

Ethics Monitor user manual for applicants

Department : ERS
Date : December 2022
Version : 2

Table of contents

<i>Table of contents</i>	2
Preface	3
1 Writing and submitting an application	4
1.1 <i>Starting a new application</i>	4
1.2 <i>Uploading files</i>	5
1.3 <i>Sharing the application with co-applicants</i>	5
1.4 <i>Saving and returning to a draft</i>	6
1.5 <i>Submitting the application</i>	6
2 Receiving and responding to a review	7
2.1 <i>Receiving the review</i>	7
2.1.1 <i>Viewing the committee's review</i>	7
2.2 <i>Responding to the review</i>	8
2.2.1 <i>Editing the application</i>	8
2.2.2 <i>Responding to reviewers' comments</i>	8
2.2.3 <i>Re-submitting the application</i>	9
3 Amendments and copies of approved applications	10
3.1 <i>Amendments</i>	10
3.2 <i>Copies</i>	10
4 Navigating the Ethics Monitor	11
4.1 <i>Home screen and dashboard</i>	11
4.2 <i>The application record</i>	12
4.2.1 <i>Actions</i>	12
4.2.2 <i>(Draft) application form</i>	13

Preface

This guide is intended as an overview of the functionalities available in Ethics Monitor. It does not contain information pertaining to any specific ethics committee.

Please be aware that the average processing time of applications that require full review is between 2 to 4 weeks, and that most committees require you to upload supplementary documentation, such as a [Data Management Plan \(DMP\)](#) and [informed consent forms](#).

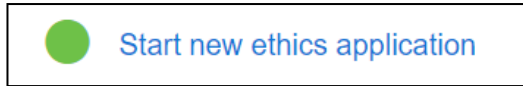
For the procedures of the different ethics committees, please consult the [ERS-website](#). Here you can also find contact details of the committee secretary. Please contact them for any questions regarding Ethics Monitor.

Internal Review Boards (IRBs) and Research Ethics Review Committees (RERCs) will be referred to as "(ethics) committee" throughout this document.

1 Writing and submitting an application

1.1 Starting a new application

On the [home screen](#), you can immediately start a new application.



If your School has more than one ethics committee, you first need to select to which committee you want to submit your application. Please consult the MyEUR page of your committee for this.¹

The application form questionnaire is divided into tabs. By clicking on "save and continue" at the end of the page, you will continue to the next tab. Alternatively, you may also switch to specific tabs by clicking on them (above and below the questionnaire).

Please, note that certain answers to the questionnaire may prompt additional questions or tabs.

Mandatory questions are highlighted with a red asterisk. Sometimes, the asterisk only appears after using "save and continue", since whether the question is mandatory or not depends on the answer to a previous question.

Block A: guidance & shortlist A: Prior ethical review A: Researcher details A: Research project details

A: Type of research A: Contingency questions Longlist Block B: follow-up questions based on shortlist

Block D: data collection about human subjects D: Participants and location D: Risks for participants

F: Supplementary documentation - Data Management

F: Supplementary documentation - Informing participants (and third-parties)

A: Type of research

(A16) Does your research involve data collection? *

Yes No

(A17) Will you be collecting data among human subjects, requiring their active participation? *

e.g., (ethnographic) interviews, focus groups, surveys, experiments.

Yes No

(A18) Will you be collecting data about human subjects, observing and analysing offline or online behaviours? *

e.g., content analysis of web threads or social media content or participatory or observational research.

Yes No

(A19) Does your research involve existing data owned by a third-party research body? *

e.g., data derived from archives or census data.

Yes No

(A20) Does your research involve content analysis of books and articles? *

Yes No

Block A: guidance & shortlist A: Prior ethical review A: Researcher details A: Research project details

A: Type of research A: Contingency questions Longlist Block B: follow-up questions based on shortlist

Block D: data collection about human subjects D: Participants and location D: Risks for participants

F: Supplementary documentation - Data Management

F: Supplementary documentation - Informing participants (and third-parties)

¹ If you are connected to an institute or department within EUR that does not have its own ethics committee, you will be able to access all application forms. If this is the case, please contact ethics@eur.nl for advice on how to continue.

Some questions contain additional **guidance notes**. By clicking the i-icon to the right of the question, additional information will be displayed.

(D3) Do you obtain consent from a 'gatekeeper'? *

Yes No i

In case of participant observation within the walls of an institution (or for instance on a website), consent needs to be sought from the one responsible for the institution.

1.2 Uploading files

Supporting documentation can be uploaded within the form wherever there is the option to "Drag files here or choose file". Multiple files can be uploaded in this file upload area. There is no limitation on the file format.

Examples of types of documents that you may be asked to upload are:

a Data Management Plan (DMP), consent form/information letter, privacy assessment, survey questionnaires/topics lists, project description/proposal.

Tip: make sure that you have all the required documentation ready before starting your application. The MyEUR page of your ethics committee usually has more information on this.

1.3 Sharing the application with co-applicants

At the start of the application, you can add the names of the researchers involved in the project. Any EUR researcher added is considered a co-applicant. Co-applicants will receive access to the application and will be able to edit and submit it.

(A9) Researcher

Researcher(s) involved

Mr Carey Atkins Remove

Ms Allene Iqbal Remove

h

Mrs Hyacinth Briggs (Erasmus School of Law)

Mr Harvey Dean

Mr Hastings Gardner

Mr Harris Gill (Erasmus School of Health Policy & Management)

Mr Quinn Hammond (Erasmus University Rotterdam)

Mr Towney Hanson (Rotterdam School of Management, Erasmus University)

Mrs Tildi Hart

Mrs Doti Higgins

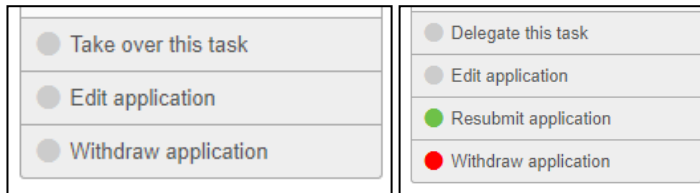
Ms Ania Hill

Mr Albatros Holloway

i

To access the application, the co-applicant needs to go to the application record screen and click "Take over this task". Alternatively, you can request your co-applicant to take over the application by clicking "delegate this task".

Please note that whoever creates the application will automatically be listed as principal investigator.



1.4 Saving and returning to a draft

Your application is saved automatically. You can exit anytime by either clicking "save for later" at the end of the application form, or "back" at the top left. At any time, you can continue the application by clicking "edit application" on the application record screen [\[see 4.2\]](#).

1.5 Submitting the application

Upon completing the questionnaire, you will be asked to confirm that you have answered all the questions truthfully before the application can be submitted. Please note that after submitting the application you will not be able to make any more changes.

2 Receiving and responding to a review

2.1 Receiving the review

After the application has been submitted, its status will change into "Awaiting [school] Research Ethics Review Committee meeting". This means that the application is currently under review.

There are three possible outcomes following a review:

- *Approved*: the research can start.
- *Amendments required*: the committee has questions or comments regarding the application. These need to be addressed, and changes need to be made accordingly. Please note that after resubmission, the ethics committee may ask for additional clarifications.
- *Not approved*: On rare occasions, the committee may not approve an application due to serious concerns about quality or integrity that could not be resolved. If your application is not approved, you are welcome to submit a new, improved application after consulting the ethics committee.

If the committee has made a decision about the application, you will be notified of this through an email from ethicsmonitor@eur.nl. Any action that may be required of you will be described in this email.

2.1.1 Viewing the committee's review

The ethics committee can share its feedback in three different ways:

- "Amendments required" letter
- Inline comments
- Notes

The "**amendments required letter**" is used to notify applicants that the ethics committee has reviewed the application and has comments or questions that need to be addressed before approval can be granted. In this letter, the committee may leave (general) feedback. You will receive the "amendments required letter" via email, but it can also be accessed and downloaded via the application record [\[see 4.2\]](#).

Inline comments are used to give feedback or ask questions related to specific answers in the application form. When editing the application, inline comments will be shown automatically. A speech bubble icon appears next to each tab with a comment.

A: Prior ethical review A: Researcher details A: Research project details ● A: Type of research
A: Contingency questions F: Supplementary documentation - Data Management
F: Supplementary documentation - Informing participants (and third-parties)


(D3) Do you obtain consent from a 'gatekeeper'? *

Yes No

Anonymous Reviewer 15 Aug 2022, 17:04

How will you gain access to the research site without gatekeeper consent?

Notes may be used for quick correspondence between the committee and the applicant. A note can also be used to share the committee's feedback. Notes are shown in the application timeline on the application record screen [\[see 4.2\]](#).

Application timeline	
 Ethics Approval	
Waiting for more information	
Ania Hill started the Ethics approval process	15 Aug 2022, 16:48
Ania Hill confirmed statements - view...	15 Aug 2022, 16:53
Ania Hill submitted the Ethics application	15 Aug 2022, 16:53
Chelsea Newton added a note: How will you gain access to the research site without gatekeeper consent?	15 Aug 2022, 17:05
Chelsea Newton requested more information	15 Aug 2022, 17:05

2.2 Responding to the review

2.2.1 Editing the application

After receiving the review, you can access the application by clicking "edit application" on the application record screen [\[see 4.2\]](#). Any changes made to the application will be tracked automatically and are visible to the ethics committee. [\[See 4.2.2\]](#) on how you can view changes and compare different versions of the application.

2.2.2 Responding to reviewers' comments

In some instances, it might not be possible to make all changes that the committee has requested – either because there is no room for this in the application form, or because you do not agree with certain comments.

In this case, it is advisable to provide information as to why a reviewer's comment was not addressed.

There are two options for this:

- Inline comments
- Notes

Inline comments can be used to address specific comments in the application form. You can post inline comments on the overview page of your application [\[see 4.2.2\]](#) Please note that inline comments cannot be posted in an application that is being edited (i.e., in a "draft application"). Only before editing an application, or after resubmitting it, are you able to post inline comments.

Notes can be posted at any stage of the review process. You can use this option either while editing an application or after resubmitting it.

(D3) Do you obtain consent from a 'gatekeeper'?

No

Since the research site is openly accessible, I don't think gatekeeper consent will be necessary.

Comment will not be visible to the applicant cancel Save comment

Anonymous Reviewer 15 Aug 2022, 17:04

How will you gain access to the research site without gatekeeper consent?

2.2.3 Re-submitting the application

When all feedback has been processed (either by making changes in the application or addressing feedback in the inline comments or notes), the application can be resubmitted in the same way that you submitted the initial version of the application.

The ethics committee will then check whether all feedback has been sufficiently addressed. If so, the application will be approved. However, based on the changes made, it is also possible that the committee may ask for further clarifications or amendments.

When the application is approved, you will receive an approval letter via email from ethicsmonitor@eur.nl. This letter can also be accessed and downloaded via the application record [see [4.2](#)]

3 Amendments and copies of approved applications

3.1 Amendments

Following approval of the ethics application, an amendment can be submitted to obtain approval for changes to the research project. Generally, when changes are made to the research project that would require a second look by the ethics committee, an amendment needs to be submitted.

The amendment form can be accessed on the application record screen of the approved application. Click "submit an amendment" on the right-hand side.

A new application is created where you are asked to describe the change in a text field and/or upload relevant documents. The amendment is then submitted and processed in the same way as the original application.

In case you would like to submit an amendment that concerns multiple elements of the application form, it is recommended to use one of the copy options.

STATUS Approved
<input checked="" type="radio"/> Submit an amendment
<input type="radio"/> Copy for a similar application (linked to original or latest copy)
<input type="radio"/> Copy as a new application (not linked to the original application)

3.2 Copies

To copy an approved application, go to the application record and select one of the "Copy [...]" options on the right-hand side.

Copy for a similar application

- It is recommended to use this option for major amendments to a project.
- The copied application remains linked to the original application (for your and the committee's reference).
- Changes to the original application are visible to the ethics committee.
- It is not possible to make another copy or submit an amendment of the original application. Only the copy can be used for this.

Copy as a new application

- It is recommended to use this option for a new, but distinct project that is very similar to a project that was previously approved.
- There is no link between the copied and original application.
- Changes to the original application are visible to the ethics committee.
- It is possible to make another copy or submit amendments of both the original and the copied application.

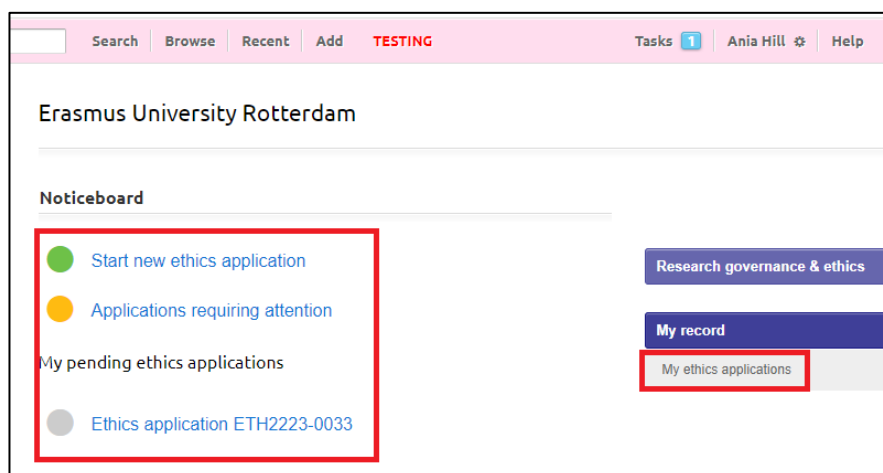
4 Navigating the Ethics Monitor

4.1 Home screen and dashboard

The home screen of Ethics Monitor displays a number of options:

- Starting a new application
- Viewing pending application
- An overview of applications that require your attention

On the right-hand side, "My ethics applications" shows you an overview of all your completed, pending and withdrawn applications.



4.2 The application record

When you select an application, you are directed to the **ethics application record page**. This page shows all information and actions related to this application:

- Key information about the application in the center
- The application timeline below
- Various action related to the application on the right (these actions may change based on the status of the application)

Ethics application ETH2223-0033

Ethics application (Start)

Title	Ethics application ETH2223-0033
Application ID	ETH2223-0033
Researcher	Ms Ania Hill
Date	15 Aug 2022
Academic year	2022 - 2023
Ethics reviewers	DPAS Research Ethics Review Committee

Application timeline

Ethics Approval	
Waiting for researcher to make amendments	
Ania Hill started the Ethics approval process	15 Aug 2022, 16:44
Ania Hill confirmed statements - view...	15 Aug 2022, 16:47
Ania Hill submitted the Ethics application	15 Aug 2022, 16:47
Noemi Peters requested amendments to be made	15 Aug 2022, 16:47
Noemi Peters sent a formal notification to the researcher	15 Aug 2022, 16:47

STATUS
Waiting for researcher to make amendments

CURRENTLY WITH
Ania Hill

- Edit application
- Resubmit application
- Withdraw application

APPLICATION
Ethics application

NOTIFICATIONS
Amendments

Download printable PDF...

Add note

4.2.1 Actions

The specific options that are displayed here may change based on the status of your application:

Status: shows in what stage of the review process the application currently is (either requiring attention from you, or from the ethics committee).

Processing buttons: these options depend on the status of the application.

- When the application is pending: edit, (re)submit or withdraw your application
- After the application is approved: submit an amendment or copy the application here [\[see 3\]](#).
- If you are co-applicant, you can take over the application by clicking "take over this task" in order to edit/submit it. Or you can delegate the application to a co-applicant by clicking "delegate this task" [\[see 1.3\]](#).

Ethics application / draft application: An overview page of the application.

Notifications: Letters from the ethics committee, including the approval letter. You can also download the letters as a PDF.

Download printable PDF: Download the entire application form as a PDF file.

Add note: You can add a note that will appear on the application timeline. Everyone who has access to the application (i.e., co-applicants and ethics committee members) can view this message. This option can be used to provide clarification or additional information. Recent notes also appear in automated emails regarding the application.

4.2.2 (Draft) application form

The (draft) **application form** is accessible through the application record screen and shows the answers that you have provide to the ethics questionnaire. It also contains all the documents that were uploaded to the application.

Inline comments

You can post (“inline”) comments in the application form by clicking the text balloons. Generally, reviewers will use this option to comment on an application. You, as applicant, can also use this option to respond to reviewers’ comments. You cannot post inline comments when the application is in draft stage [see 2.2.2].

Ethics ETH2223-0033: Ms Ania Hill : Application

Title Improving quality

Principal Investigator Ms Ania Hill

Guidance

I have read and understand the above listed documents.

I have discussed my project with at least one staff member, namely:

John Doe

Prior ethical review

Has the same or a highly similar research proposal been approved by an EUR Research Ethics Review Committee or a non-EUR Research Ethics Review Committee?

No

Do you need ethics approval for a (targeted) journal?

No

Do you need ethics approval for a (targeted) funding organization(s)?

No

SECTIONS

- [Guidance](#)
- [Prior ethical review](#)
- [Researcher details](#)
- [Research project details](#)
- [Type of research](#)
- [Risks to the researcher\(s\)](#)
- [Location](#)
- [Power relationships](#)
- [Data management and privacy approval](#)
- [Closing details](#)

VERSIONS

- 15 Aug 2022 (Ania Hill)
- 15 Aug 2022 (Ania Hill)
- 15 Aug 2022 (Ania Hill)

Application versions

A new version of the application is created each time an application is edited and resubmitted. Previous versions of the application will be listed and can be accessed on the right-hand side of the application form (under “Versions”).

Viewing comments and changes

Inline comments and changes to the application can be viewed by using the “show comments” and “show changes” buttons at the top of the application form, possible in combination with “filter questions”. Any changes made to the first version of the application are highlighted in green, with deleted text highlighted in red. When there are more than two versions of the application, by default only the changes to the latest version are shown. Changes to older versions can be viewed by selecting a different version in the drop-down menu next to the “changes from” button. Now *all* changes from that version onwards are visible.