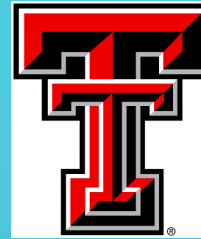


CAYUSE IRB



TEXAS TECH UNIVERSITY

Human Research
Protection Program™

CREATING MODIFICATIONS IN LEGACY STUDIES

FEBRUARY 2016

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.

My Role: Researcher + New Study

In-Draft 0 **Awaiting Approval** 0 **Pre-Review** 0 **Under Review** 0

My Studies

[504527](#) Faith-healing Beliefs within the Christian Community

[View All](#)

Approved Studies

[504527](#) Faith-healing Beliefs within the Christian Community

My Tasks

All Tasks Complete

Submissions by Type

Initial	0
Withdrawal	0
Modification	1
Renewal	0
Incident	0
Closure	0
Legacy	1

Studies Expiring in 30 days

No Expiring Studies

Expired Studies

No Expired Studies

LEGACY SEARCHES

- Under the main menu, select Studies and enter the researcher's name or the study number in the Search field.

The screenshot displays the 'cayuse IRB' web application interface. On the left is a dark blue sidebar menu with the following items: Dashboard, Studies (highlighted with a red arrow), Submissions, Tasks, Meetings, and Reporting. The main content area is white and features a 'My Role: Researcher' dropdown menu at the top. Below it is a search bar containing the text '504527', with a yellow arrow pointing to the search input. The search results are displayed in a table with two columns: 'IRB#' and 'Study Title'. The first row shows the IRB number '504527' (underlined) and the study title 'Faith-healing Beliefs within the Christian Community'. At the bottom of the page, there is a '25 per page' dropdown menu.

IRB#	Study Title
504527	Faith-healing Beliefs within the Christian Community

CAYUSE IRB DASHBOARD

- Clicking on the study number brings up the study in the Study Details screen.



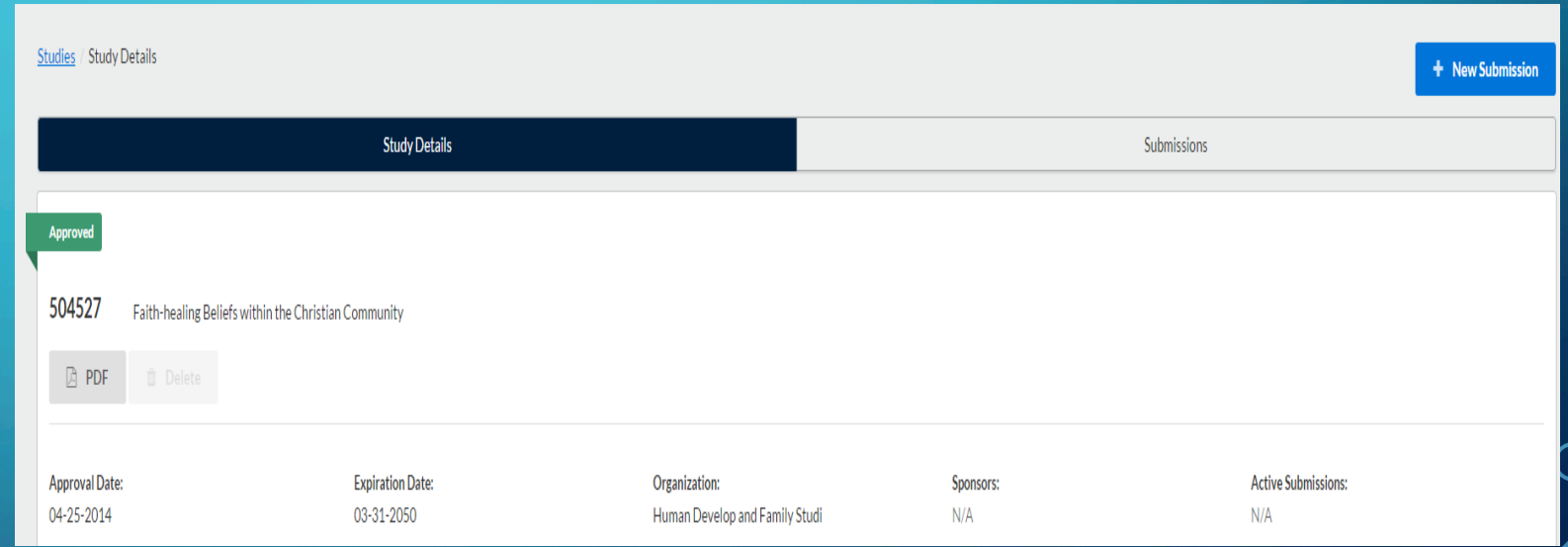
My Studies

[504527](#) Faith-healing Beliefs within the Christian Community

[View All](#)

Approved Studies

[504527](#) Faith-healing Beliefs within the Christian Community



Study Details

[+ New Submission](#)

Study Details | Submissions

Approved

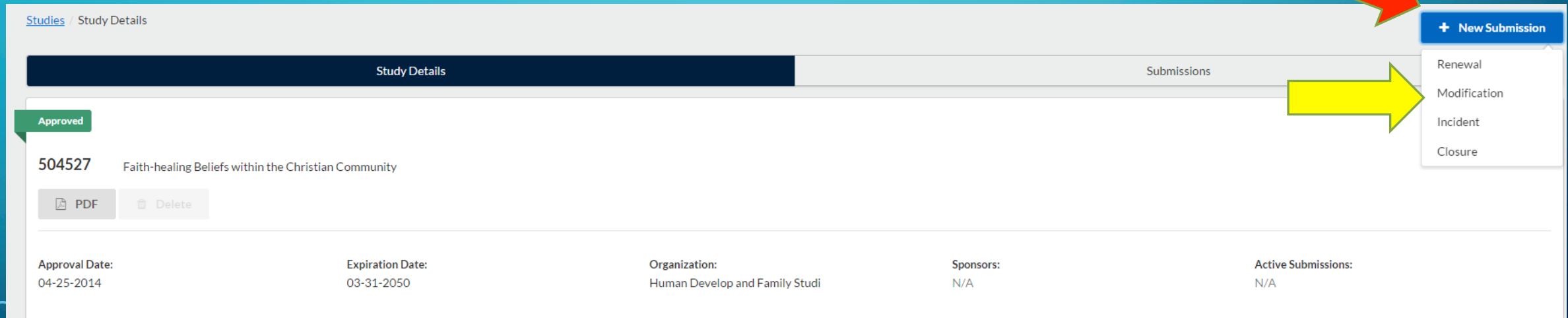
504527 Faith-healing Beliefs within the Christian Community

[PDF](#) [Delete](#)

Approval Date:	Expiration Date:	Organization:	Sponsors:	Active Submissions:
04-25-2014	03-31-2050	Human Develop and Family Studi	N/A	N/A

CREATING A MODIFICATION

- Click on **+ New Submission** and then Modification.



The screenshot shows a web application interface for a study. At the top, there is a breadcrumb trail: [Studies](#) / Study Details. Below this, there are two tabs: "Study Details" (active) and "Submissions". A red arrow points to a blue button labeled "+ New Submission" in the top right corner. A yellow arrow points to a dropdown menu that appears after clicking the button, containing the following options: "Renewal", "Modification", "Incident", and "Closure".

Approved

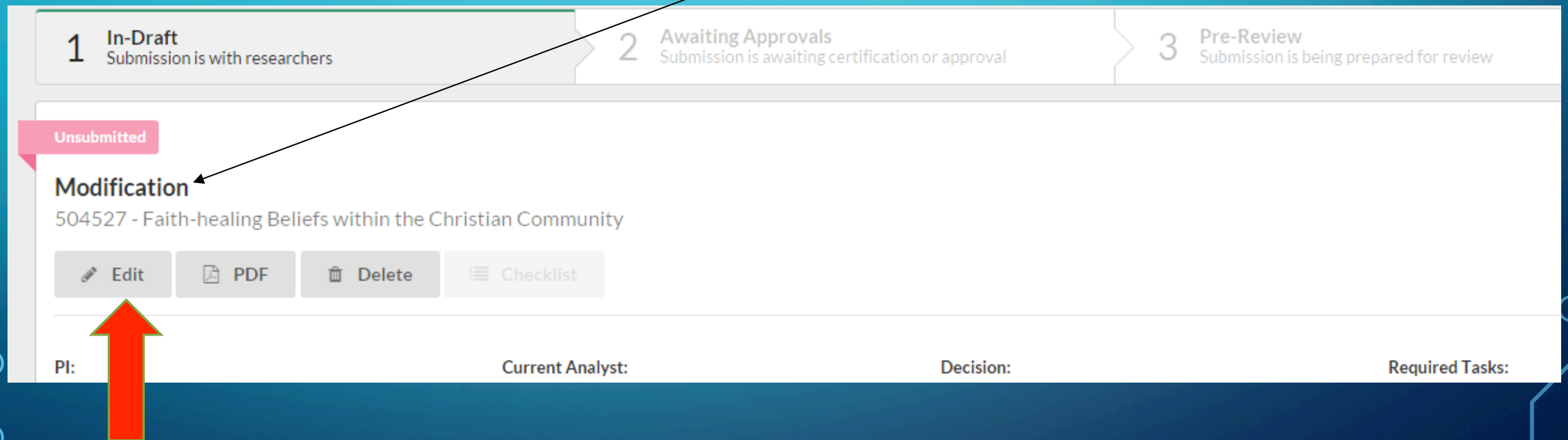
504527 Faith-healing Beliefs within the Christian Community

[PDF](#) [Delete](#)

Approval Date: 04-25-2014	Expiration Date: 03-31-2050	Organization: Human Develop and Family Studi	Sponsors: N/A	Active Submissions: N/A
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CREATING A MODIFICATION

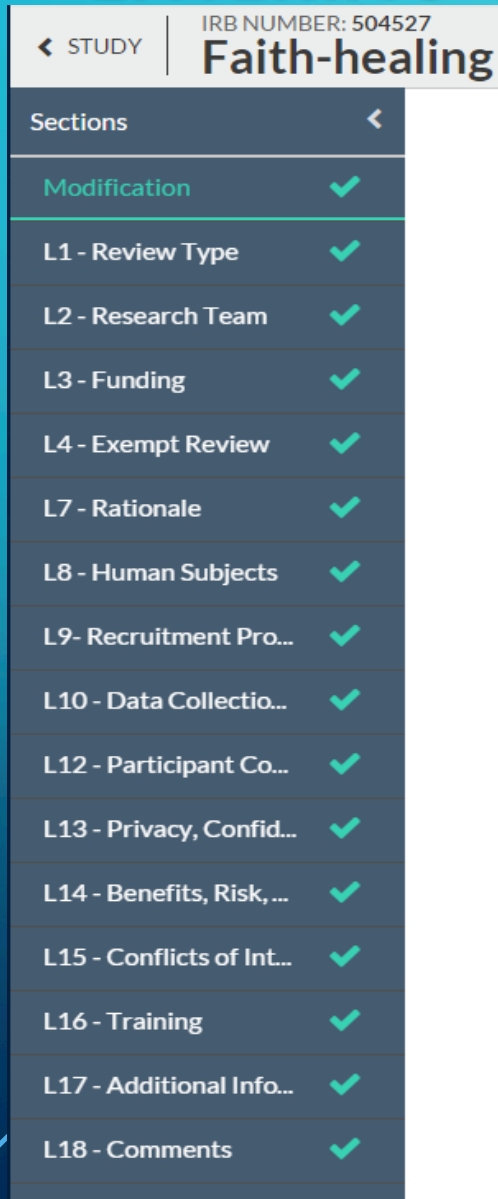
- The Submission Details screen is created. Notice the Modification label.
- Click on the Edit button.



The screenshot displays a submission workflow with three stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), and 3. Pre-Review (Submission is being prepared for review). Below the workflow, a pink 'Unsubmitted' tag is visible. The main content area shows a 'Modification' for submission 504527, titled 'Faith-healing Beliefs within the Christian Community'. A toolbar contains buttons for 'Edit', 'PDF', 'Delete', and 'Checklist'. A red arrow points to the 'Edit' button. At the bottom, there are labels for 'PI:', 'Current Analyst:', 'Decision:', and 'Required Tasks:'.

CREATING A MODIFICATION IN CAYUSE IRB

ENTERING THE MODIFICATION IN CAYUSE IRB



STUDY IRB NUMBER: 504527	
Faith-healing	
Sections	<
Modification	✓
L1 - Review Type	✓
L2 - Research Team	✓
L3 - Funding	✓
L4 - Exempt Review	✓
L7 - Rationale	✓
L8 - Human Subjects	✓
L9 - Recruitment Pro...	✓
L10 - Data Collectio...	✓
L12 - Participant Co...	✓
L13 - Privacy, Confid...	✓
L14 - Benefits, Risk, ...	✓
L15 - Conflicts of Int...	✓
L16 - Training	✓
L17 - Additional Info...	✓
L18 - Comments	✓

- 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.

Modification	
L1 - Review Type	✓
L2 - Research Team	✓
L3 - Funding	✓
L4 - Exempt Review	✓
L7 - Rationale	✓
L8 - Human Subjects	✓
L9- Recruitment Pro...	✓
L10 - Data Collectio...	✓
L12 - Participant Co...	✓
L13 - Privacy, Confid...	✓

Modification

Cayuse IRB Modification:

Provide a summary of the changes you are requesting in the text box below. Details of the changes are required in the appropriate sections. The "Compare" feature is a useful tool as you edit each section.

Legacy IRB Modification Option 1:

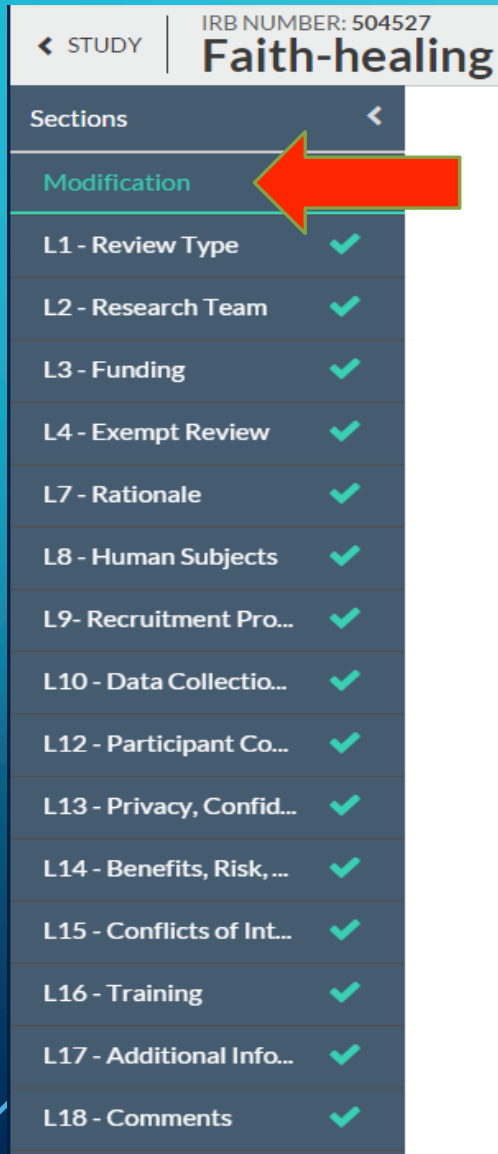
Provide a summary of the changes you are requesting in the text box below. Details of the changes are required in the appropriate sections. This will allow the PI and the IRB Reviewer the use of the "Compare" feature.

Legacy IRB Modification: Option 2:

Provide a summary of the changes you are requesting in the text box below. Attach a document that incorporates all amendments, if any (a clean copy), and highlight the changes you are requesting now according to your summary.

CREATING A MODIFICATION IN CAYUSE IRB

OPTION 1 – ENTERING THE MODIFICATION IN CAYUSE IRB



The screenshot shows the Cayuse IRB interface for a study titled "Faith-healing" with IRB number 504527. A sidebar menu on the left lists various sections, with "Modification" highlighted in green and a red arrow pointing to it. The other sections listed are L1 - Review Type, L2 - Research Team, L3 - Funding, L4 - Exempt Review, L7 - Rationale, L8 - Human Subjects, L9 - Recruitment Pro..., L10 - Data Collectio..., L12 - Participant Co..., L13 - Privacy, Confid..., L14 - Benefits, Risk, ..., L15 - Conflicts of Int..., L16 - Training, L17 - Additional Info..., and L18 - Comments. Each section has a green checkmark to its right.

- In the Modification screen summarize the changes being made to the study.

Modification

List the changes you are requesting. Make the changes in the appropriate section(s).

B *I* U & ☰ ☷ 🔗 🖼️

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

CREATING A MODIFICATION IN CAYUSE IRB

OPTION 1 – ENTERING THE MODIFICATION IN CAYUSE IRB

- Click on each section(s) that needs to be modified and provide the relevant information .

IRB NUMBER: 504527
Faith-healing

STUDY

Sections

- Modification ✓
- L1 - Review Type ✓
- L2 - Research Team ✓
- L3 - Funding ✓
- L4 - Exempt Review ✓
- L7 - Rationale ✓
- L8 - Human Subjects** ←
- L9- Recruitment Pro... ✓
- L10 - Data Collectio... ✓
- L12 - Participant Co... ✓
- L13 - Privacy, Confid... ✓
- L14 - Benefits, Risk, ... ✓
- L15 - Conflicts of Int... ✓
- L16 - Training ✓
- L17 - Additional Info... ✓
- L18 - Comments ✓

L8 - Human Subjects

8.1 Define the target population.

Check if applicable.

- Gender
- Age Range
- Nationality, Ethnicity or Religion (if applicable).
- Non-English Speaking Subjects (if applicable)
- Vulnerable Populations (if applicable)
Federal regulations require additional protection for research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (45 CFR 46 Subparts B, C, & D)
- Other (if applicable)

8.2 Describe the population of human subjects to be recruited. (e.g., college administrators, journalists, volunteers from First Baptist Church, etc.).

B I U S : : : ↺ ↻

Rich text editor area for describing the population of human subjects to be recruited.

8.3 Number of subjects

1000

CREATING A MODIFICATION IN CAYUSE IRB

OPTION 1 – ENTERING THE MODIFICATION IN CAYUSE IRB

STUDY	IRB NUMBER: 504527
	Faith-healing
Sections	<
Modification	✓
L1 - Review Type	✓
L2 - Research Team	✓
L3 - Funding	✓
L4 - Exempt Review	✓
L7 - Rationale	✓
L8 - Human Subjects	✓
L9 - Recruitment Pro...	✓
L10 - Data Collectio...	✓
L12 - Participant Co...	✓
L13 - Privacy, Confid...	✓
L14 - Benefits, Risk, ...	✓
L15 - Conflicts of Int...	✓
L16 - Training	✓
L17 - Additional Info...	✓
L18 - Comments	✓

- 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.

Information Sheet

* Explain when and how the Information Sheet will be provided to subjects.

B I U [List Bullets] [List Numbered] [Link] [Image]

The information sheet will be posted to the Qualtrics site and displayed prior to the online survey.

* Enter or attach the information sheet.

B I U [List Bullets] [List Numbered] [Link] [Image]

See attached copy

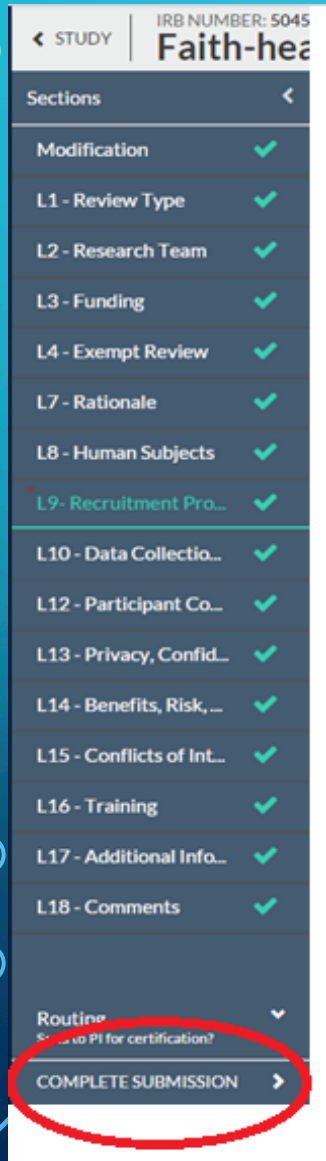
Attach (if applicable).

ATTACH

Attachment B - Information Sh... | X

CREATING A MODIFICATION IN CAYUSE IRB


OPTION 1 – ENTERING THE MODIFICATION IN CAYUSE IRB

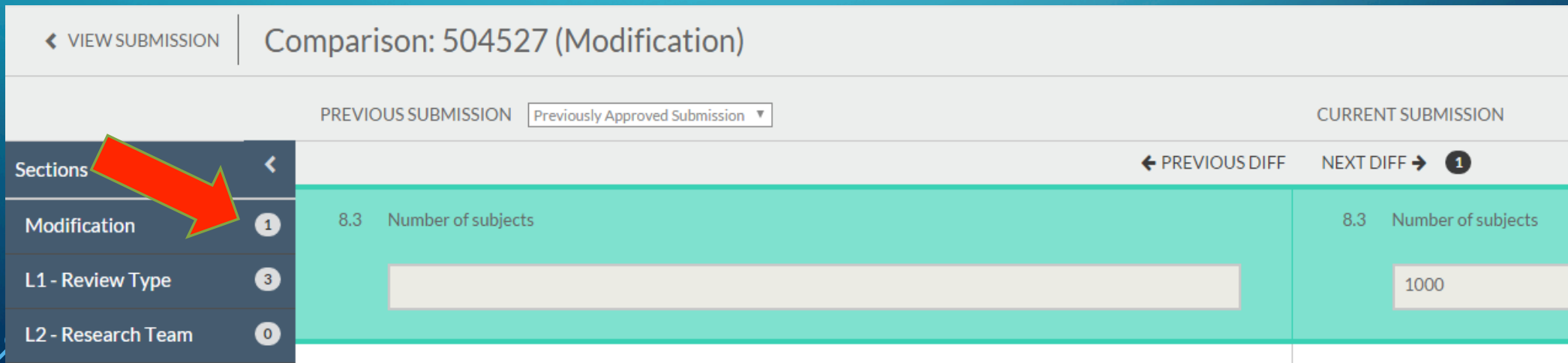


- When all changes have been completed, ensure each section has a green check mark next to it.
- At the bottom of the menu, click on **COMPLETE SUBMISSION**.
- Once confirmed, the modification moves forward for certification.
- Once certified by the PI, the modification submission moves to the HRPP for pre-review.

CREATING A MODIFICATION IN CAYUSE IRB

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.



Comparison: 504527 (Modification)

PREVIOUS SUBMISSION: Previously Approved Submission

CURRENT SUBMISSION

Sections: <

- Modification: 1
- L1 - Review Type: 3
- L2 - Research Team: 0

8.3 Number of subjects

8.3 Number of subjects

1000

← PREVIOUS DIFF NEXT DIFF → 1

CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING A MODIFICATION

STUDY	IRB NUMBER: 504527
Faith-healing	
Sections	<
Modification	✓
L1 - Review Type	✓
L2 - Research Team	✓
L3 - Funding	✓
L4 - Exempt Review	✓
L7 - Rationale	✓
L8 - Human Subjects	✓
L9 - Recruitment Pro...	✓
L10 - Data Collectio...	✓
L12 - Participant Co...	✓
L13 - Privacy, Confid...	✓
L14 - Benefits, Risk, ...	✓
L15 - Conflicts of Int...	✓
L16 - Training	✓
L17 - Additional Info...	✓
L18 - Comments	✓

- 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.

Modification

Cayuse IRB Modification:

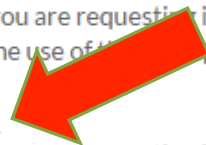
Provide a summary of the changes you are requesting in the text box below. Details of the changes are required in the appropriate sections. The "Compare" feature is a useful tool as you edit each section.

Legacy IRB Modification Option 1:

Provide a summary of the changes you are requesting in the text box below. Details of the changes are required in the appropriate sections. This will allow the PI and the IRB Reviewer the use of the "Compare" feature.

Legacy IRB Modification: Option 2:

Provide a summary of the changes you are requesting in the text box below. Attach a document that incorporates all amendments, if any (a clean copy), and highlight the changes you are requesting now according to your summary.







CREATING A MODIFICATION IN CAYUSE IRB

OPTION 2 – ATTACHING A MODIFICATION

- Complete the summary of changes to be made.

Summary of Changes.

B **I** U    

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 ~~500~~ 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).



* Enter or attach the information sheet.


B **I** U     

See Attached

Attach (if applicable).

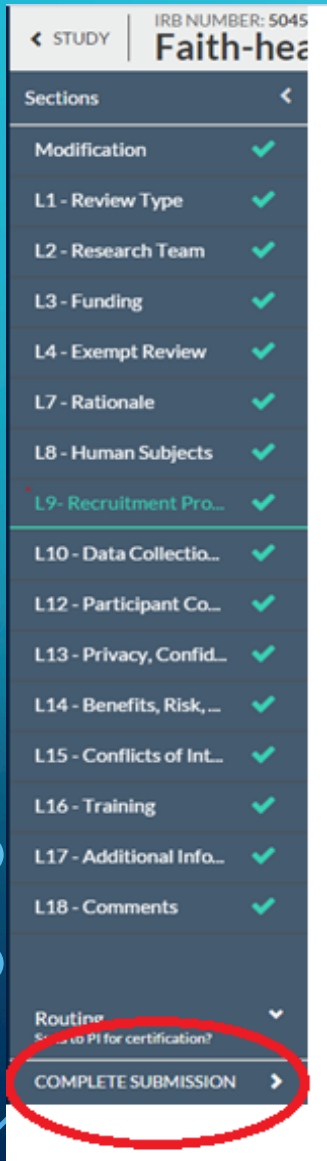
ATTACH

 Proposal.docx | 



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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