

More Information Required

After your submission is reviewed, you will receive a notification that more information is required before your study can be approved. Log into Cayuse and click on your initial submission and click on Edit.

Locating the Comments in your Application

The screenshot shows the Cayuse application interface. At the top, there are navigation tabs: Dashboard, Studies, Submissions, Tasks, and Meetings. Below this, the breadcrumb trail shows 'STUDY' and 'IRB NUMBER: IRB-FY2019-'. The left sidebar contains a list of sections, each with a status indicator (checkmark or speech bubble) and a count of comments. The sections are:

- 1- Basic Information (checkmark)
- 2- Research & Review (checkmark)
- 3- Study Personnel Information (checkmark)
- 4- Study Design & Methods (checkmark)
- 5- Subject Information (checkmark)
- 6- Subject Recruitment (1 comment)
- 7- Study Procedures (2 comments)
- 8- Informed Consent Process (6 comments)
- 9- Study Instruments (1 comment)
- 10- Risks & Benefits (2 comments)
- 11- Protecting the Confidentiality of Your Study (checkmark)

The main content area on the right shows the 'Preparing and Completing the Application' section. It contains text explaining that not all sections need to be finished and that sections with red asterisks indicate required information. Below this, there are two sections with radio button options:

- * TWU Campus: Please select your campus. Note that only one campus can be selected.
 - Dallas
 - Denton
 - Houston
- * Is this activity research?
 - Yes
 - No
 - Unsure

This shows how many reviewer comments you have to address in each section.

Expand Comments

The image shows a screenshot of a study form interface. On the left is a sidebar menu with sections 1 through 11. Section 7, 'Study Procedures', is highlighted in green and has a comment bubble with the number '2'. Section 8, 'Informed Consent Proc...', has a comment bubble with '6'. Section 9, 'Study Instruments', has a comment bubble with '1'. Section 10, 'Risks & Benefits', has a comment bubble with '2'. Section 11, 'Protecting the C...', has a checkmark. The main content area shows two sections: '* Time Commitment' and '* Subject Data, Specimens, and Records'. The 'Time Commitment' section has a text input field containing the text: 'Each interview session will last between 1-3 hours with a maximum time commitment of three hours. We will end the interview due to fatigue, illness, or other reasons.' Below this input field is a comment bubble with the number '1' and the text 'Expand Comments'. The 'Subject Data, Specimens, and Records' section has a question: 'Does this project involve the collection or use of materials, either directly or through identifiers linked to individuals?' with radio buttons for 'Yes' and 'No'. Two red callout boxes with arrows point to the comment bubbles. The first callout points to the '2' bubble in the sidebar and says: 'This comment bubble indicates there are 2 comments total to address in this section.' The second callout points to the '1' bubble below the 'Time Commitment' section and says: 'This shows you that there is 1 comment you need to address for this question.'

Sections

- 1- Basic Information ✓
- 2- Research & Review ✓
- 3- Study Personnel Information ✓
- 4- Study Design & Methods ✓
- 5- Subject Information ✓
- 6- Subject Recruitment 1
- 7- Study Procedures 2
- 8- Informed Consent Procedures 6
- 9- Study Instruments 1
- 10- Risks & Benefits 2
- 11- Protecting the Confidentiality of Your Information ✓

*** Time Commitment**

What is the time commitment for the subjects? Include the maximum time commitment for the subjects.

Each interview session will last between 1-3 hours with a maximum time commitment of three hours. We will end the interview due to fatigue, illness, or other reasons.

1 Expand Comments

*** Subject Data, Specimens, and Records**

Does this project involve the collection or use of materials, either directly or through identifiers linked to individuals?

Yes

No

This comment bubble indicates there are 2 comments total to address in this section.

This shows you that there is 1 comment you need to address for this question.

Addressing Comments

1- Basic Information ✓

2- Research & Review... ✓

3- Study Personnel I... ✓

4- Study Design & M... ✓

5- Subject Informati... ✓

6- Subject Recruitment 1

7- Study Procedures 2

8- Informed Consent Proc... 6

9- Study Instruments 1

10- Risks & Benefits 2

11- Protecting the C... ✓

● Collapse Comments

IRB Reviewer 05-02-2019 12:37 PM
This is time commitment for the subjects not the investigator. The 120 hour needs to be eliminated.
Reply

Sandy Owens 05-10-2019 9:47 AM
Please provide the total time commitment for each participant, not for all participants combined.

08-09-2019 12:40 AM
I say 1-3 hours and deleted the 120 hr commitment.

Addressed 08-09-2019 12:29 AM by [redacted]

*** Subject Data, Specimens, and Records**

Does this project involve the collection or use of materials (data or specimens) records, either directly or through identifiers linked to these individuals?

Yes
 No

1) This is the comment from the reviewer that you are required to address. You can answer questions by replying to the comment. If the reviewer asked you to make changes, be sure to edit your response in the actual text box. Use the bold or underline function to indicate where you made the change(s).

2) Sometimes the analyst has a clarifying comment or an additional comment.

3) The PI can (should) reply here to let the reviewer know that they have made changes.

4) Make sure you address all comments. Do not skip over them. After you make the revisions you must change the status from "Not Addressed" to "Addressed" for each comment. Once you address everything in the section, you will see a green check mark by that section. When you complete all revisions, you can re-submit.