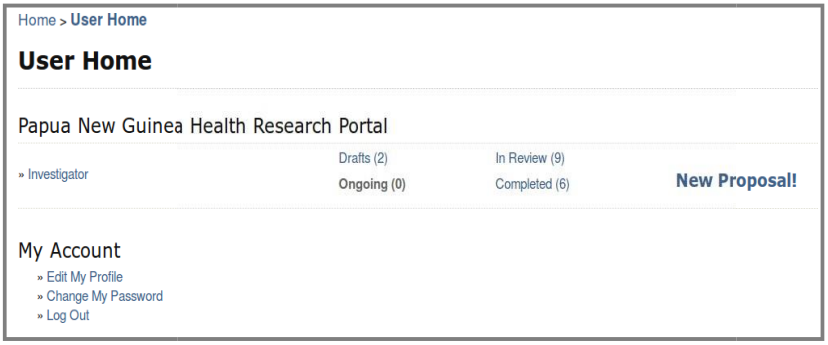
USER MANUAL FOR BHUTAN HEALTH RESEARCH PORTAL

Research Ethics board of Health

1. Investigator / Submitter / WHO Technical Officer

1.1 User Home



Once "logged in", this webpage is available anywhere you are on the website by clicking on the "**User Home**" header tab. All the features related to the investigator role (submitting proposals, tracking reviews, submitting post-approval documents, accessing meeting information) will be accessible through this header tab. On your "User Home" main page you have different action possible:

- You can access to your submissions by clicking on the "**Investigator**" link.
- The "**Drafts**" link shows you how many draft proposals you have. By clicking on it you will also access to your draft proposals. If you don't have any archived submissions this link is inactive.
- The "**In Review**" link shows you how many researches currently under review you have. By clicking on it you will access to your researches under review as to track their review. If you don't have any under review researches this link is inactive.
- The "**Ongoing**" link shows you how many ongoing research s you have. By clicking on it you will also access them and being able to submit your post-approval documents (completion report, protocol amendment, etc.). If you don't have any submissions this link is inactive.
- The "**Completed**" link shows you how many completed researches you have. By clicking on it you will access them. If you don't have any completed researches this link is inactive.
- You can submit a new proposal by clicking the "**New Submission**" link.

The "**My Account**" section allows you to edit your profile information, to change your password or to log out.

1.2Your Submissions

This is the "Proposals" webpage of an Investigator. When you log in you access directly to this webpage. By default, it shows your draft proposals. The top part of this webpage allows you to switch between the different categories of your proposals. The categories are the same as those described in your "**User Home**" with a new category: "**Archive**". Not approved proposals, withdrawn researches and the completed researches you decided to send to this category are considered as "Archived Proposals"

In case of a lot of submissions you may search a submission by using the searching tool on the top of this page. Type a keyword/title and/or frame your search by dates and launch your search by using the "**Search**" button.

You also have on this page a link to start a new submission: "**Click Here**".

PROPOSAL ID	DATE OF SUBMISSION	TITLE	REVIEW ROUND	STATUS
2014.7.MC	April 14, 2014	A TITLE WE CAN REMEMBER	MRAC - Progress Report - 1	Revise and Resubmit RESUBMIT WITHDRAW
—	—	IUBIUB	MRAC - Initial Review - 1	Draft DELETE
—	—	ZEVZEV	MRAC - Initial Review - 1	Draft DELETE

1 - 3 of 3 Items

According to which category you are, different columns are displayed on the list of your proposals:

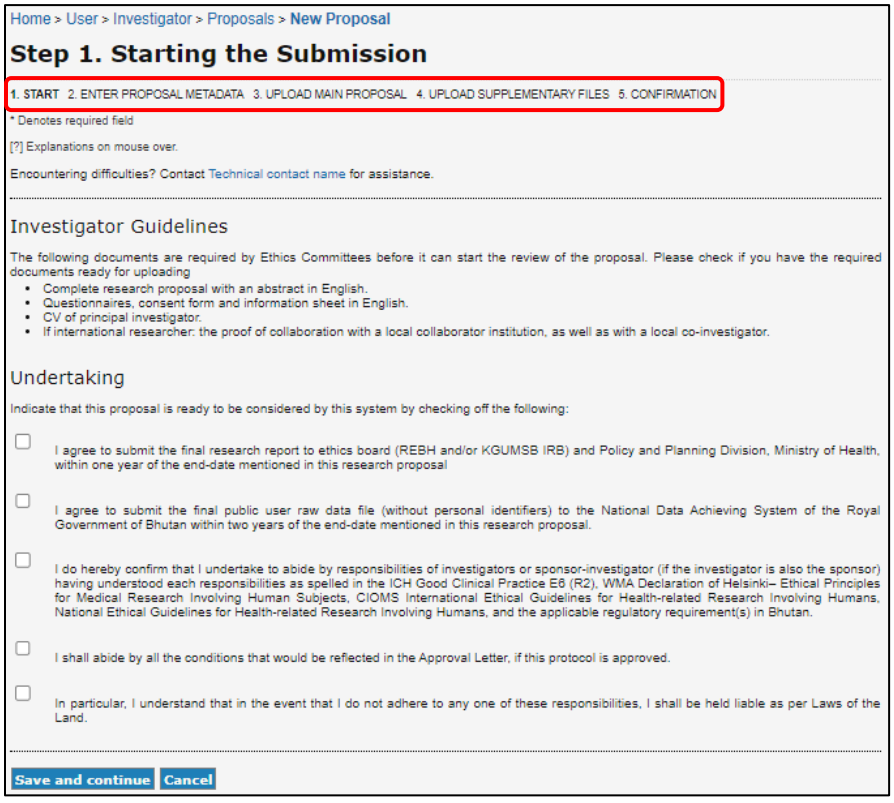
- **PROPOSAL ID**: The identification code of your proposal (for more information see chapter: Miscellaneous – Understanding Proposal's ID).
- **DATE OF SUBMISSION**: The date when you submitted your proposal.
- **TITLE**: The scientific title of your proposal. Please click on the title of a specific proposal to access its specific information.
- **REVIEW ROUND**: The last round of review of your proposal.
- **STATUS**: The review status of the last round of review.
- **ACTION**: Diverse actions you can undertake like submitting a progress report, the final report, a protocol amendment.

1.3 Submitting A New Proposal

You are able to submit a new proposal by using the "**New Submission**" link in your "User Home" webpage or by clicking on the "Click Here" under "**Start a new submission**" in your "Proposals" webpages.

A new submission goes through a five stages process. In all the steps of the submission process, a star ("*") denotes a required field and a question-mark ("[?]") indicates information on mouse over.

1.3.1 Step 1 – Starting the Submission



This page is the first step of a new submission. For reviewing the proposal, the health authority in the country might request you to provide diverse information or document (i.e., final report of the research study, the raw data no later than 12 months of completion of data collection/field work through this system). These are requirements for submitting a proposal. Please read them carefully and check the boxes if you agree.

The "Investigator Guidelines" are here to remind you of the documents you may need to provide with your proposal. Please note that a missing document can result in the non-approbation of your research proposal.

If multiple ethics committees are using this web platform, you will be requested to choose to which committee you want to submit your research proposal.
Your proposal will then be saved into the database as a draft proposal. It will appear in the "Draft proposals" category of the "Proposals" webpage and you will be able to continue the steps of the submission whenever you want. As a "draft" proposal, your submission will not be accessible by anyone.

Please also keep in mind that you can always navigate between the completed steps and correct your information using the links on the top of each step (please refer to red frame of the above example).

If you want to leave this page without saving, please click on the "**Cancel**" button.

1.3.2 Step 2 – Entering the Metadata

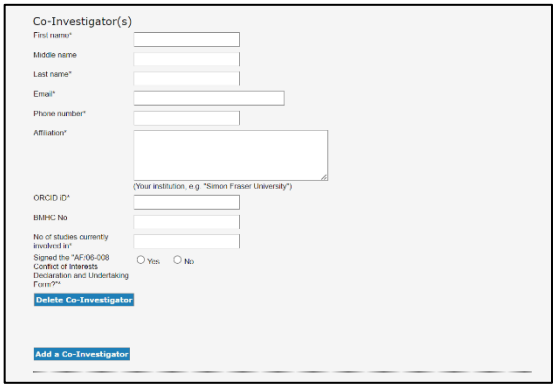
During the step 2 of the submission of a proposal you will be asked to fill the main proposal's metadata. The main proposal's metadata is made up of 3 different parts:

Investigator and Co-INVESTIGATOR (s)

These data concern the submitter of the research. You are asked to fill the name, middle name, last name, e-mail, phone number and affiliation. Most of the time the submitter is the user logged in: you. Therefore, to facilitate your work into this webpage the Health Research Portal automatically fill these fields with your data. If the data is incorrect, you can edit them by clicking on the respective fields. To add a Principal Investigator (PI), click on the "**Add a Principal Investigator**" button. If you are the Principal Investigator, then click on the checkbox "**Submitter is the principal investigator**". Once clicked, the PI details will be pre-filled using Submitter's details.

For the Principal Investigator, the ORCID ID, BMHC No, Number of studies currently involved in and declaration of having signed the "Conflict of Interest" form or not is also a required field.

You may want to add co-investigator(s) for the research. For adding a co-investigator, please click on the "**Add a Co-Investigator**" button. You can add up to 5 co–investigators.



In this case, please fill up the information concerning the Co-Investigator of your research. You can delete a co-investigator by clicking on the "**Delete Co-Investigator**" Button.

Title and abstract and proposal details

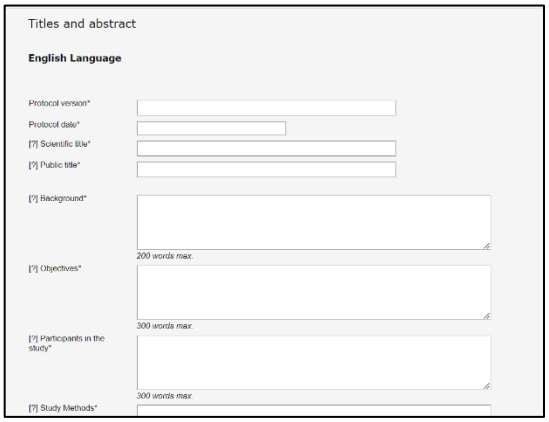
These data concern main explanations of your proposal – for instance protocol version, protocol date, titles, abstract, keywords etc.

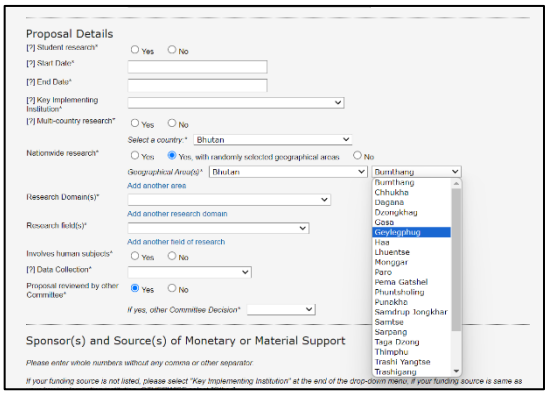
Depending of your responses, some additional required fields may appear (e.g., student research, human subjects involved).

For some other fields you are able to add as much information as you want (i.e., Research Fields or Districts involved). In this case, please click on the "**Add another …**" link under the concerned field or selection menu.

If the proposal is reviewed by another committee, then you will also have to put in what is/was the status of the proposal review – Under Review, Approved or Rejected.

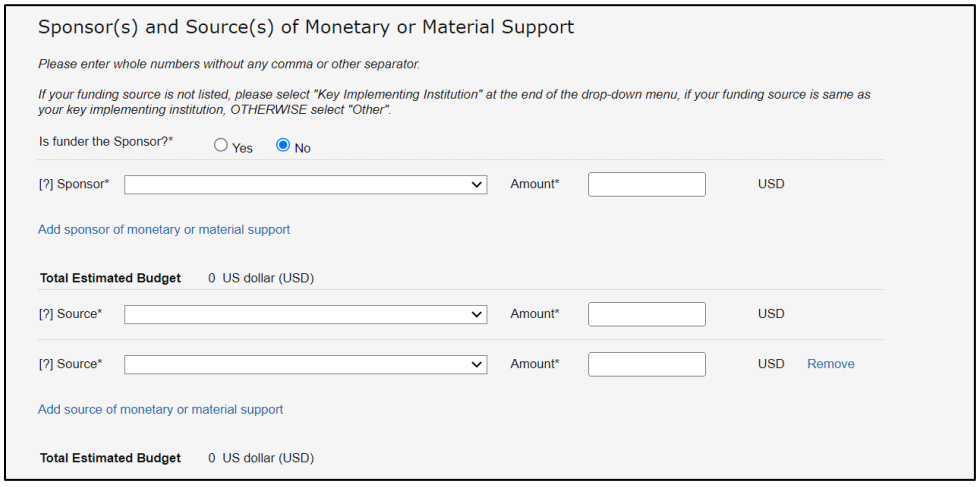
Don't forget that more explanations are available on mouse over.





Source(s) of Monetary or Material Support

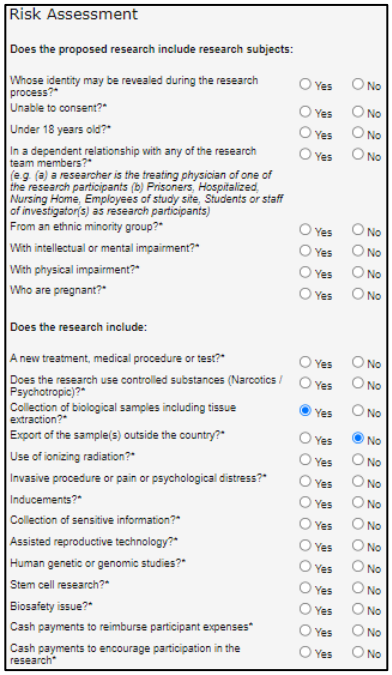
These data concern your source(s) of monetary or material support for your research.

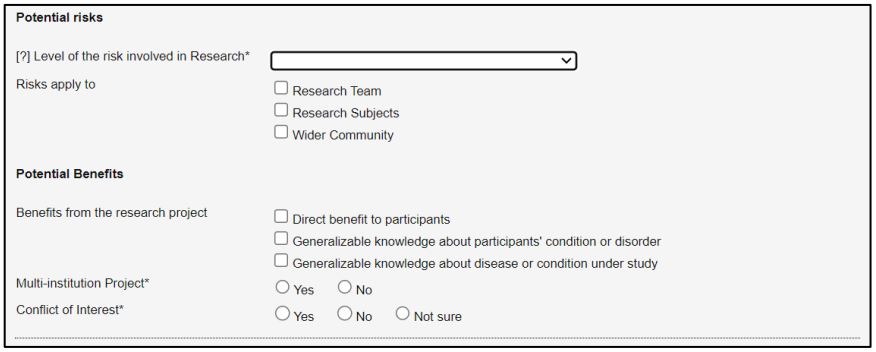


Like the previous section, depending of your answers, some required fields might appear

- Choose if funder is the sponsor. If “No”, then you can choose the Sponsor and Source from their respective dropdowns and type the amount in USD. If “Yes “, then you need to choose only the funding Source.
- If your funding source/sponsor is same as your key implementing institution, then please select “**Key Implementing Institution**” from the dropdown list.
- If your funding source/sponsor is not listed, then please select “Others” and provide the details.
- You can add multiple sources/sponsors by clicking on link provided under the Sponsor or Source sections.

Risk Assessment



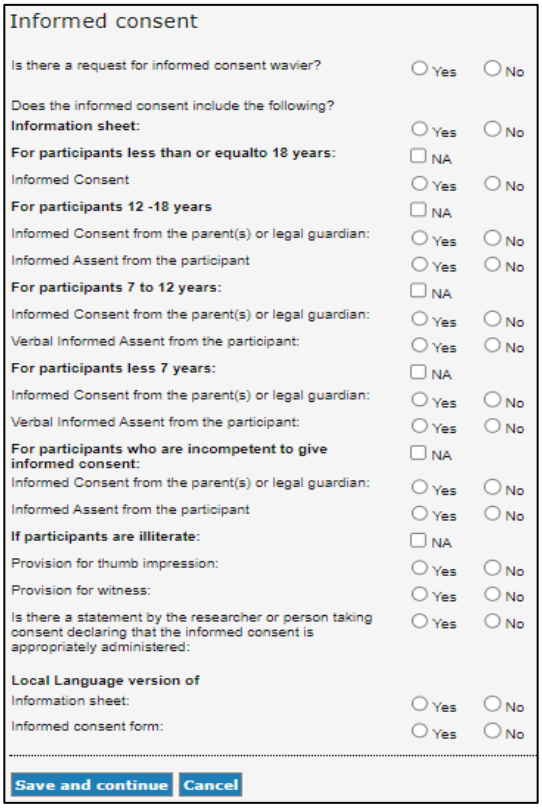


You should be careful when completing this section. By doing so, it helps you to understand all the risks related to your proposal.

Informed Consent

This section is related to all the "consents" being sought under the research.

- For participants less than or equal to 18 years
- For participants between 12-18 years
- For participants between 7-12 years
- For participants less than 7 years
- For participants who are incompetent to give informed consent
- If participants are illiterate



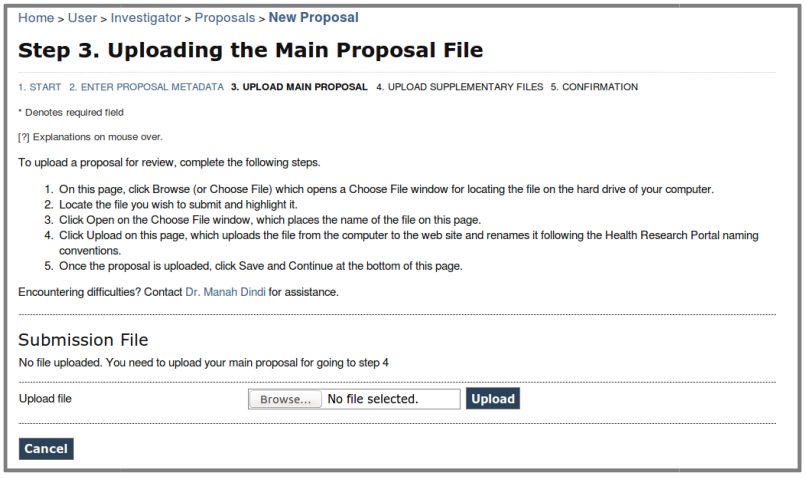
Local Language version of consents documents may also be captured

Click on the "**Save and continue**" button for saving your proposal and continuing this submission. Like all the steps of the submission process, once your proposal saved you can get back to it whenever you want.

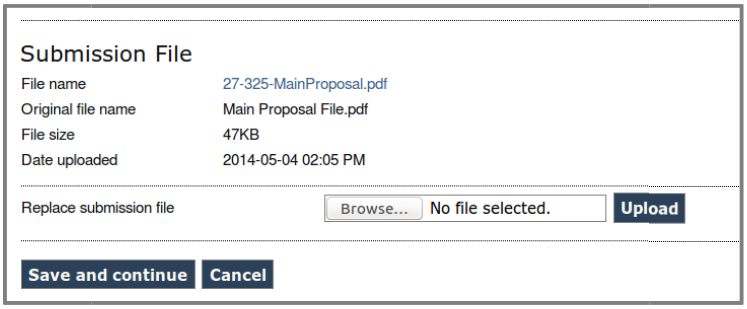
If you want to leave this page without saving, please click on the "**Cancel**" button.

1.3.3 Step 3 – Uploading the Main Proposal File

In the third step of a new submission, you must upload the main proposal file:



Please follow the instructions on the screen in order to upload your file. If no file has been uploaded the "**Save and continue**" button doesn't appear.

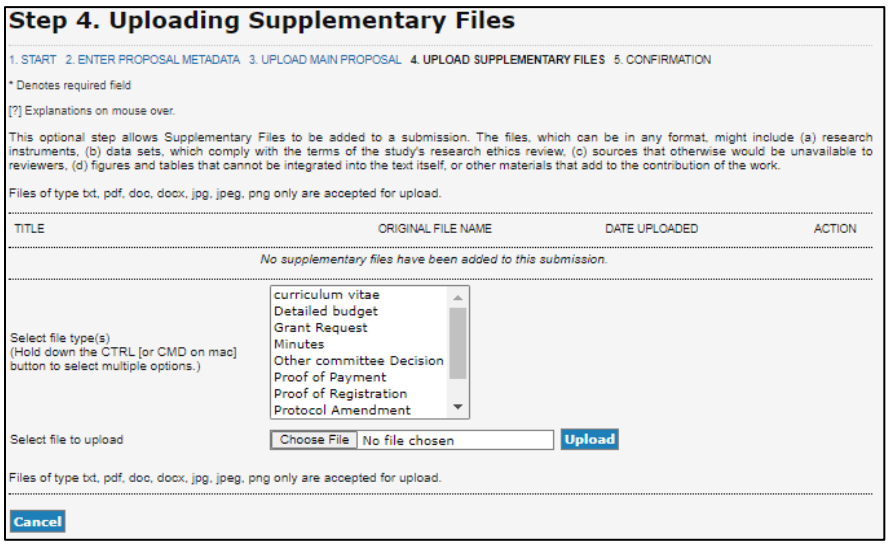


Once your file is uploaded you see it on the page. At this step you can upload only one file. You will be able to upload supplementary files during the step 4. If you want to replace the file uploaded, please do same steps as before.

Click on the "**Save and continue**" button for saving your proposal and continuing this submission. If you want to leave this page without saving, please click on the "**Cancel**" button.

1.3.4 Step 4 – Uploading Supplementary Files

This optional step allows you to add supplementary files to your proposal.



You firstly need to select the type of file you want to upload. Selecting multiple options is possible by holding down the "CTRL" button of your keyboard (or "CMD" button if you are using a Macintosh) and clicking on desired options. If you select "Other" on this menu a new field appears on its right. In this case, please specify the file type you want to upload.

As in step 3, for uploading a supplementary file you need to open a "Choose File" window by clicking on the "Browse" button, to locate your file and to upload it with the "Upload" button.

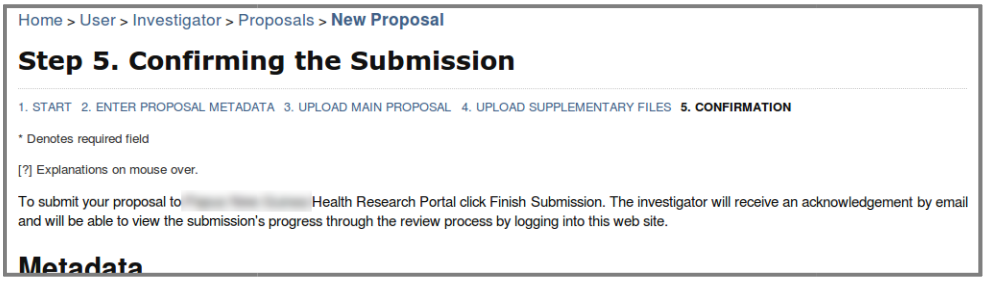
Each supplementary file uploaded will appear into the table above the "file type" selection menu:

TITLE	ORIGINAL FILE NAME	DATE UPLOADED	ACTION
Summary	Summary Of My Proposal.pdf	05-04	DELETE
Informed Consent	Consent form and Information sheet.pdf	05-04	DELETE
Questionnaires	Questionnaires.pdf	05-04	DELETE
Questionnaires	Questionnaires.pdf	05-04	DELETE
Other Committee Decision	Other ERC Decision for My Proposal.pdf	05-04	DELETE
Curriculum Vitae	CV of the principal investigator.pdf	05-04	DELETE

In this example, 6 files have been uploaded. The table provide their title, their original file name and their date of upload. If ever you want to remove an uploaded file, please you use the "Delete" link on the right of the table.

Click on the "Save and continue" button for saving your proposal and continuing this submission. If you want to leave this page without saving, please click on the "Cancel" button.

1.3.5 Step 5 – Confirming the Submission

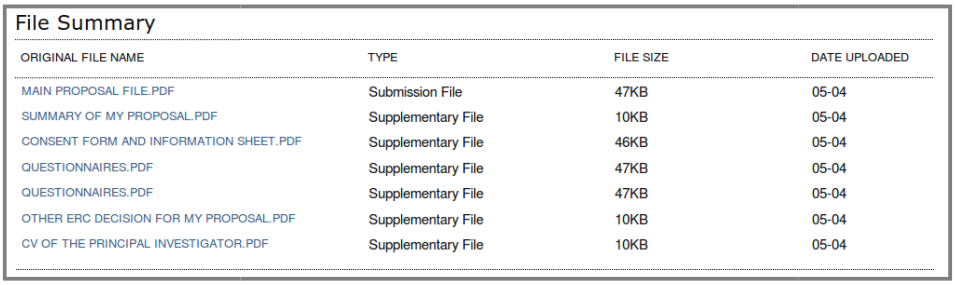


The step 5 of the submission process allows you to check every data you provided to the Health Research Portal before submitting your proposal to review. If you want to modify your data you can go back to any step you want by clicking on its name (see above screenshot).

This last step is composed of 3 main parts:

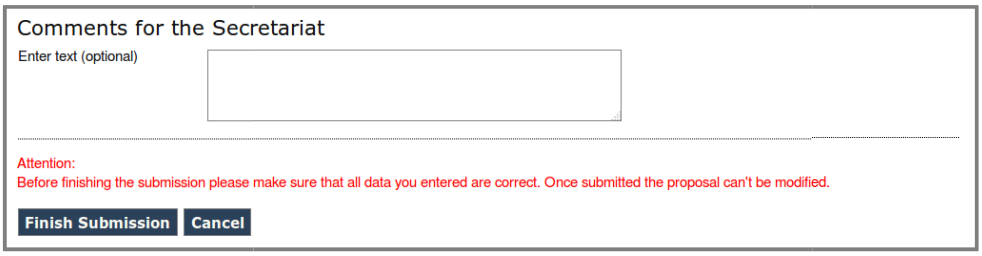
- The "**Proposal Details**" part sum up your proposal metadata provided in step 2

- The "**File Summary**" sum up your main proposal file and your supplementary files if you added some


File Summary

ORIGINAL FILE NAME	TYPE	FILE SIZE	DATE UPLOADED
MAIN PROPOSAL FILE.PDF	Submission File	47KB	05-04
SUMMARY OF MY PROPOSAL.PDF	Supplementary File	10KB	05-04
CONSENT FORM AND INFORMATION SHEET.PDF	Supplementary File	46KB	05-04
QUESTIONNAIRES.PDF	Supplementary File	47KB	05-04
QUESTIONNAIRES.PDF	Supplementary File	47KB	05-04
OTHER ERC DECISION FOR MY PROPOSAL.PDF	Supplementary File	10KB	05-04
CV OF THE PRINCIPAL INVESTIGATOR.PDF	Supplementary File	10KB	05-04

- If you would like to add a comment for the secretariat of the Ethical Committee you chose, please fill the "**Comments for the Secretariat**" field.



You can submit your proposal to review by clicking on the "Finish Submission" button. But be careful. Once your proposal submitted you are not able to modify it anymore.

If you want to leave this page and to keep this proposal as a draft please click on the "Cancel" button. All data you entered will be saved and you will be able to finish your proposal by coming back to your "Submissions" webpage.

1.4 Post-Submission Actions

Once your proposal submitted, diverse events can require you to operate the concerned actions through the Health Research Portal. This is the case if, for example, you need to resubmit your proposal to the committee, to submit your final report, or to amend your proposal.

1.4.1 Re-Submission

The committee in charge of reviewing your research proposal, your report or your amendment, might decide that your submission is incomplete (or required some revision) and you should re-submit it. In that case, your proposal is automatically placed in your "Draft Proposals" (please refer to the chapter "2.1 User Home").

Under the status of the concerned proposal, you will see a "**Resubmit**" link. Depending of what is concerned by the review, you will be re-directed to the related webpage.

For example, if the decision of the committee concerns the initial review of your proposal, you will be guided through the 5 steps of the submission process where you will be able to modify the metadata or the files of your research proposal. In contrast, if the decision concerns your progress report, you will be able to upload a new one.

1.4.2 Post-Approval Amendment

During the progress of your research, you might need to amend some of its protocol details. If this is the case, you need to inform the committee in charge of your research and seek a new approval.

Because you are currently doing your research, you will find it in your "Ongoing researches" (please refer to the chapter “2.1 User Home”). Under the "Action" column, you will see diverse links, including "**Protocol Amendment**". Please be careful to choose the correct research as this action cannot be undone.

The protocol amendment consists in going through the 5 steps of the submission process again and modifying the metadata and/or files. However please be careful to the guidelines provided on the of the steps. You might be required to upload additional documents or to provide specific information. Once the step 5 completed, your research will go through a new round of review by the concerned committee. You will therefore find it on your "Proposals under review" category.

1.4.3 Progress / Final Report

During your research or at its end, you will need to provide to the committee in charge a progress or a final report.

Because you are currently doing your research, you will find it in your "Ongoing researches" (please refer to the chapter “2.1 User Home”). Under the "Action" column, you will see diverse links, including "Progress Report" and "Final Report". Both of these links will redirect you to the upload page of report. Before uploading the report, please read carefully the instructions provided by your committee.

Only one document can be uploaded. If your report is composed of multiple documents, please merge them into one before the upload.

Once uploaded, your research will be subject to a new round of review by your committee.

Special considerations for the final report:

Once your final report approved, this one will be automatically made publicly available through this system. Although you will then have the possibility to modify it, we recommend you to ensure the quality of your report.

Because you research is now completed, you will find it under your "**Completed researches**".

1.4.4 Modifying Your Final Report

This chapter considers that your previous final report for the concerned research has been approved by your committee. If not, please refer to the chapter "2.4.1 Re-submission".

Because your previous final report has been approved, you will find your research under your "Completed researches" category (please refer to the chapter "2.1 User Home"). Under the "Action" column, you will see diverse links, including "**Modify Final Report**". You will be requested to upload your new final report. Once this one submitted, it will be subject to a new round of review by the concerned committee

1.4.5 Withdrawing a Proposal

If your research is considered as a "Draft", "Under Review" or "Ongoing", you are able to withdraw it. Under the column action of the concerned category, you will find a link "**Withdraw**". You will be requested to provide a report and/or to specify the reason of this withdrawal.

NOTE TP INVESTIGATORS

****Note: All related files should be combined as single file. For example, the CV of investigators should be combined into a single file and submitted as one single document instead of multiple files.***