Update on IRB Activities & Guidance for Researchers

SEPTEMBER 2022

CHAPMAN UNIVERSITY

Agenda

- IRB activities since March 2022
- Key policy updates
- New exempt determination application in Cayuse
- Tips for PIs

IRB Personnel

Dr. Rebecca Forster
IRB Chair

Dr. Mary Kennedy
IRB Vice Chair

NEW MEMBERS

Dr. Lilia Monzo

Dr. David Pincus

Dr. Viet-Huong Nguyen

Dr. Jerika Lam

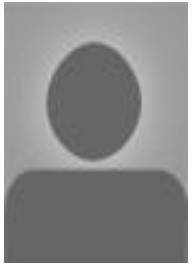
Dr. Ian Barnard

Mr. Ivan Portillo

Dr. Jo Smith

Lisa Rooney, JD

Ms. Cheryl Byers



Ms. Tina McCraw

IRB activities in Spring/Summer 2022

- IRB member training
- Updated policies and guidelines
- Developed a simplified exempt process

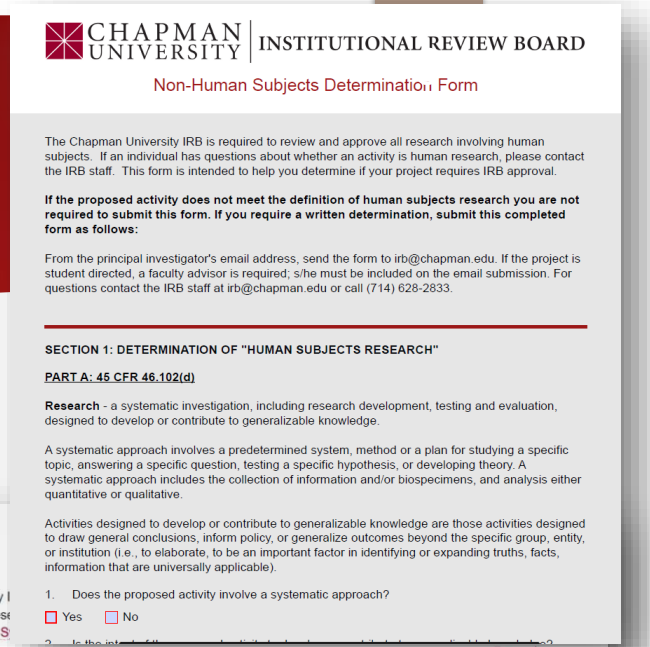
Is it Human Subject Research?

- The Office for Human Research Protections (OHRP) definition of research:
  - Systematic investigation
  - Intended to produce generalized knowledge
- Examples of non-research activities:
  - SLO assessment, course evaluations
  - Student classroom projects limited to the classroom
    - See guidelines and suggested documentation on IRB website

Is it Human Subject Research?

https://www.chapman.edu/research/integrity/irb/forms-and-instructions.aspx

- If you need a formal non-human subject determination
  - A PDF form is available on the IRB website
    - Coming soon in Cayuse
  - When in doubt – consult with the IRB first!



CHAPMAN UNIVERSITY | INSTITUTIONAL REVIEW BOARD

Non-Human Subjects Determination Form

The Chapman University IRB is required to review and approve all research involving human subjects. If an individual has questions about whether an activity is human research, please contact the IRB staff. This form is intended to help you determine if your project requires IRB approval.

If the proposed activity does not meet the definition of human subjects research you are not required to submit this form. If you require a written determination, submit this completed form as follows:

From the principal investigator's email address, send the form to irb@chapman.edu. If the project is student directed, a faculty advisor is required; s/he must be included on the email submission. For questions contact the IRB staff at irb@chapman.edu or call (714) 628-2833.

SECTION 1: DETERMINATION OF "HUMAN SUBJECTS RESEARCH"

PART A: 45 CFR 46.102(d)

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A systematic approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.

Activities designed to develop or contribute to generalizable knowledge are those activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution (i.e., to elaborate, to be an important factor in identifying or expanding truths, facts, information that are universally applicable).

1. Does the proposed activity involve a systematic approach?

☐ Yes ☐ No

Research and Creative Activity / Research Integrity

Institutional Review Board (IRB)

- IRB Policies
- IRB Application System
- Training and Continuing Education
- PI Responsibilities
- **Forms**
- Informed Consent Process
- Single IRB Reviews
- Clinical Trials
- Board Members

Forms

Chapman University I
of human subject rese
the IRB Application S

Expand

Non-Research Determination

The federal regulations include a very specific definition for what constitutes "research" (see 45 CFR 46.102(d)) and for what is meant by a "human subject" (see 45 CFR 46.102(f)). A formal determination from the IRB can be made if their project either is not research and/or does not involve human subjects (e.g., as may be required by a student's doctoral dissertation committee, a funding agency, or a journal editor). The IRB will not provide a formal written determination after the project has been initiated.

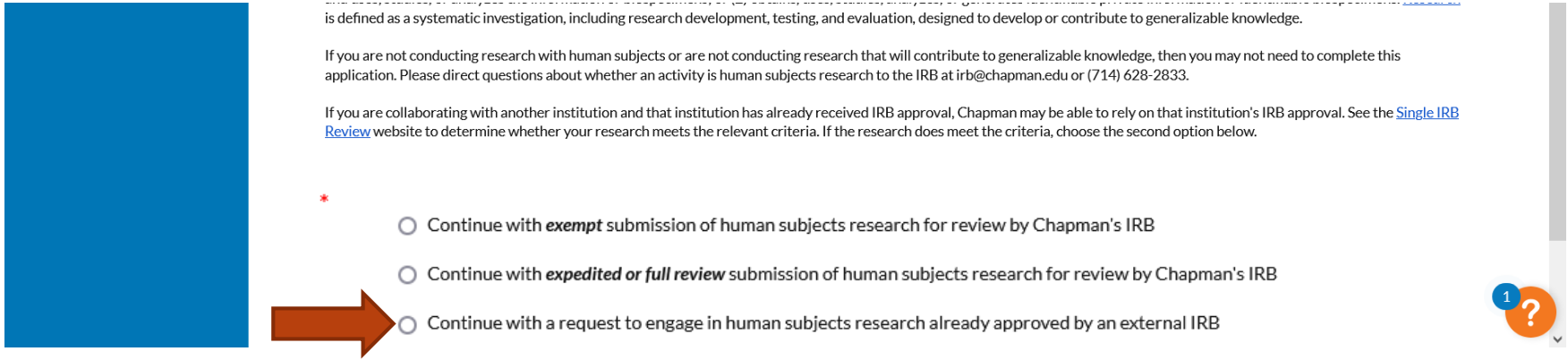
If you are unsure whether your project meets this criteria, contact the IRB staff before submitting your application for review.

- The federal research regulations [45 CFR 46] do not require the IRB to make a formal determination that projects are not research, or do not involve human subjects. Thus, this Non-Research Determination Form should be used only if a formal determination is required by a university entity (e.g., dissertation committee) or by an external agency.

Single IRB Review

https://www.chapman.edu/research/integrity/irb/single-irb-reviews.aspx

- Reminder: Put in place a **reliance agreement** if you are collaborating with another institution on an **expedited** or **full-board** protocol.
  - Reliance agreements in Cayuse



Check out our website for more guidelines, policies, and templates

Policies and guidelines:

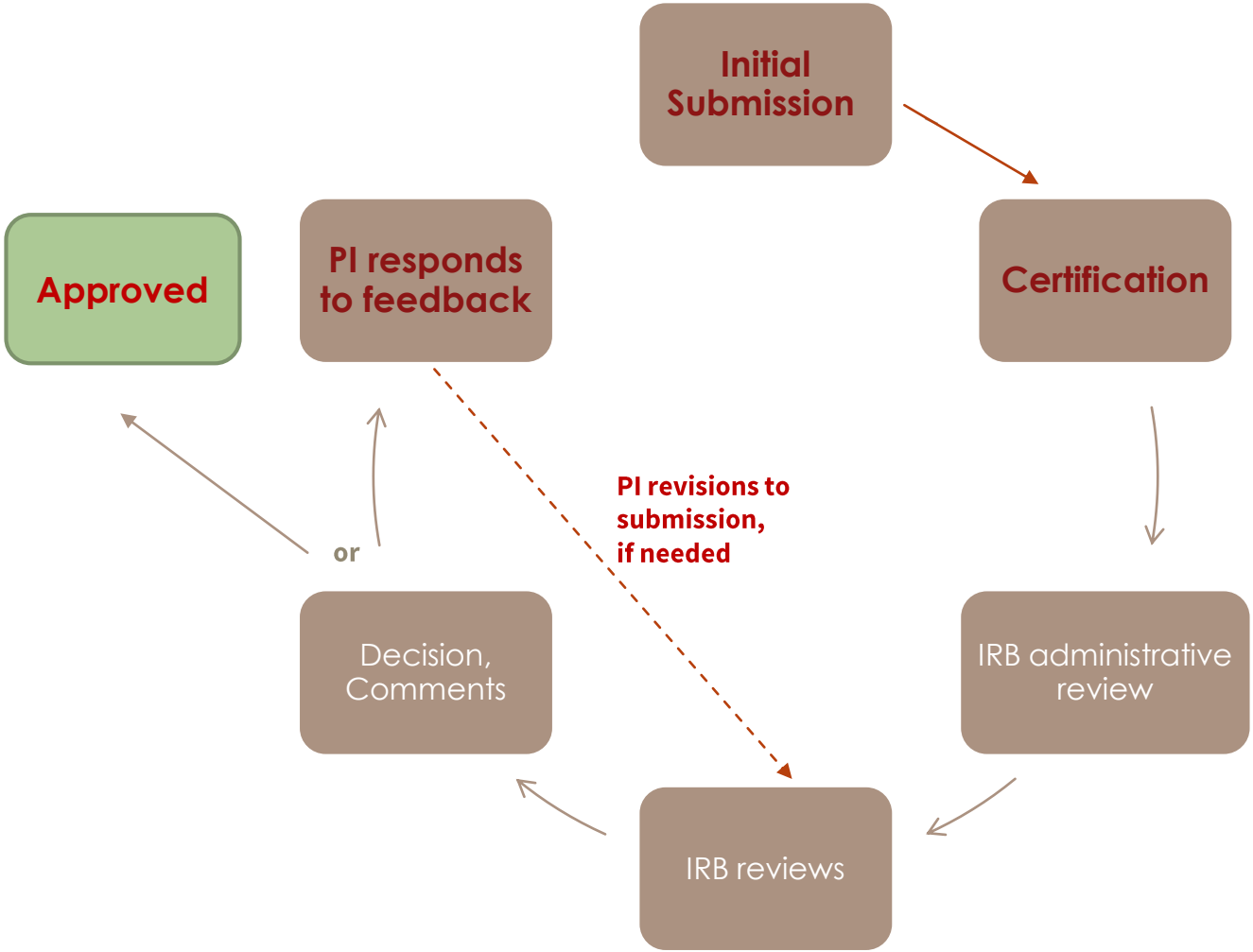
https://www.chapman.edu/research/integrity/irb/policies.aspx

Templates of information sheets and informed consent documents:

https://www.chapman.edu/research/integrity/irb/informed-consent-process.aspx

IRB Review Process

Process for Initial Reviews



New Exempt Determination in Cayuse

- **New, shorter IRB application for exempt studies launched in September**
  - No longer requires modification for change in study personnel
  - Remember to inform the IRB of changes in the study protocol

How do I know if my research falls under Exempt, Expedited, or Full Categories?

Exempt

For research to qualify as "Exempt" from the Code of Federal Regulations pertaining to the Protection of Human Subjects (45 CFR 46 full text), the research must be considered minimal risk. Additionally, human subject involvement must fall within one of eight categories listed in 45 CFR 46.104. Read descriptions of the exempt research categories, with examples.

Expedited

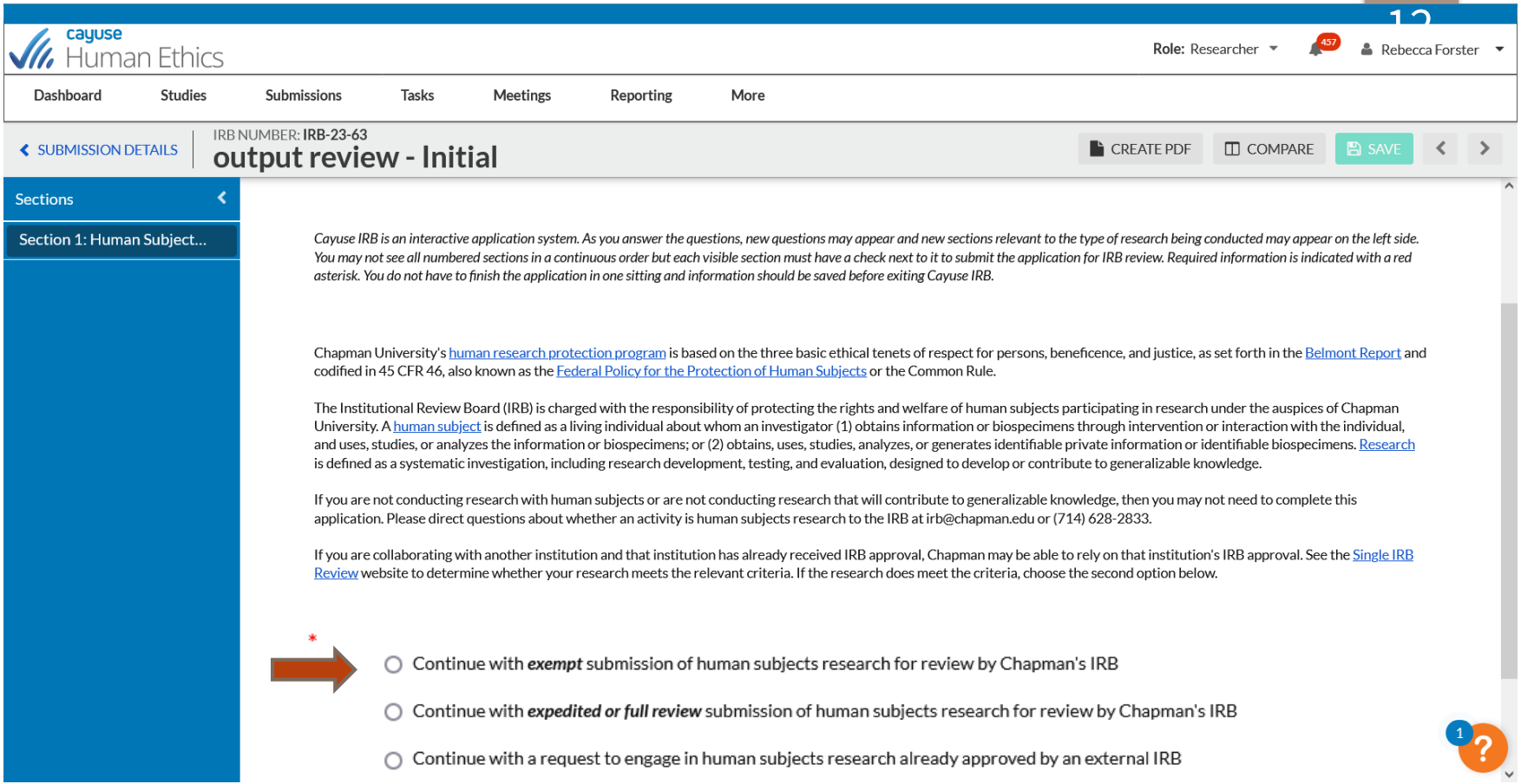
For research to qualify for "Expedited" review, the research must present no more than minimal privacy, psychological, and/or physical risk to human subjects, and involve only procedures listed in one or more of the nine expedited categories. Read descriptions of the nine expedited research categories, as defined by the Office for Human Research Protections (OHRP).

NOTE: The expedited categories describe research that is eligible for expedited review. However, full committee review may be required if determined by the IRB.

Full

If the research does not qualify as Exempt or Expedited based on the above research category descriptions, the research will require full committee review.

https://www.chapman.edu/research/integrity/irb/index.aspx


cayuse
Human Ethics
Role: Researcher
457
Rebecca Forster
Dashboard
Studies
Submissions
Tasks
Meetings
Reporting
More
SUBMISSION DETAILS
IRB NUMBER: IRB-23-63
output review - Initial
CREATE PDF
COMPARE
SAVE
Sections
Section 1: Human Subject...
Cayuse IRB is an interactive application system. As you answer the questions, new questions may appear and new sections relevant to the type of research being conducted may appear on the left side. You may not see all numbered sections in a continuous order but each visible section must have a check next to it to submit the application for IRB review. Required information is indicated with a red asterisk. You do not have to finish the application in one sitting and information should be saved before exiting Cayuse IRB.
Chapman University's human research protection program is based on the three basic ethical tenets of respect for persons, beneficence, and justice, as set forth in the Belmont Report and codified in 45 CFR 46, also known as the Federal Policy for the Protection of Human Subjects or the Common Rule.
The Institutional Review Board (IRB) is charged with the responsibility of protecting the rights and welfare of human subjects participating in research under the auspices of Chapman University. A human subject is defined as a living individual about whom an investigator (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
If you are not conducting research with human subjects or are not conducting research that will contribute to generalizable knowledge, then you may not need to complete this application. Please direct questions about whether an activity is human subjects research to the IRB at irb@chapman.edu or (714) 628-2833.
If you are collaborating with another institution and that institution has already received IRB approval, Chapman may be able to rely on that institution's IRB approval. See the Single IRB Review website to determine whether your research meets the relevant criteria. If the research does meet the criteria, choose the second option below.
*
Continue with exempt submission of human subjects research for review by Chapman's IRB
Continue with expedited or full review submission of human subjects research for review by Chapman's IRB
Continue with a request to engage in human subjects research already approved by an external IRB
1

Streamlining Behind-the-Scenes IRB Processes

- **Process changes to exempt application reviews**
  - IRB checklists revised to reduce redundancy and improve efficiency
- **Changes to the modification reviews** to expedited and full committee applications
  - Combined Administrative and Reviewer checklists to reduce redundancy and improve efficiency

Institutional Review Board (IRB)

IRB Policies

IRB Application System

Training and Continuing Education

PI Responsibilities

Forms

Informed Consent Process

Single IRB Reviews

Clinical Trials

Board Members

- **Frequently Asked Questions (FAQs)**

Frequently Asked Questions (FAQs)

Below are frequently asked questions related to Institutional Review Board (IRB) policies, procedures, and processes. Contact the IRB if your question is not answered below.

Expand

How do I submit a research study for IRB review?

What does the IRB look for when it reviews a research study?

In general, the IRB reviews studies to make sure that risks to participants are minimized, research proceeders are consistent with sound research design, informed consent is obtained and documented, and the privacy and confidentiality of participants is protected. The IRB must follow Federal regulations specified under 45 CFR 46, which is also known as the Common Rule. When IRB members review a research study, they follow a checklist to make sure the relevant Federal regulations are being met. To facilitate IRB review of your research study, consider using the IRB Reviewer Checklist to evaluate your own application in Cayuse IRB before submitting it to the IRB.

What is a faculty advisor's role for student-directed research?

Does "Exempt" mean IRB review is not needed?

Does an "Expedited" submission get a faster review?

I want to collaborate with investigators unaffiliated with Chapman. What is needed?

Streamlining Behind-the-Scenes IRB Processes

- **Changes to the modification reviews** to expedited and full committee applications
  - Only one IRB member to review/approve expedited modifications
  - Our goal for expedited modifications has been shortened to 1 week unless received on a Friday.

Sail Through The Review

TIPS FOR RESEARCHERS

Tips for Researchers

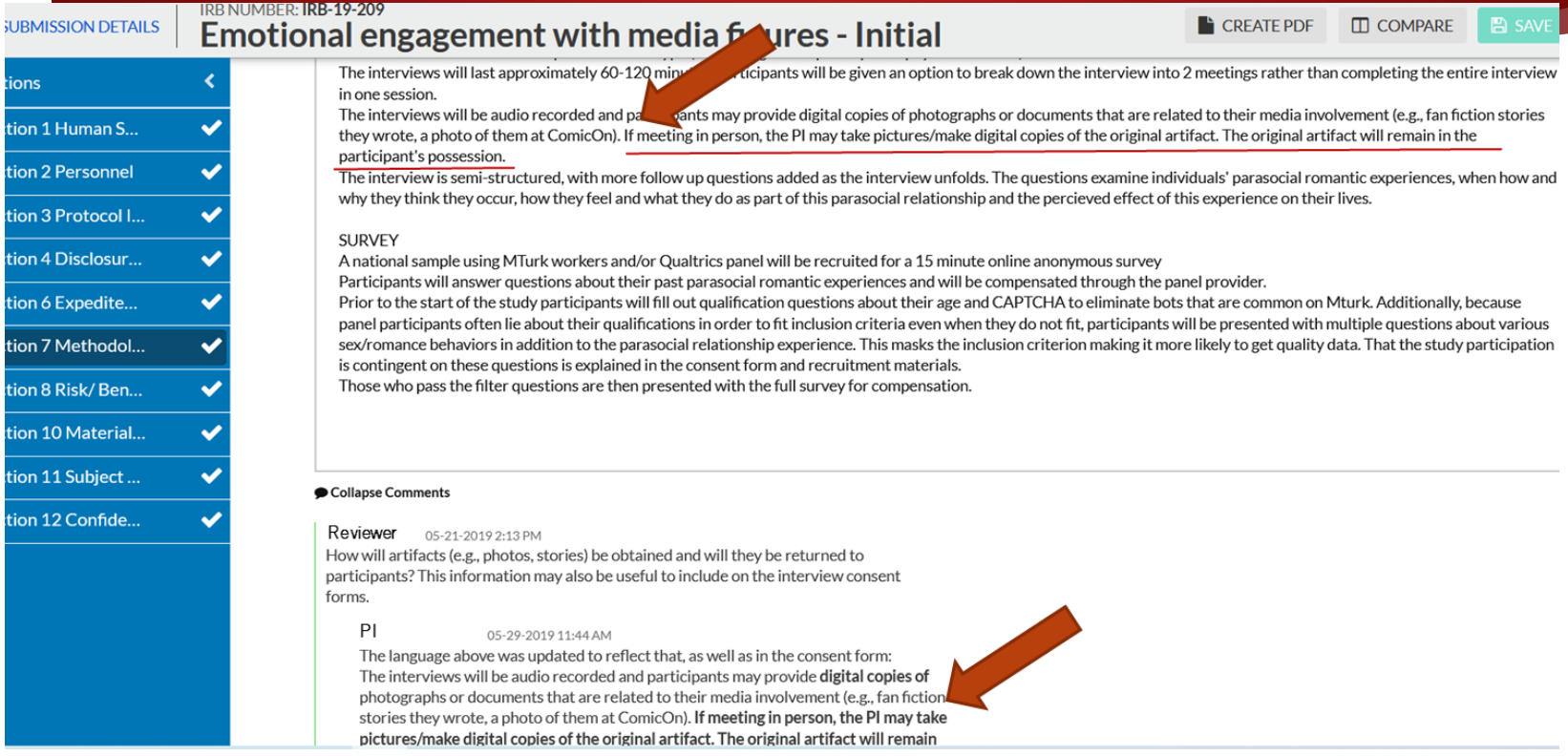
- **Pay attention to details**
  - Respond to all parts of the questions in Cayuse
  - Upload PDF versions of documents
  - Be consistent across the application:
    - Number of participants
    - Procedures in application matches consent

Tips for Researchers

Consider and address risks both in study procedures & recruitment

- Address each risk and how it will be minimized
- Risks in application should match consent documents

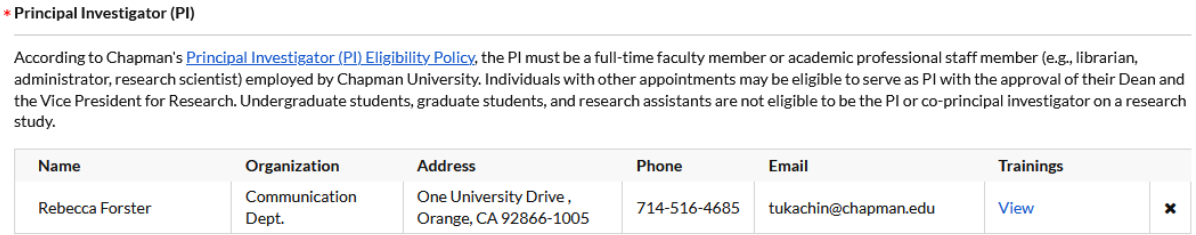
Tips for Researchers



Tips for Researchers

Qualifications & training

- PI must be full time faculty or staff
- Make sure your CITI is up-to-date and uploaded on Cayuse
- Make sure all study personnel's CITI training is up to date



* **Principal Investigator (PI)**

According to Chapman's Principal Investigator (PI) Eligibility Policy, the PI must be a full-time faculty member or academic professional staff member (e.g., librarian, administrator, research scientist) employed by Chapman University. Individuals with other appointments may be eligible to serve as PI with the approval of their Dean and the Vice President for Research. Undergraduate students, graduate students, and research assistants are not eligible to be the PI or co-principal investigator on a research study.

Name	Organization	Address	Phone	Email	Trainings	
Rebecca Forster	Communication Dept.	One University Drive , Orange, CA 92866-1005	714-516-4685	tukachin@chapman.edu	View	✖

Questions?

- IRB (irb@chapman.edu)
- Director of Research Integrity, Position posted; in the meantime, contact Michelle Christy at (mich15571@chapman.edu)
- IRB Chair, Rebecca Forster (tukachin@chapman.edu)
- IRB Vice Chair, Mary Kennedy (markenne@chapman.edu)

Links to topics addressed in Q&A

- **How do I know if my research falls under Exempt, Expedited, or Full Categories? Including full-board review due dates**
  - https://www.chapman.edu/research/integrity/irb/index.aspx
- **Non-human research determination**
  - https://www.chapman.edu/research/integrity/irb/forms-and-instructions.aspx
- **What is a reliance agreement, and should Chapman rely on another institution's IRB or should the other IRB rely on Chapman?**
  - https://www.chapman.edu/research/integrity/irb/single-irb-reviews.aspx
- **Informed consent & information sheets templates, including authorization of deception**
  - https://www.chapman.edu/research/integrity/irb/informed-consent-process.aspx
- **Sample reviewer checklist. What does the IRB look for when it reviews a study?**
  - https://www.chapman.edu/research/integrity/irb/faqs.aspx
- **Policies and guidelines (including student research, using stamped consent documents, signature requirements)**
  - https://www.chapman.edu/research/integrity/irb/policies.aspx