CAYUSE IRB

CREATING MODIFICATIONS IN
LEGACY STUDIES
GENERAL INFORMATION

• **Legacy** studies in Cayuse IRB are electronic conversions of the existing paper folders maintained by the HRPP prior to implementation.

• Limited information was taken from the study and transferred into a new format. Co-investigators were not added during the initial conversion.

• Legacy files utilize the paper 6-digit numbering system.

• All Legacy changes are called Modifications.

• There is no need to enter the entire study into Legacy. The modification will include only those changes that need to be made to the already existing, approved study.

• There are 2 modifications options available: 1) complete the summary and enter the new information in the appropriate section(s) of the modification form, or 2) complete the summary and attach a revised version of the paper study with highlighted changes.
LOCATING THE STUDY

• Typically, the study will show up on the PI’s Dashboard unless the PI has more than 5 active studies. If the study isn’t in the window click on “View All” or a search for the study by name or number can be conducted from the Studies screen.
LEGACY SEARCHES

• Under the main menu, select Studies and enter the researcher’s name or the study number in the Search field.
CAYUSE IRB DASHBOARD

• Clicking on the study number brings up the study in the Study Details screen.
CREATING A MODIFICATION

- Click on + New Submission and then Modification.
CREATING A MODIFICATION

• The Submission Details screen is created. Notice the Modification label.
• Click on the Edit button.
• The modification submission menu indicates that each section has been completed without any changes having been made.

• Notice there is not a Complete Submission option available at the bottom of the menu yet.
CREATING A MODIFICATION

- In Legacy, PIs have the option of making and submitting trackable changes in the various sections or attaching a revised paper copy with highlighted changes.
• In the Modification screen summarize the changes being made to the study.

1. Increasing the target population to 1000
2. Adding TechAnnounce and church websites as a source of recruiting
3. Adding the online survey to Qualtrics
• Click on each section(s) that needs to be modified and provide the relevant information.
• All sections allow the copy and pasting of information from other sources.
• Recruiting documents may be manually entered, copy and pasted OR attached in their entirety.
CREATING A MODIFICATION IN CAYUSE IRB

OPTION 1 – ENTERING THE MODIFICATION IN CAYUSE IRB

- When all changes have been completed, ensure each section has a green check mark next to it.

- At the bottom of the menu, click on COMPLETE SUBMISSION.

- Once confirmed, the modification moves forward for certification.

- Once certified by the PI, the modification submission moves to the HRPP for pre-review.
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OPTION 1 – USING THE COMPARE FEATURE FOR REVIEW

• Any changes to the study made in Cayuse IRB can be tracked through the use of the Compare feature.

• Click on the **COMPARE** button at the top right corner of the Modification screen.

• The bubbles opposite the section title indicate the number of changes made to that section.

• The green highlighted fields under each section indicate where changes were made.
Option 2 allows the researcher to attach a copy of the existing approved study, complete with the present and prior approved amendments without making changes to the individual sections of the online submission.

The ‘Compare’ feature is not available for use with this option.
CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING A MODIFICATION

• Complete the summary of changes to be made.

Summary of Changes:

1. Increase the target population to 1000
2. Recruit through TechAnnounce and through individual church webpages nationwide
3. Post the information sheet and survey to Qualtrics

Attach document here.

ATTACH
CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING AN AMENDMENT SUBMISSION

• Make the changes in a clean copy of the approved study that includes all past amendments.

• Indicate the changes that were made:
  • In MS Word by “Track Changes” or highlighted.
  • In .pdf format by highlighting the additional changes.

II. Subjects:
The subject population for this study will include everyone from all walks of life. The study looks to recruit and survey around 900-1000 participants over the age of 18. Recruiting will be accomplished through a notice in TechAnnounce, emails to churches, and face-to-face requests for participants to complete either an online Qualtrics survey or paper survey. Permission to conduct research will be requested of church leaders prior to any contact with the membership. Email addresses posted to their church websites will be used as points of contact. There is no risk involved because the surveys will be kept anonymous. No compensation will be offered and the survey will take less than 3 minutes.
CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING A MODIFICATION

• Attach the entire revised study (with track changes or highlights).
CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING A MODIFICATION

• Save and submit the Modification.
• The PI will then confirm the submission and certify it.
• Once certified, it is forwarded to the HRPP for pre-review.
Thank you!

If you have any questions, please feel free to contact the HRPP.

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