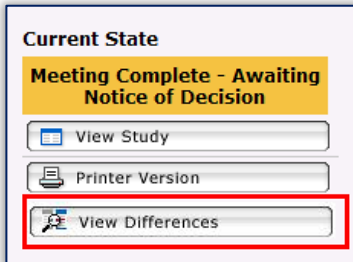


View Changes & Differences in a Study

VIEW CHANGES MADE TO A STUDY

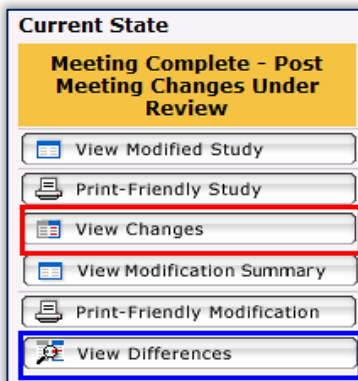
This functionality is used when a PI or Study Team Member want to view the changes that have been made to a study. This can be done in a number of states.

1. Log in to IRISS: <https://iriss.ucalgary.ca/IRISSPROD/login/>
2. You will find the study under your REB Tab. Click on the name of the study to open the Study Workspace.



Certification File (Initial Application):

3. To review the changes, click on **View Differences**, on the left hand side of the Study Workspace.



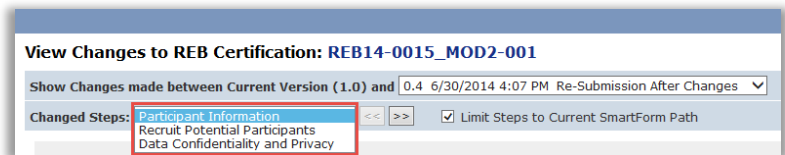
Modification File (Amendment to the Initial Application):

4. To reievw the changes, click on **View Changes**, on the left hand side of the Study Workspace.
5. To review changes made to the Modification Summary form, click on **View Differences**.

6. Click on the drop down arrow to the right of the white box beside **Show Changes made between Current Version (1.0) and**. Select the appropriate version number to review changes made prior to that date. You may have to choose more than one date to see all changes depending on the number of times the study went back and forth between the PI and Reviewing Committee.

1.0	9/17/2014 4:05 PM	Approved Modification
0.6	8/22/2014 4:12 PM	Re-Submission After Changes
0.5	7/11/2014 12:12 PM	Re-Submission After Changes
0.4	6/30/2014 4:07 PM	Re-Submission After Changes
0.3	6/30/2014 4:06 PM	Initial Submission
0.2	6/30/2014 4:05 PM	Modification Created

7. The system will load the pages that have been changed. Click the drop down arrow to the right of **Changed Steps** on the second light blue bar to see the pages that have been changed. Scroll down to see the changes made to the first page noted in the list.



View Changes & Differences in a Study

8. The old value will show underneath the question in the pink box and the new value / wording will show above (new wording will be highlighted in green). **Note:** If the new value is a number or a yes/no response, it may not be highlighted in green.

Participant Information

All questions preceded by a red asterisk () are required responses that map you to the application sections that are relevant to your study. All questions within the section to which you are mapped must be addressed.*

1.0 * Describe the population that will be included in this study:
testing

2.0 * Describe and justify the inclusion criteria for participants:
testing

3.0 Describe and justify the exclusion criteria for participants, if applicable:
testing

4.0 * Will members of the research team be interacting/contacting participants in any way?
 Yes No

Old Value: no

Yes examples include: interventional studies, survey/questionnaire administration, qualitative studies etc.
No examples include: secondary data analysis including health records review, database linkage etc.

5.0 Participants

5.1 How many participants do you expect to recruit (including controls, if applicable)?
100

Old Value: 10

5.2 Of these how many are controls, if applicable?
20

Old Value: 2

5.3 If this is a multi-site study, how many participants are expected to be enrolled by all investigators at all sites in the entire study? (including controls, if applicable)
50

Old Value: 2

6.0 Provide justification for sample size:
Justifications for sample size is:

[None]

7.0 * Does the research specifically target aboriginal groups or communities?
 Yes No

Note: description includes age range, health status, gender, etc.. Justification includes safety, uniformity, research methodology, statistical requirement, etc..

Note: possible answer: Half, Random, Unknown, or an estimate in numbers, etc.

9. To see the next page that was changed, click on the drop down arrow to the right of **Change Steps** and select the next page you want to review or click the << >> arrows to the right of the box.

Continue until you have reviewed all pages and then click **Close** at the top of the page to bring you back to the study workspace.

View Changes to REB Certification: REB14-0015_MOD2-001

Show Changes made between Current Version (0.5) and 0.4 6/30/2014 4:07 PM Re-Submission After Changes

Changed Steps: Participant Information << >> Limit Steps to Current SmartForm Path Close

Reviewer Notes: Recruit Potential Participants

Important! Do not use the **Previous** or **Next** buttons to the right of **Reviewer Notes** on the yellow bar as this will take you out of the View Changes or View Differences and into the study. If you do this by mistake, exit the study and follow the steps above to get back to where you were.

QUESTIONS?

General Inquiries: info@hreba.ca

Technical “how to” Inquiries: iriss.support@ucalgary.ca