

Navigating Reasons for Delay

How to Avoid Delays in the Review Process

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Overview

01

Building a complete Kuali Protocol

Following prompts, providing sufficient detail, and uploading required materials.

02

Putting It Into Practice

Be the IRB: identifying inconsistencies that delay IRB review.

03

Administrative Requirements

Human subjects protection training and ancillary review.

04

Avoid Mid -Review Changes

Finalizing the study design before submission and minimizing procedural changes.

Not following the instructions in the Kuali protocol

- Responses that do not address the prompts requested in the protocol will be flagged, and additional details and information will be requested.

- Make sure that you select all applicable options when completing the protocol. The protocol utilizes branching logic, and failure to select the correct options will result in needed prompts not appearing.
  - If the correct prompts are not selected, needed information will be missing from your protocol; this can create delays, as the needed information will only be reviewed for the first time upon resubmission.



Select all that apply…

Imagine you are conducting a research study where you'll be investigating UCR students' knowledge of mental health resources available to them on campus and their opinions of these resources.
To obtain this information you plan on conducting individual interviews. Additionally, you will record the interviews, so that you can focus on observing your interviewees' nonverbal behaviors and body language. Which "procedures" should you select?

Research Procedures

- [ ] Applying for Federal Certificate of Confidentiality
- [ ] Audio, Visual or Digital Recordings
- [ ] Behavioral Observations (in physical and/or online settings, including social media)
- [ ] Clinical Trial
- [ ] Creating Registry / Repository
- [ ] Community-Based Research / Community- Engaged Research
- [ ] Deception or Partial Disclosure
- [ ] Genetic Analysis / Genotyping
- [ ] Interview / Focus Groups
- [ ] Survey / Questionnaire
- [ ] Noninvasive procedures routinely employed in clinical practice (e.g., EEG, fMRI, physiological measurements)
- [ ] Collection of Biospecimens (e.g., Blood draws, cheek swab, biopsy)
- [ ] Use of Existing Data/Records/Biospecimens
- [ ] Other

Not providing required attachments

The Supporting Information section of the Kuali protocol should include participant facing documents.

Most protocol submissions should include a consent form/information sheet.

Researchers must upload their recruitment materials. In-person scripts, text messages, and even informal modes of communication should be presented to the IRB for review.

All data collection instruments, interview guides, intervention materials, and description of stimulants, must be provided to the IRB for review.





Providing inconsistent information between the IRB protocol and the supporting materials.

1. Inconsistent information is the most common reason for delays.
2. Avoid having too many chefs in the kitchen.
3. It is recommended that the research team create a central document/file that outlines the recruitment materials, compensation amounts, procedures, duration of procedures, interval between procedures, consent process, and so on and check this document with the Kuali Protocol and other Supporting Materials.
4. Ensuring consistency across all materials is key for a quicker review process.

BE THE IRB

Activity Time: In this portion of the workshop, you'll take on the role of an IRB reviewer.

In groups, you'll review the Study Timeline attachment and the Informed Consent Document for the same proposed study.

When reviewing the documents, keep an eye out for inconsistencies. Once you spot an inconsistency, make a note of it. We will discuss what revisions to the consent and/or timeline should be made after everyone reconvenes in 10 minutes.



What Did You Find?

- What inconsistencies did you find between the study design and the informed consnet?
- Why might these inconsistencies delay the review process?
- Why do you think these mistakes happen?



Not providing requested information after review...

Do not “cherry pick” comments.

All comments made by reviewers must be addressed.

If you do not agree with a comment, provide your reasoning and the rationale for why you disagree. The IRB will listen and consider your response if you provide your reasoning.

Make sure that you utilize the reply feature to address requested revisions and make changes to the text of the protocol when necessary.



Not completing the Human Subjects Protection Course for all those involved in the research

1. Approval cannot be processed until all personnel have completed training.
2. Consider removing personnel until they have completed training.
3. Personnel can be added at any time via amendments.
4. Complete the training that best corresponds with the research you'll be conducting.
    - Biomedical Research Invesitgators
    - Social & Behavioral Research Investigators
    - Research with Data or Laboratory Specimens ONLY



Incomplete Ancillary Review by Department Chair or designee

1. IRB Submissions cannot be approved without Department Sign Off (Ancillary Review).
2. If your Department Chair has recently changed, please inform the IRB of this. The Kuali Protocol System is programmed to send the ancillary review request to the assigned Department Chair; however, if a change has been made researchers should notify the IRB, so that the review can be reassigned.

Adding or removing research activities or procedures once the review process has begun



Please note, adding or removing research procedures once the initial review has taken place can significantly delay the review process.

Adding or removing procedures can impact the level of review for the protocol, and therefore create additional requirements that must be followed to appease the regulations.

Case Study...

A researcher submits a protocol that involves surveying college students, who are sexually active, regarding their knowledge on safe-sex practices, contraception, and STIs. The IRB reviews the study and sends the protocol back to the researchers with some minor revisions.

A few weeks go by and the researchers resubmit the protocol. Upon review, the IRB discovers that the researchers have revised their study to now include blood draws. The researchers now want to test participant blood samples, to see if their is a correlation between participant knowledge and sexually transmitted infections.

Why might this addition delay the review process? What implications might this change have?



Additional Submission issues...

Submitting the protocol before contacting the IRB office to discuss research ethics issues

Submitting before having a definitive study design and procedures.



Additional Resources

Please visit: https://research.ucr.edu/kuali -research .
This site is being continually updated with IRB information and resources as they become available.

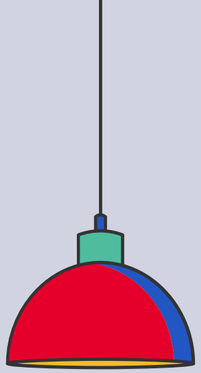
KUALI training resources

https://research.ucr.edu/orc-faq

https ://research .ucr .edu/kuali -research#will -training -be-available -for



THANK YOU!



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