Update on IRB Activities & Guidance for Researchers

SEPTEMBER 2022
Agenda

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

NEW MEMBERS

Dr. Rebecca Forster
IRB Chair

Dr. Mary Kennedy
IRB Vice Chair

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
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!

Is it Human Subject Research?

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

A study 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
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

1. **Initial Submission**
2. **IRB reviews**
3. **Decision, Comments**
4. **PI responds to feedback**
5. **Certification**
6. **IRB administrative review**
7. **PI revisions to submission, if needed**
8. **Approved**

- The process starts with the **Initial Submission**.
- Following an **IRB review**, there can be a **Decision** and **Comments**.
- If revisions are needed, the process returns to **PI responds to feedback**.
- After revising, it moves to the **Certification** stage.
- Finally, the process concludes with an **Approved** decision.
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, Part 46), 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 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) 681-2833.

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
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
# 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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How do I submit a research study for IRB review?</td>
<td></td>
</tr>
<tr>
<td>What does the IRB look for when it reviews a research study?</td>
<td></td>
</tr>
<tr>
<td>In general, the IRB reviews studies to make sure that risks to</td>
<td></td>
</tr>
<tr>
<td>participants are minimized, research procedures are consistent with</td>
<td></td>
</tr>
<tr>
<td>sound research design, informed consent is obtained and documented,</td>
<td></td>
</tr>
<tr>
<td>and the privacy and confidentiality of participants is protected. The</td>
<td></td>
</tr>
<tr>
<td>IRB must follow Federal regulations specified under 45 CFR 46, which</td>
<td></td>
</tr>
<tr>
<td>is also known as the Common Rule. When IRB members review a research</td>
<td></td>
</tr>
<tr>
<td>study, they follow a checklist to make sure the relevant Federal</td>
<td></td>
</tr>
<tr>
<td>regulations are being met. To facilitate IRB review of your research</td>
<td></td>
</tr>
<tr>
<td>study, consider using the IRB Reviewer Checklist to evaluate your own</td>
<td></td>
</tr>
<tr>
<td>application in Cayuse IRB before submitting it to the IRB.</td>
<td></td>
</tr>
<tr>
<td>What is a faculty advisor’s role for student-directed research?</td>
<td></td>
</tr>
<tr>
<td>Does “Exempt” mean IRB review is not needed?</td>
<td></td>
</tr>
<tr>
<td>Does an “Expedited” submission get a faster review?</td>
<td></td>
</tr>
<tr>
<td>I want to collaborate with investigators unaffiliated with Chapman.</td>
<td></td>
</tr>
<tr>
<td>What is needed?</td>
<td></td>
</tr>
</tbody>
</table>
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

• Respond to reviewer comments in the text box of the application.

Cayuse does not keep the comment thread.

The interviews will last approximately 60-120 minutes. Participants will be given an option to break down the interview into 2 meetings rather than completing the entire interview in one session. The interviews will be audio recorded and participants may provide digital copies of photographs or documents that are related to their media involvement (e.g., fan fiction stories they wrote, a photo of them at ComicOn). If meeting in person, the PI may take pictures/make digital copies of the original artifact. The original artifact will remain in the participant's possession.

The interview is semi-structured, with more follow up questions added as the interview unfolds. The questions examine individuals' parasocial romantic experiences, how and why they think they occur, how they feel and what they do as part of this parasocial relationship and the perceived effect of this experience on their lives.

SURVEY
A national sample using MTurk workers and/or Qualtrics panel will be recruited for a 15 minute online anonymous survey. Participants will answer questions about their past parasocial romantic experiences and will be compensated through the panel provider. Prior to the start of the study participants will fill out qualification questions about their age and CAPTCHA to eliminate bots that are common on Mturk. Additionally, because panel participants often lie about their qualifications in order to fit inclusion criteria (even when they do not fit, participants will be presented with multiple questions about various sex/romance behaviors in addition to the parasocial relationship experience. This masks the inclusion criterion making it more likely to get quality data. That the study participation is contingent on these questions is explained in the consent form and recruitment materials.

Those who pass the filter questions are then presented with the full survey for compensation.
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.
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