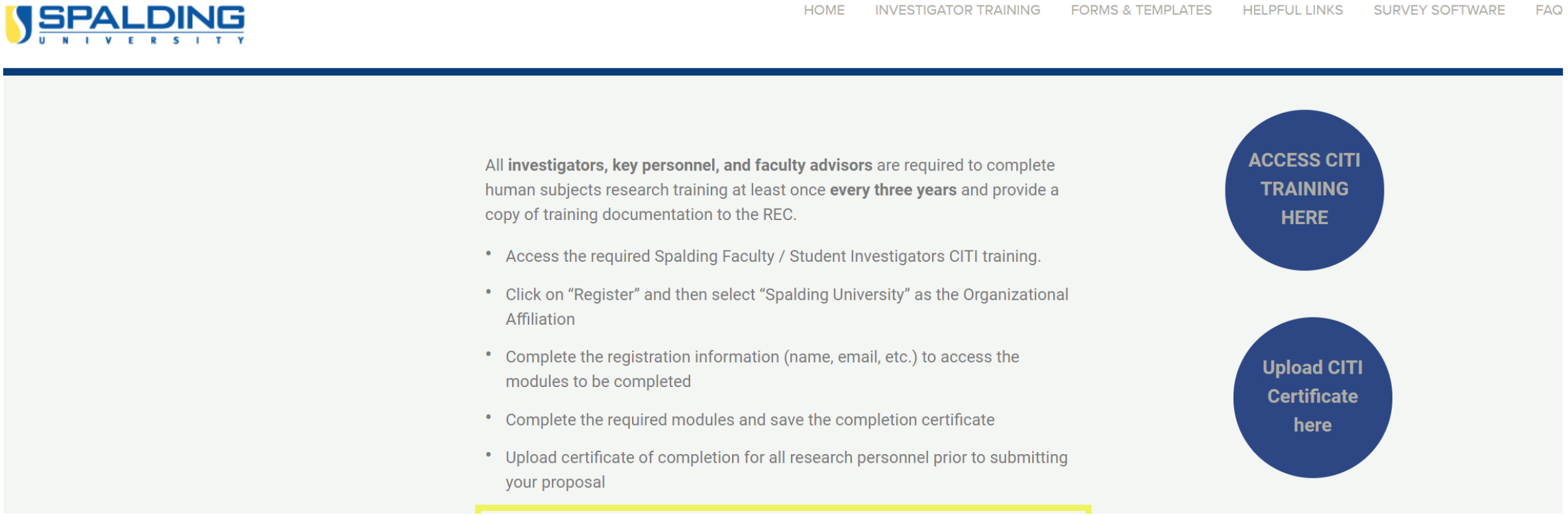
PROPOSAL SUBMISSION & REVIEW

https://rec.spalding.edu/

START WITH VISITING THE REC WEBSITE



http://www.citiprogam.org



DETERMINE IF YOUR PROJECT QUALIFIES AS HUMAN SUBJECTS RESEARCH

IS THIS HUMAN SUBJECTS RESEARCH? [45 CFR 46.102 E (1-3)]

2 questions to ask:

1. **What is the purpose of the project?**
   - Research is a **systematic** investigation designed to develop or contribute to **generalizable** knowledge.
   - Activities designed for the **sole** purpose of program evaluation / improvement at a specific organization are NOT research
2. **What is human subjects research (i.e. how is human subject defined)?**
   - A **living** individual **about whom** an investigator obtains information or biospecimens through **intervention** or **interaction** with the individual(s) OR generates or uses **identifiable private information** or biospecimens.
   - Survey = interaction
   - Environmental modification = intervention

PROGRAM EVALUATION RESEARCH

- Collecting data for process improvement may not be considered human subjects research.
  - PROGRAM EVALUATION / IMPROVEMENT
  - QUALITY ASSURANCE / IMPROVEMENT

- **Systematic investigation** of programs designed to contribute to **generalizable knowledge** of "best practices" IS considered human subjects research

PROGRAM EVALUATION RESEARCH

- TO CONSIDER:
  - Are you collecting information solely for the purpose of improving a process internally?
  - Will you ask /collect private information about individuals as a part of the program eval / improvement project?

- Program eval / improvement / development PLUS human subjects research
  - Only the research component (e.g. pre / post- surveys) needs to be outlined 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

DETERMINE THE TYPE OF REVIEW

Research projects are reviewed at three different levels:

- 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
- EXPEDITED: No more than minimal risk
- FULL COMMITTEE: Studies that involve more than minimal risk

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

WHAT ABOUT EXEMPTIONS?

EXEMPT REVIEW (1-2 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

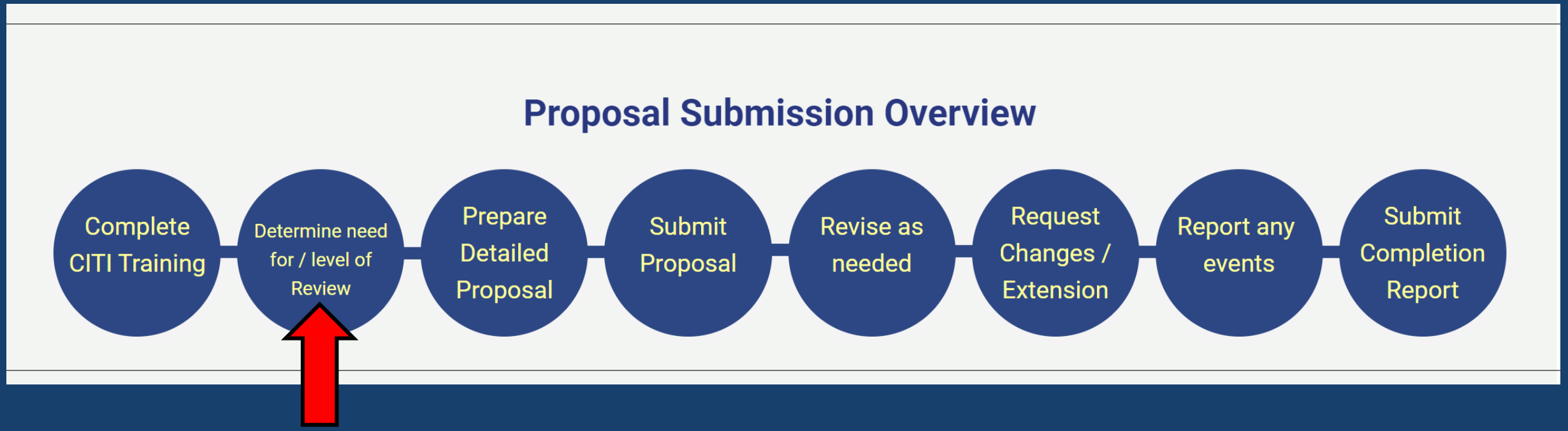
SUMMARY OF EXEMPTIONS

- 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

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

DOES MY PROJECT QUALIFY FOR EXPEDITED REVIEW?



EXPEDITED REVIEW (2-4 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

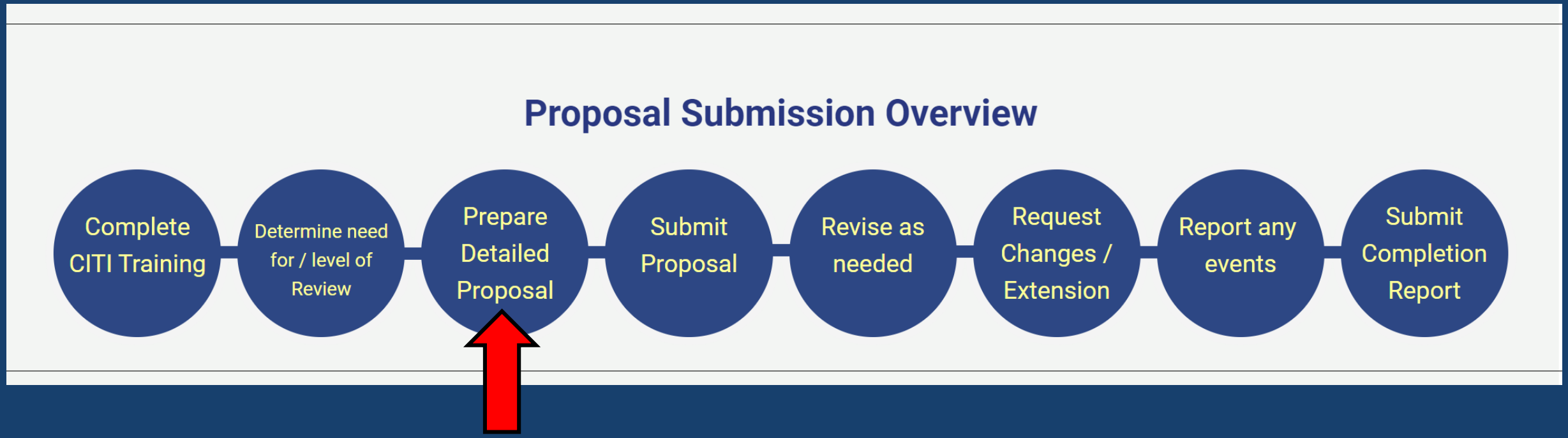
  See the full list of expedited categories here.

FULL COMMITTEE REVIEW (4-6 WEEKS)

- Research that involves more than minimal risk
  - Minors if data are sensitive
  - Vulnerable populations (prisoners, individuals with impaired decision making abilities, pregnant women, fetuses, newborns)
  - 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

WHAT DO I NEED TO SUBMIT?



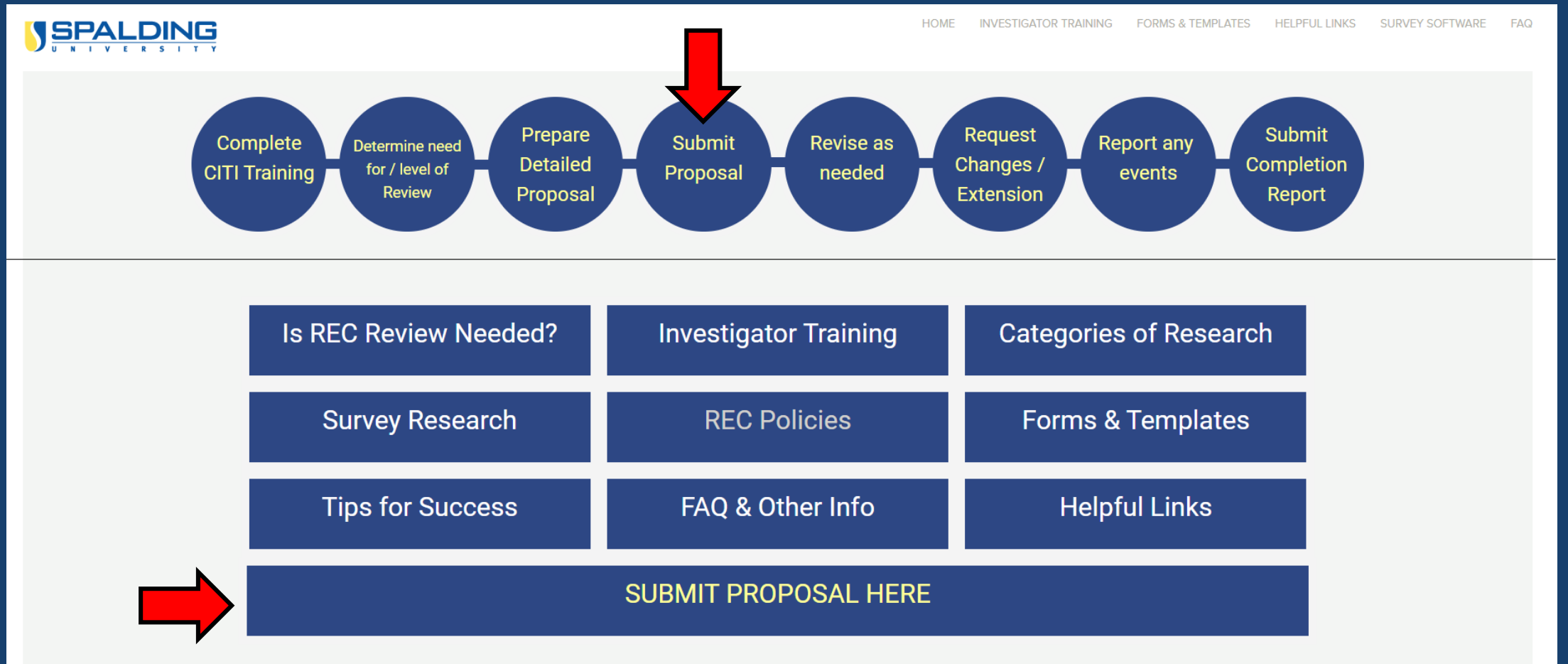
https://rec.spalding.edu/research-ethics-committee/tips-for-submitting/

PROPOSAL COMPONENTS

- JOTFORM COVER PAGE
  - Investigator info
  - CITI certificate(s)
  - Site(s) of research
  - Target population
  - Duration
  - Funding
  - Review category
- PROPOSAL DETAILING:
  - Background / purpose of research
  - Recruitment process
  - Consent process
  - Data collection / research procedures and methodology
  - Risks and benefits of research
  - Data storage and confidentiality
  - Appendices and attachments

SUBMIT PROPOSAL VIA THE REC WEBSITE

- JOTFORM for submission



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

RESEARCH WITH CHILDREN: ASSENT
45 CFR 46 SUBPART D

- Assent (failure to object is NOT assent)
  - Should be solicited when appropriate
  - Verbal or written at appropriate grade level
  - Assent not necessary if:
    - Limited capability of some or all children involved; OR
    - Intervention may provide direct benefit and is not available outside of the research

RESEARCH WITH CHILDREN: PARENTAL PERMISSION 45 CFR 46 SUBPART D

- Parental permission
  - At least one parent:
    - No more than minimal risk; OR
    - More than minimal risk but may provide direct benefit to child AND favorable risk:benefit
  - Both parents:
    - More than minimal risk and no direct benefit
      - Minor increase in risk (no significant threat to well-being)
      - Likely to yield important information regarding disease or condition
    - Otherwise not approvable but opportunity to understand, prevent or alleviate serious problem affecting children
      - Must be reviewed by HHS Secretary appointed pane of experts
    - Wards may not participate in these types unless:
      - it is related to status as wards; or
      - In schools, camps, etc. where most children are not wards; AND
      - REC must appoint an advocate for the ward

RESEARCH WITH CHILDREN: PARENTAL PERMISSION 45 CFR 46 SUBPART D

- Waiver or alteration of permission allowed only if:
  - All general waiver conditions (45 CFR 46.116(f)) are met; and
  - There is no more than minimal risk; and
  - Both assent and parental permission are sought
- For research requiring permission from both parents:
  - If one parent is deceased, unknown, incompetent;
  - or not reasonably available;
  - or one parent has legal custody

→ permission from both parents is not required

PROPOSAL COMPONENTS CONTINUED

- Consider timeline of project events and describe accordingly
- Include all materials that will be used as attached appendices
  - Recruitment scripts (emails, social media posts, fliers, etc.)
  - Consent / assent / permission forms (or waiver request if applicable)
  - Video / photo release forms
  - Questionnaires / surveys (in full) / interview prompts, etc.
  - Debriefing script / form
  - Site permission letter
  - Any other documentation that will be used in the study
    - Intervention protocols

INFORMED CONSENT

Must Include the Following Information:

- Statement of research
- Purpose of the research
- Procedures involved in the research
  - Who, what, when, where, how long
- Alternatives available should a subject decide not to participate in the research
- All foreseeable risks and discomforts to the subject, including physical injury, psychological, social, or economic harm, discomfort, or inconvenience
- Benefits of the research to society and possibly to the individual subject (if any)

INFORMED CONSENT CONTINUED

Must Also Include the Following Information:

- Length of time the subject is expected to participate
- Payment for participation (if applicable)
- Statement that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' right to confidentiality and right to withdraw from the study at any time without any consequences
- Explanation of how privacy / confidentiality will be maintained
- Investigator contact information
- REC Statement and contact information, including current chair

CONSIDERATIONS FOR WAIVER OF CONSENT

- No more than minimal risk
- 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

ANONYMITY & CONFIDENTIALITY

Anonymity

- Protects subjects' privacy by maintaining no record of their identity
- Consent forms constitute a record, which is why they are sometimes waived to protect anonymity of subjects

Confidentiality

- Protects subjects' privacy by:
    1. Keeping identifying information separate from the data gathered;
    2. Coding any identifying categories in the data set;
    3. AND locking up the list of subjects by code until the list is destroyed

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

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

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

OTHER CONSIDERATIONS

- READING LEVEL
  - Ensure understanding of material
  - 8th grade level or lower, unless specific justification is provided for otherwise
  - Applies to consent form AND any other written information provided to the participant
- SNOWBALL SAMPLING
  - Using current participants to recruit others
  - May be acceptable in certain circumstances-must use caution not to incidentally disclose private information of participants / potential participants
  - Cannot provide compensation for referrals
  - Good alternative: give participants flyers, etc to pass along rather than asking for names.

WHEN CAN I START COLLECTING DATA?

- After all requirements of the REC have been fulfilled; and
- An approval letter from the Chair of 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 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.

QUESTIONS?

PLEASE VISIT THE REC PAGE ON YOUR SPALDING PORTAL. THERE YOU CAN FIND…

- Links to forms and templates required for your proposal submission
- Submission form
- Links to OHRP and other helpful websites
- Examples of completed forms
- Other information to help with your proposal preparation and submission

REC CONTACT INFO

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REC website: http://www.rec.spalding.edu/