Research Dashboard UHasselt: manual

Introduction

All studies/projects/programs with health science practices or medical and pharmalogical procedures (in this manual referred to as 'study' types) conducted within the UHasselt, need to be submitted and approved through the Research Dashboard of UHasselt before the start of the study. If there is doubt to which ethical committee the study needs to be submitted, reach out to ctu@uhasselt.be.

For each of the following study types, a specific approval procedure is implemented in the Research Dashboard:

- Prospective study (experiment)
- Clinical trial (investigational product), clinical investigation (medical device), performance study (in vitro diagnostic medical device)
- Retrospective study, case report
- Project related to services of participating departments, advertisement, internal quality and/or project using only anonymous questionnaires: fast tracks are available
- Study with secondary use of human bodily material (biobank)
- Quality-related study on behalf of a governmental institute

The Research Dashboard is a joint realisation of the clinical trial unit (CTU) and ethics committee (EC) of UHasselt. This manual describes the functioning of the Research Dashboard and contains instructions to guide users through the approval procedures. The Research Dashboard is built exclusively in English and can be reached at https://researchdashboard.uhasselt.be/ .

In case of questions or problems, please contact the CTU through CTU@uhasselt.be or contact one of the following members of the CTU:

Coordinator		
Cindy Rochus	Cindy.rochus@uhasselt.be	+32 11 26 92 40
CTU Legal advisor		
Mila van Limpt	Mila.vanlimpt@uhasselt.be	

1. Access to the Research Dashboard

To initiate the approval process for a study at UHasselt, researchers and sponsors need to submit a request through the Research Dashboard of UHasselt. The Research Dashboard is accessible through the following link: https://researchdashboard.uhasselt.be. Access to the dashboard is safeguarded with multi-factor authentication. All access will require either an authenticator app or an SMS authentication.

The link to the Research Dashboard will lead to the following landing page:
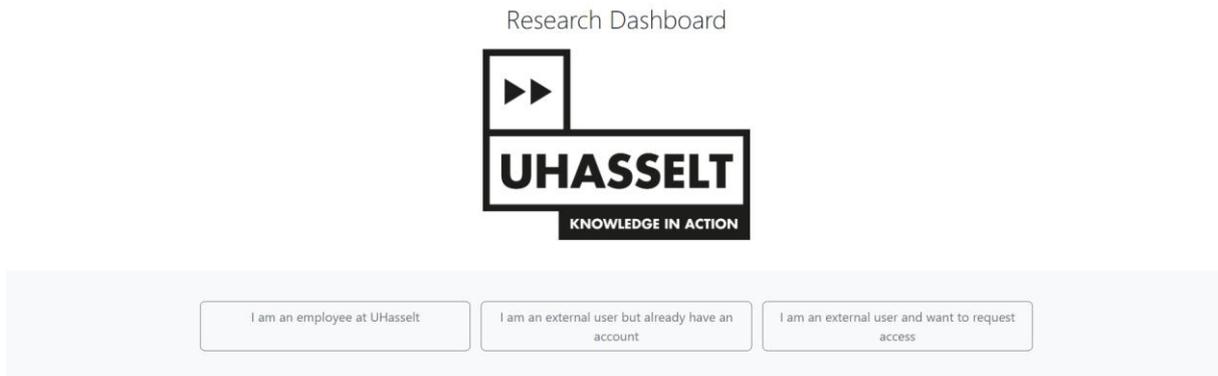
The procedure to obtain access differs depending on the user being internal or external.

1.1. Internal users

All persons with an active account within UHasselt, i.e., all employees, are granted automatic access to the Research Dashboard, after selecting the option 'I am an employee at UHasselt'.

If internal users are logged into a UHasselt laptop or PC, the login to the Research Dashboard will be done automatically. Outside of UHasselt, the login can be done by using the users' UHasselt email address and corresponding password, followed by multi-factor authentication.

1.2. External users

External users, e.g., students, monitors/clinical research associates (CRAs) and employees of a sponsor, a contract research organization (CRO) and/or other participating sites, have two options to obtain access to the Research Dashboard.

Option 1: By requesting access

External users can request access to the Research Dashboard by clicking on the option 'I am an external user and want to request access'. The user will need to provide his/her first name, last name, email, mobile phone, company and a reason for the access request (e.g., study title and local Principal Investigator of the study the user wants to create). Please do not use a generic email address and ensure to provide the mobile phone number in the correct format.

The CTU of UHasselt will review the user's information. If applicable, the CTU will grant access to the Research Dashboard.

Upon approval of the CTU, the external user receives a confirmation email with login information. To log into the Research Dashboard, the user should now select the option 'I am an external user but already have an account'.

Option 2: By invitation from a registered user

An external user can be invited to the Research Dashboard by a previously registered user. To request access for an external user, the previously registered user should click on 'Invite person' in the left-hand column of the Research Dashboard and fill in the external user's first name, last name, email, mobile phone and company. Please do not use a generic email address and ensure to provide the mobile phone number in the correct format.

Alternatively, multiple persons can be invited simultaneously to the Research Dashboard by uploading an Excel file containing the required information, allowing an efficient registration. For more information, please contact ctu@uhasselt.be .

Upon submission of an invitation request, the user's account will be automatically created without the need for approval by the CTU. Subsequently, access to a study can be granted by adding the user to a custom actor type in the 'Actors' tab (see section 6.3) of the respective study.

The external user receives a confirmation email with login information. To log into the Research Dashboard, the user should now select the option 'I am an external user but already have an account'.

ATTENTION: Users who have been inactive in the Research Dashboard for 6 months will receive an email that their account will be inactivated if they do not log into the dashboard before a specified date. Failure to log into the Research Dashboard by that date will lead to an inactivation of the account.

2. My profile

New users are asked to complete their profile information, especially with regard to their CV and Good Clinical Practice (GCP) certificate.

Go to 'My profile' in the left-hand column, select 'My CV' and upload your CV. This is strongly recommended for all local principal investigators (PIs). The CV needs to be signed and dated and is valid for three years.
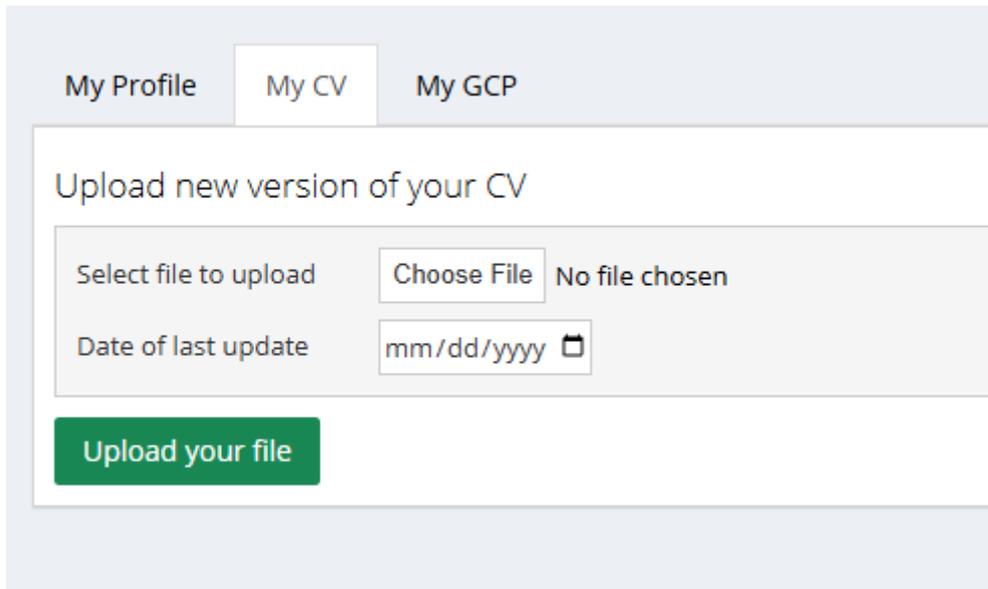
Go to 'My profile' in the left-hand column, select 'My GCP' and upload a valid GCP certificate. This is mandatory for all users who are performing studies at UHasselt. A GCP certificate is valid for three years.
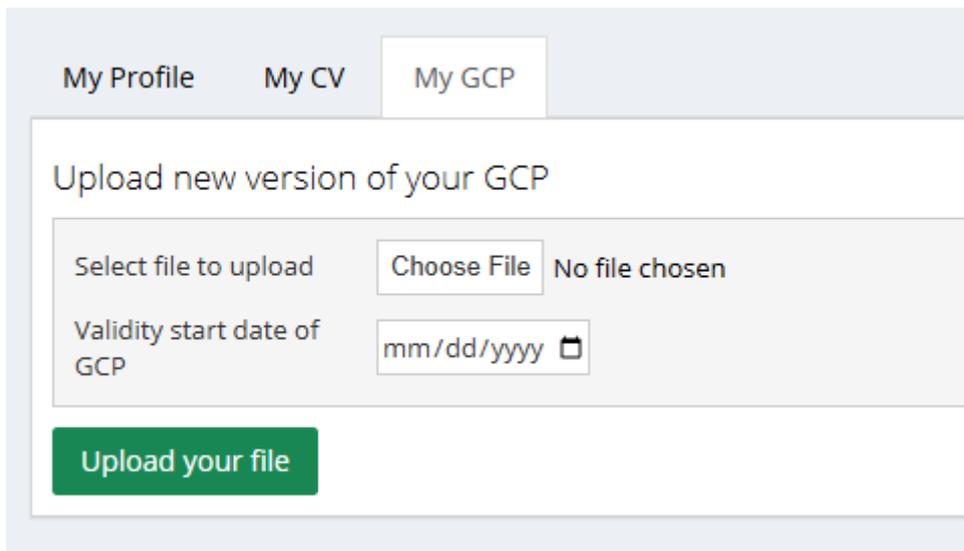
Users should keep their profile up to date at all times. Other profile-related options, such as setting up an out of office and delegating tasks to other users, are described below.

2.1. My profile

In 'My profile' it is possible for users to register an out of office, to assign a delegate and to verify which groups they are allocated to.

Out of office: Register your out of office in the Research Dashboard and assign a delegate who will receive emails and/or actions that are generated by the dashboard during your absence. Registering your out of office is recommended in order to guarantee an efficient approval flow. The Research Dashboard provides the possibility to receive the emails and/or actions yourself as well for verification purposes upon your return.

Delegates: Select a user that can follow up on your emails and/or actions during an out of office or permanently. To be able to perform an action, the delegate should have access to the respective study. Therefore, the delegate should be added to a custom actor type in the 'Actors' tab (see section 6.3) of the respective study. As to participating departments, delegates can be temporarily added to the approval group through which they have access to the studies that require approval of the respective participating department. Please contact ctu@uhasselt.be if applicable.

My Groups: Under 'My groups' you can find more information on which groups you are a member of. The advantage is that a group can be directly added to a study, granting access to the study for each group member. Currently, a new group can only be created by the CTU of UHasselt. In case this is necessary, please contact ctu@uhasselt.be.

2.2. My CV

Local PIs are advised to upload a signed and dated CV to their profile. Please note that a CV is valid for a period of three years. Currently, uploading the CV of the local PI of the study is mandatory in each study request, regardless of the upload of the CV in the profile of the PI. A future update of the Research Dashboard will enable an automatic upload of the CV (if still valid) from the profile of the local PI to each new study request. Uploading the CV to the PI profile will remain recommended as this allows the CTU of UHasselt to provide the CV to sponsors upon request.

2.3. My GCP

All individuals involved in clinical research are required to obtain a valid GCP certificate. Please upload your GCP certificate to your profile. Note that a GCP certificate is valid for a period of three years.

The CTU of UHasselt organizes in cooperation with Jessa Hospital and ZOL, GCP courses for starting and experienced researchers and study staff. The GCP courses are offered in person and online and are accessible to both internal and external persons. Upon successful completion of the assessment, an internationally recognized (TransCelerate Biopharma) certificate is obtained. For more information concerning our GCP sessions, please contact ctu@uhasselt.be.

3. General approval flow

Figure 1 illustrates the general approval flow in the UHasselt Research Dashboard. Depending on the study type, certain steps may or may not be applicable. The approval flow of the CTU and/or EC and the legal approval flow can start and run independently. Both flows will need to be approved before the contract signing phase starts, if applicable.
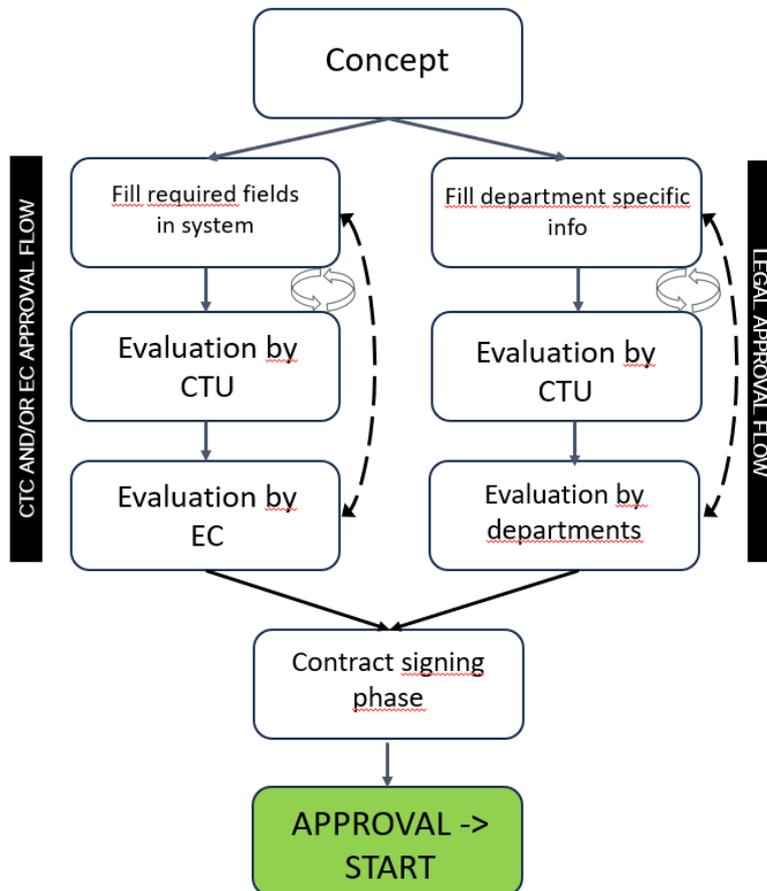
Figure 1. General approval flow of studies within the Research Dashboard.

3.1. CTU and/or EC approval flow

Upon the creation of a study request (see section 0), the Research Dashboard will show all fields that need to be completed in order to be able to submit the request for approval to the local PI, the promotor and the CTU. This process is explained with more detail in section 5 and section 0.

3.2. Legal approval flow

Contract negotiations can be initiated in two ways:
1. Together with submission of the CTU and/or EC approval flow
2. Independent from the CTU and/or EC approval flow, by sending an email to ctu@uhasselt.be.

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At least the following information should be filled in before the legal approval flow can be initiated:

- In the tab 'Actors': Add the contact persons that will be responsible for the contract negotiations, both from the local study team and the sponsor.
- In the tab 'Request' → 'Study information' → 'Study conduct': Select the involved participating departments. Please only add the participating departments that will carry out study-specific activities and that are different from the department of the PI.
- In the tab 'Contract and budget': Provide all requested information, including the subtabs.

For more details on the legal approval flow, please see section 8.

3.3. Contract signing phase

When both the CTU and/or EC flow and the legal flow have been approved, the CTU will contact the sponsor to start the contract signing process. When all parties have signed the contract, the CTU will upload the signed contract in the Research Dashboard and change the phase of the request into 'Study approved, open for enrollment'. All contact persons will receive a notification of this phase change. More details can be found in section 0.

4. General layout of the Research Dashboard

On the left-hand side, the Research Dashboard contains a column with the main system options. Below, an overview of all possible options is provided. Please note that not all users have access to all options. More information can be found in the specific sections of this manual.

TABLE 1: OVERVIEW OF THE LEFT-HAND COLUMN TABS OF THE PORTAL	
Name	**Information**
Requests	An overview of the studies (requests) you have access to.
My actions	An overview of all the open actions assigned to you. In each specific study, actions are also visible in the tab 'My open actions'.
My Open Questions	
My profile	Access to your profile, with the possibility to upload a CV and GCP certificate and to assign delegates for your notifications and tasks during an out of office period.
Study type finder	Tool to select and start the correct study type request. In case of questions, please contact ctu@uhasselt.be.
Templates	Document and contract templates that can be used during the submission process. In the different tabs of the study request, the template that can be used is mentioned.
Procedures	An overview of the procedures that are available for the use of the UHasselt Research Dashboard.
Department control panel	An overview of the open approval requests to the PI and participating departments. Access is restricted to the participating departments, the PI and the study team members that are set as contact persons for study submission in the 'Actors' tab. Each line also contains a link that will lead directly to the specific study.
Invite person	All registered users in the portal can invite other persons to the portal by adding the required information in this form. Do not forget to also add the respective person to the studies they need to have access to.
EC meetings	Access is restricted to EC administrators.
Admin	Access is restricted to EC and CTU administrators.

5. Create or find a study request

Both internal and external users can create and submit a new study request in the Research Dashboard. This can be done by navigating to the 'Requests' section in the left-hand column of the dashboard and subsequently selecting 'Add new'. First, the type of request needs to be selected. The different types of requests are described in more detail in section 5.1. In case of doubt about the correct type of request, please check the study type finder (see section 5.2). In case of doubt, please contact ctu@uhasselt.be.
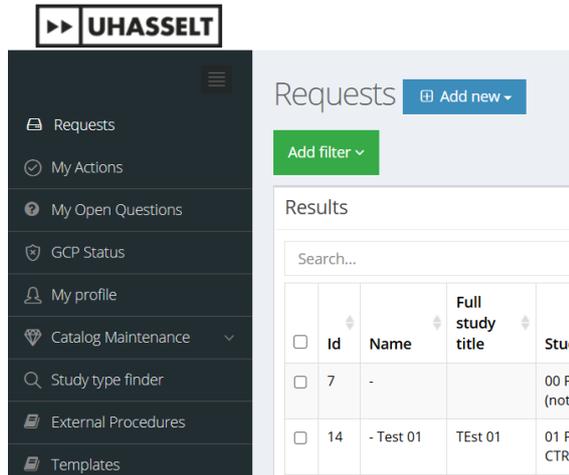
5.1. Type of request

Different types of requests can be created:

- 00 Prospective study (not CTR, MDR, IVDR)
  - Interventional experiment (Law of 7 May 2004)
  - Non-interventional experiment (Law of 7 May 2004)
- 01 Prospective study CTR/MDR/IVDR
  - Clinical trial with investigational product (Clinical Trial Regulation (CTR) and Law of 7 May 2017)
  - Clinical investigation with medical device (Medical Device Regulation (MDR) and Law of 22 December 2020)
  - Performance study with in vitro diagnostic medical device (In Vitro Diagnostics Regulation (IVDR) and Law of 15 June 2022)
- 02 Retrospective study
  - This type of request includes retrospective studies and case reports.
- 03 Fast tracks
  - Anonymous questionnaires: The study collects data through anonymous questionnaires from UHasselt staff or patients and/or collects data from UHasselt staff only by using qualitative techniques.
  - Advertisement external study: All study activities take place outside of UHasselt, including obtaining informed consent. The role of UHasselt is limited to communication to potential participants (e.g., flyer or poster in university, email notification to staff).
  - Retrospective register: The aim of the study is to generate a retrospective register, for which no scientific questions have been determined yet. To use this register for a

scientific study in a later stage, this retrospective study will need to be submitted to and approved by the EC of UHasselt.

- o UHasselt as service-provider: The study activities performed at UHasselt are limited to providing a service for a sponsor or for another study site (e.g., the biobank is involved in an external study).
- 04 Biobank study
  - o The study investigates previously collected human bodily material (e.g., blood, tissue) stored within the biobank of UHasselt. No new data, nor samples are collected in this study type.
- 05 Quality study
  - o The study is related to the quality of the activities of health care professionals, carried out without intervention and on the initiative of a federal public service, an institution of public utility which does not operate a hospital, or a body set up within it by law or royal decree (Law of 7 May 2004, art. 3, § 3).

ATTENTION: Once a new request has been created, deletion or modification of its type will be impossible. Therefore, in case of uncertainty, it is essential to inform yourself thoroughly about the appropriate study type. The 'Study type finder' in the left-hand column of the dashboard can be used to find the appropriate study type (see section 5.2).

5.2. Study type finder

To find the appropriate study type, the 'Study type finder' in the left-hand column of the dashboard can be used. After responding to a series of questions, the system will suggest the appropriate study type. By clicking on 'Review' and subsequently 'Submit', the user will be automatically redirected to a new request of the appropriate type.

ATTENTION: It is not possible to change the study type afterwards. In case of doubt, please contact ctu@uhasselt.be.

5.3. Find an existing request

To find all the requests that you have access to, easily click on 'Requests' in the left-hand column of the Research Dashboard.

Requests can also be found using the 'Search' function. Alternatively, a filter can be set by selecting 'Add filter'. This allows to only view requests in a certain phase (Where phase is ...) or of a certain study type (Where template is ...).

6.   General layout of a study request

Every study type consists of a main menu with different tabs. Some of the tabs have subtabs and not all tabs are applicable to all the study types. You are allowed to work over the different tabs during the submission process. All changes are automatically saved.

| General | Request | Actors | Documents | Questions | Control panel | Involved persons | Monitors | Monitor visits | Invoicing | Amendments |
| Manage centra | My open actions | Log | Request history |

Throughout a request, different types of fields are used:

- o   Free text: This field has no restrictions concerning the format of the text.
- o   Typeahead single selection: This field automatically generates a list of suggested answers in real-time when you type.
- o   Radio buttons: A single answer must be selected.
- o   Check boxes: Multiple answers can be selected.
- o   Dropdown list: An answer can be selected from a dropdown list.
- o   Date: A date can be entered in the following format DD/MM/YYYY or by selection from the calendar displayed in the field.

For clarity, some fields are accompanied with additional information (marked with 🔮).

6.1.   General

The tab 'General' gives an overview of the study request and allows you to submit the request. It is <u>not possible</u> to enter any information in this overview, as these fields are linked to data that will be filled in the other tabs of the Research Dashboard. As long as essential fields (marked as ⚠️) are missing, it will not be possible to submit the application:

| General | Request | Actors | Documents | Questions | Control panel |
| My open actions | Log | Request history |

Id	11
Template	00 Prospective study (not CTR, MDR, IVDR)
🇬🇧 Name	UH-2025-006 - TEST
🇬🇧 Summary	
Phase	Concept
Submit request	⚠ This request has essential field(s) invalid.
	• See tab 'Request'
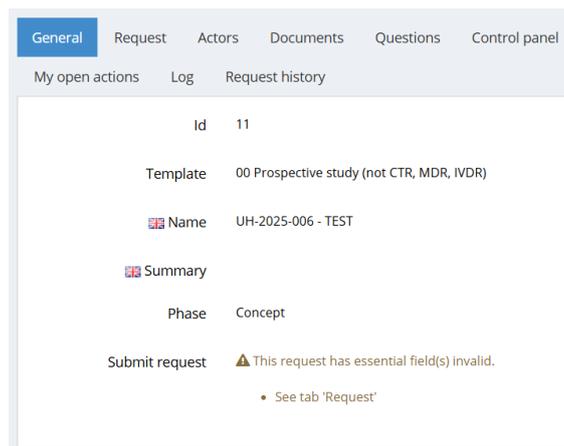
Please note that all fields and documents related to the submission for the CTU and/or EC approval flow can no longer be changed once the request has been submitted. Therefore, your request must be complete and accurate before submission. Fields and documents related to the legal approval flow (i.e., contract negotiations) remain accessible after submission of the request (see also sections 6.4 and 8).

6.2. Request

In the tab 'Request', all details about the study request need to be filled in. Depending on the type of request, specific tabs will appear with conditional questions. If certain tabs are not displayed, those tabs do not apply to your request. It is important to fill in the questions in the indicated order, so that the correct fields and/or tabs appear, and so that no fields are forgotten. Please note that some of the subtabs refer to other tabs of the main menu. For example, as indicated in the tab 'Involved parties', persons need to be added through the tab 'Actors'.

In several tabs, documents will need to be uploaded using the provided blue buttons. When uploading documents using the blue buttons, the documents will automatically be placed in the correct folder of the 'Documents' tab. It is obligatory to add a version number and version date for each document.

When all essential fields in the 'Request' tab are filled in, you will be able to submit the request in the 'General' tab.

This gives an overview of the different subtabs in the 'Request' tab.

6.3. Actors

In the 'Actors' tab, all involved study members can be added. It is crucial for the follow-up of the approval status of the request to add each person in the right category. Table 3 gives an overview of the different custom actors.

Both persons of the local study team and of the sponsor can be allocated as contact person for the study submission and/or contract negotiation. Contact persons of study submission will receive email notifications related to the CTU and/or EC approval flow, whereas contact persons of contract negotiation receive email notifications related to the legal approval flow.

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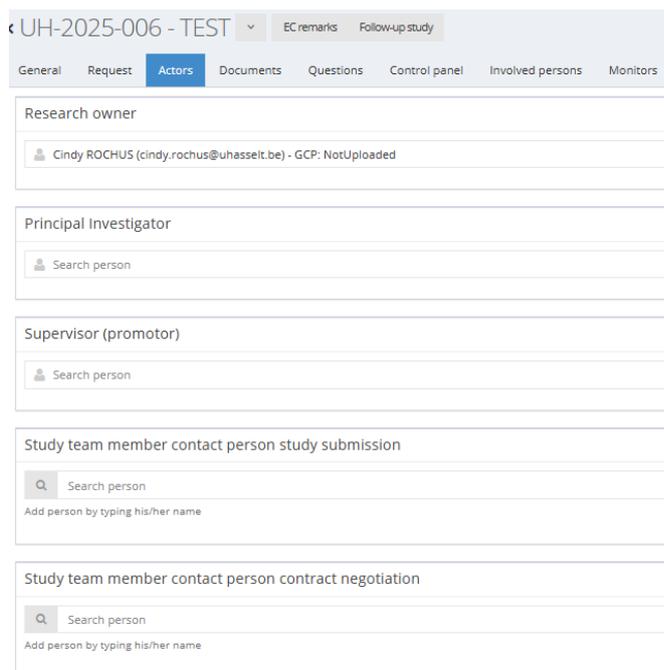
6.4. Documents

6.4.1. Upload documents

In the 'Documents' tab, you can find an overview of all documents related to the request. Although it is possible to directly upload documents in this tab, it is strongly recommended to upload your documents using the 'Request' tab and the provided blue buttons when submitting an initial request. In this way, you are ascertained that all obligatory documents are uploaded and that the correct category is assigned automatically. The addition of a version number and version date for each document is mandatory.

Alternatively, and in later stages of the request, documents can be uploaded directly in the 'Documents' tab. This can be done by the green '+Add' button in the top right corner. Enter the necessary information for each document (version and category are obligated). By assigning the document category, the document will also become visible in the corresponding question of the request itself.

ATTENTION: All documents must be uploaded separately. Zip files are not permitted, your request will be found inadmissible.

For some document categories, templates are available in the left-hand menu of the Research Dashboard, under the tab 'Templates'. Most of the templates (e.g., protocol, informed consent, contract, annual progress reports) are optional to use.

ATTENTION: If your research involves the biobank as a participating department, please use the obligatory biobank templates under category M and upload these in the 'Contract and budget' tab of your request. The differences between the two biobank templates is the requirement of registration only versus registration and (temporary) storage of the samples.

6.4.2. Download documents

In the 'Documents' tab, you can search for and download a specific document. Filtering can be done by the column headers (e.g. only documents of a specific category or in a specific status).
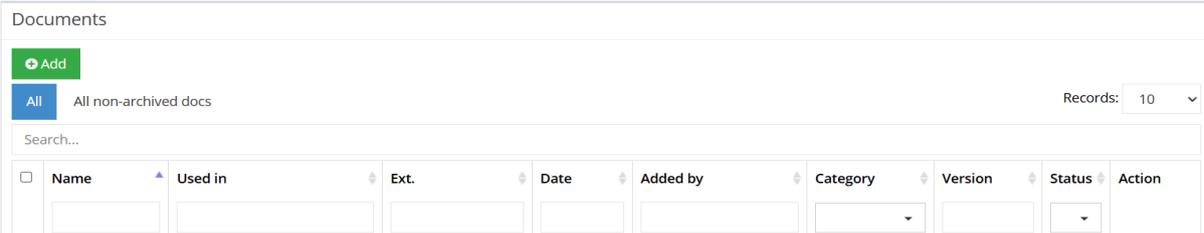
	Name	Used in	Ext.	Date	Added by	Category	Version	Status	Action
☐									

Documents (panel with ⊕ Add button, All / All non-archived docs, Records: 10, Search... field)

Documents can be downloaded by clicking on their name. Alternatively, in case you want to download multiple documents at the same time, please select the respective documents in the first column, and download these simultaneously using the symbol in the 'Action' column:
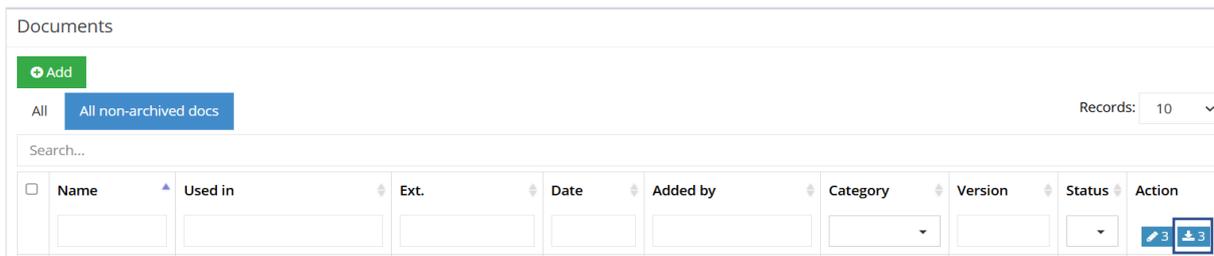
6.4.3. Archive documents

To have an overview of all documents that are still valid, please do not forget to archive old versions of documents, by changing the status to 'archived'. This can be done by using the blue pencil next to the respective document. In case multiple documents have to archived simultaneously, these can be selected in the first column, after which the status of the selected documents can be changed simultaneously. Additionally, the option is provided to only view the non-archived documents:
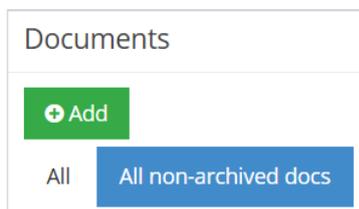
Of note, only the UHasselt CTU can permanently delete documents from the dashboard.

6.5. Control panel

The tab 'Control panel' allows for the contract negotiations with the PI department and the involved participating departments. The control panel provides an overview of the status of all approval requests and allows communication with the respective departments.

Approval requests can only be initiated by the CTU of UHasselt. The CTU will start the applicable approval requests after reviewing the request submission, if all information is present. It is also possible to start the legal approval process at an earlier stage (independent from submission) by contacting ctu@uhasselt.be .

At least the following information should be filled in before the legal approval flow can be initiated:
- In the tab 'Actors': Add the contact persons that will be responsible for the contract negotiations, both from the local study team and the sponsor.
- In the tab 'Request' → 'Study information' → 'Study conduct': Select the involved participating departments. Please only add the participating departments that will carry out study-specific activities and that are different from the department of the PI.
- In the tab 'Contract and budget': Provide all requested information, including the subtabs.

For more details on the legal approval flow, please see section 8.

6.6. Monitors

Monitors can be added to your request through the 'Monitors' tab. Select the option 'I want to add a new entry' and complete the required information marked with a red line in front of the field.

6.7. Monitor visits

When a monitor is visiting the site, the monitoring visit must be added at least two weeks in advance through the 'Monitor visits' tab. Subsequently, the CTU will ensure that all accesses are granted to the monitor, or -in case of a follow-up visit- are still valid during the respective visit.

6.8. Amendments

The tab 'Amendments' can be used to submit an amendment for an approved study.

- If UHasselt is not the central EC or if the study is already approved by an independent EC (e.g., for CTR/MDR/IVDR), please only upload the approval letter and the new documents after approval by the central or independent EC. The status of the amendment will automatically change to 'approved'.
- If UHasselt is the central EC, an approval request will be started upon submission of the amendment. The detailed process is described in section 10.4.

6.9. My open actions

A user's open actions related to a specific study can be found in the tab 'My open actions'. Users also receive (action) notification emails throughout the process in which the actions required by the user are described and a link is included that directs to the specific action.

6.10. My Open Questions

All the open questions related to a specific study can be found it the tab 'My open questions'. Users also receive email notifications when questions are addressed to the user and if answers are expected. A user can add a general question to everyone added to the study at any time.

In the tabs above the user can find the questions address to them, that they requested and where answer is expected.

Questions can be asked to specific persons involved in the study, but also to groups, like CTU, Legal or EC,…

Ask a question   ✕

Question

[   ]

Details

[   ]
[   ]

Documents

[Choose Files] No file chosen

Audience

Actors

☐ Cindy ROCHUS

Departments

☐ Legal department (Obligated in case of an external sponsor)

General

☐ CTU   ☐ EC

[Submit   ]

To note: All the persons added to the study in 'Actors' can see all the questions related to the study, even if they are not addressed to them.

6.11. Log and Request history

Once your study request is submitted, the status of individual approval steps can be followed in the 'Request history' tab.

In the 'Log' tab, the Research Dashboard keeps track of a detailed audit trail with an overview of all additions/adaptations that occurred within a request.

7. Submission of a new request

7.1. Submission of the request

All essential fields and tabs (marked as ⚠) need to be completed before a study request can be submitted for the CTU and/or EC approval flow. By clicking on the green 'Submit request' button within the 'General' tab the request can be submitted and will proceed to the next phase (the updated phase is visible once you leave the study).

Please note that by submitting your study, the Research Managers and Business Developers of your research group will be added to your study automatically. If you want to include them before this, they can be added manually to the study team in the tab 'Actors'.
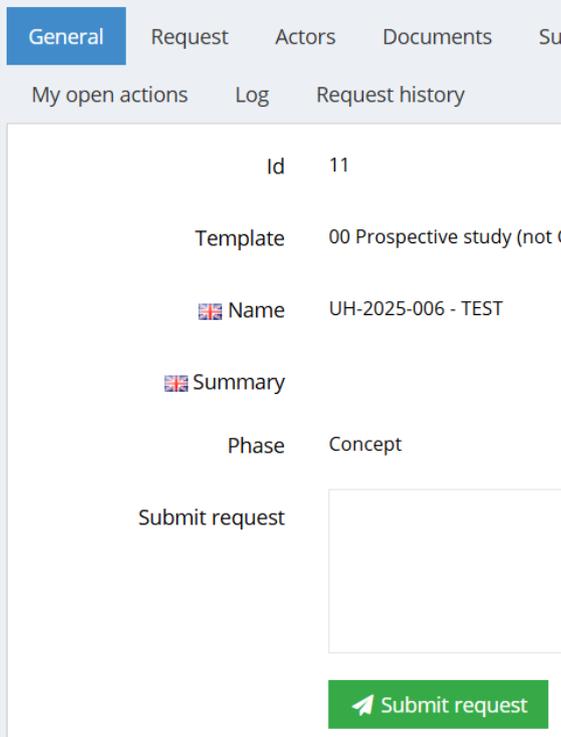
Further steps and follow-up of the approval flow are described in section 10.

8. Legal approval flow

As described in section 3.2 and section 6.5, contract negotiations can be started independently from or together with submission of the CTU and/or EC approval flow.

8.1. Clinical trial agreement: available templates versus sponsor template

In case of an external sponsor, or in case UHasselt is the sponsor and multiple sites are involved, a clinical trial agreement (CTA) or a study agreement must be concluded to define the roles and responsibilities of the parties involved, including a data processing agreement (DPA) for the exchange of coded data.

Several CTA templates are available for the different study types. Please contact ctu@uhasselt.be for access to these templates.

Importantly, for multicentric studies with UHasselt as sponsor, please contact ctu@uhasselt.be.

ATTENTION: Always add the contract as a Word document in the Research Dashboard (no PDF), so that the legal department can suggest possible changes using track changes.

8.2. Negotiations with the PI department

In the 'Contract and budget' tab, subsection 'Department Principal Investigator/promotor', please upload a file specifying the budget allocated to the PI/promotor department. The dashboard also shows the person that should receive the invoice proposals during the course of the study.

8.3. Negotiations with the involved participating departments

It is essential to indicate the involved participating departments in the 'Study information' subtab of the 'Request' tab. In case of an external sponsor, selection of the legal department is obligatory. Only departments performing study-specific activities need to be selected. In case of doubt, please contact the UHasselt CTU. Per department, a specific tab under 'Contract and budget' will appear and will need to be completed to initiate the legal approval flow and budget negotiations. Please note that all contract negotiations will take place in the Research Dashboard.

8.4. Start of the contract negotiations

As described in section 3.2 and section 6.5, the contract negotiations can be started by contacting ctu@uhasselt.be or by submitting the study using the 'General' tab upon completing all essential information.

The CTU of UHasselt will review the contract negotiation information, and if necessary, contact the requestor to complete or adapt the information. If all information is complete, the CTU will start the corresponding approval requests in the tab 'Control panel'. Automatically, the status will be set to 'started', with a corresponding deadline. The respective departments will receive an email notification to process the request and approve or give comments within two weeks.

8.5. Follow-up and response in contract negotiations

All persons with access to the study will be able to follow the contract negotiations and communicate with all involved departments using the 'Control panel' tab. All persons indicated as contact person contract negotiation, both from the local study team and the sponsor, will receive email notifications when the status of an approval request changes.

Each department involved will update the control panel by giving comments or by approving. The status of the respective line in the control panel will change to 'comments sent' or 'approved', respectively. In both cases, all contact persons for the contract negotiation will be notified.

In case of comments, the dashboard will send a notification to the contact persons, including a request to answer these comments and resubmit the approval request. By selecting 'edit existing line' the contact person can write a response and resubmit the request.

The status of the respective line changes to 'restarted', and the deadline is automatically reset.

The department will receive a notification and the process can repeat itself up to approval.

8.6. Completion of the contract negotiations

When all participating departments have approved their requests and the study has been approved by the CTU of UHasselt (and EC if applicable), the system will send a notification to the CTU in order to start the contract signing process. The CTU will reach out to the contact persons for contract negotiations to make further arrangements concerning the signing of the contract. This process is explained further in section 9.5.

9. Follow-up of a submitted study request

A study will proceed through different phases before an approval is given. Depending on the study type, some phases may or may not be applicable. An overview of the different phases before approval is shown in the table below.

TABLE 6: OVERVIEW OF THE POSSIBLE PHASES OF A STUDY/PROJECT UP TO APPROVAL

Phase	Information	Applicable in study type
Concept	All essential fields and tabs have to be filled. After that, the study request can be submitted using the 'General' tab to the following applicable phase.	00, 01, 02, 03, 04, 05
Waiting for site suitability to be signed	Phase only applicable for CTR/MDR/IVDR studies.The CTU received the request to sign the site suitability and will have it signed by the Rector and Dean of the applicable faculty.	01
Waiting for submission to CTU	Phase only applicable for CTR/MDR/IVDR studies. All essential fields and tabs have to be filled. After that, the study request can be submitted using the 'General' tab to the following applicable phase.	01
Waiting for approval PI/Promotor	The PI and promotor (if different from the PI) will receive consequently an approval request for the study request. The status of the approval request can be followed in the tab 'Request history'.	00, 01, 02, 03, 04, 05
Waiting for approval CTU	Upon approval of the PI (and promotor), the request is automatically sent to the CTU for approval. Contact persons of the study submission will receive an e-mail notification.	00, 01, 02, 03, 04, 05
Waiting for approval ethical committe and/or participating departments	Upon approval by the CTU, the request is submitted to the EC and participating departments (unless already started previously).	00, 01, 02, 03, 04, 05
Waiting for contract to be signed	When all necessary approvals have been received, the CTU will start the contract signing procedure and update the phase of the study. When the signing process is complete, the CTU will upload the final signed contract in the Research Dashboard and approve the start of the study.	00, 01, 02, 03, 04, 05
Study approved - open for enrollment	The CTU will change the phase of the study into 'Study approved - open for enrollment' when all approvals have been obtained and the contract has been signed by all parties. The study can then start within UHasselt.	00, 01, 02, 03, 04, 05
Study archived	Two years after the definite end date, the study will automatically change from phase into 'Study archived'.	00, 01, 02, 03, 04, 05
Study refused	If the study is not approved to start at UHasselt, the CTU will change the phase to 'Study refused' and specifies the reason.	00, 01, 02, 03, 04, 05

9.1. Waiting for site suitability to be signed

The phase 'Waiting for site suitability to be signed' is only applicable for study type '01 Prospective study CTR/MDR/IVDR'. Limited information, for which essential fields are indicated as ⚠, is necessary to request the signing of the site suitability statement. Upon filling out the essential fields (e.g., title, acronym, department, sponsor, PI, promotor) and uploading the site suitability statement, the request for signature can be submitted through the 'General' tab using the green button.

The UHasselt CTU will automatically receive an email notification to have the site suitability statement signed by the Rector and the faculty's Dean. The signed document will be sent as attachment to the requestor and uploaded into the Research Dashboard as soon as possible. Please take into account a signature period of one to maximum two weeks.

After the signing, the phase of the study automatically changes to 'Waiting for submission to CTU: all essential fields and tabs need to be filled, after which the study request can be submitted using the 'General' tab to the following applicable phase. The phase 'Waiting for submission to CTU' is only applicable for CTR/MDR/IVDR studies and is comparable to the 'Concept' phase of other study types.

9.2. Waiting for approval PI/Promotor

In the Concept phase (or the phase 'Waiting for site suitability to be signed' in case of study type '01 Prospective study CTR/MDR/IVDR'), all essential fields marked as ⚠ need to be filled. Afterwards, the green button to submit the request will appear in the 'General' tab. Upon submission, the status will change automatically to 'Waiting for approval PI/Promotor'. The PI and Promotor (if different from the PI) will receive successively an approval request for the study. In the email notification the PI (and Promotor if applicable) will find the link that will automatically direct to the respective action in 'My actions' in the left-hand column of the Research Dashboard. Alternatively, the action can be found in the respective study in the tab 'My open actions'.

Of note, if the PI or Promotor declines the request, the phase of the study will return to 'Concept' (or the phase 'Waiting for site suitability to be signed' in case of study type '01 Prospective study CTR/MDR/IVDR') and an email notification with the reason of decline is sent to the contact persons of study submission (and the PI in case the head of department declines). The study can be resubmitted through the 'General' tab after adjusting the study request based on the comments of the PI or Promotor. This process can repeat itself. Of note, if the PI approved but the Promotor declined the request, resubmission will skip the request to the PI as the PI already approved in the previous stage.

The status of the approval requests can be followed in the tab 'Request history'. Reminders to the PI and Promotor are automatically sent after five days. Additionally, an escalation to the UHasselt CTU is set at eight days to avoid unnecessary delays.

9.3. Waiting for approval CTU

Upon approval by the PI and Promotor , the study automatically will be submitted to the CTU and a study number will be generated. The request will be locked against changes (apart from the 'Contract and budget' tab and associated document categories).

The UHasselt CTU will receive an action request to review the study request. In case of comments, the contact persons of the study submission will receive an email notification with an attachment containing the comments.

The phase of the study will return to 'Concept'. Adaptations can be made to the study request to resolve the CTU comments. When the necessary documents/fields in the Research Dashboard are updated and a **reply** to the CTU comments is uploaded in the 'Documents' tab, under category 'A5. Correspondence with clinical trial unit', the study can be resubmitted to the CTU using the 'General' tab. The phase of the study will change automatically to 'Waiting for approval CTU'. This process can repeat itself up to approval.

When the CTU approves the study request, the contact persons for study submission will receive an email notification that the study phase changed into 'Waiting for approval ethical committee and/or participating departments'.

9.4. Waiting for approval ethical committee and/or participating departments

Upon approval by the CTU, the CTU contact person will start the EC approval process (if applicable) and/or the necessary approval requests with the participating departments (if applicable and not

started in an earlier step). When a study is submitted under CTR/MDR/IVDR the UHasselt EC will not review the study since it will be reviewed by an independent EC.

More information regarding clinical trials can be found via the following link [Europese Verordening 536/2014 | FAGG](#). For more information regarding clinical investigations, please see [https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulps tukken/klinische_evaluatie/aan_te_melden_onderzoeken](#) .

9.4.1. Approval of the ethics committee

At the start of the EC approval flow a meeting date of the UHasselt EC will be selected during which the study will be discussed, taking into account the legally applicable deadlines. An email will be sent to the PI and contact persons for the study submission stating that the study request is declared admissible.

If a personal presentation by the local PI is required, the local PI, as well as the contact person(s) for study submission, will receive an action notification via email. A meeting date of the EC and time slot will be allocated to the study request. Using the link in the action notification the PI or contact person will be able to indicate:

- o Who will present the study at the meeting?
- o Is the assigned time slot suitable?
- o Will the presenter attend the meeting live or online?

If the meeting slot is not acceptable, the PI or contact person has the ability to decline and suggest a time slot which is more suitable.

The meeting slot will then be adjusted and a new action notification will be sent to the PI and the contact person(s) to confirm. The UHasselt EC provides 15 minutes per study, of which 10 minutes are foreseen for the PI (or its delegate) to give an oral presentation. The remaining 5 minutes are for questions of the EC members.

The advice from EC members, experts and other participating sites (if applicable when UHasselt is the central EC) will be collected and drafted into a preliminary advice letter.

When UHasselt is the local EC, the advice letter will be automatically sent to the central EC. The central EC will consolidate all remarks of the participating sites into a preliminary advice letter which will be sent to the indicated contact persons. Please await this consolidated advice and formulate a response with the adjusted documents to the central EC. The central EC will, if agreed with all the adjustments made, provide a definitive advice letter. When the UHasselt EC receives the definitive advice letter from the central EC, the UHasselt EC will upload the letter to the Research Dashboard. The contact persons for study submission will receive an action notification to upload the updated and approved documents.

When UHasselt is the central EC, the preliminary advice letter will be sent to the contact persons for study submission in the attachment of an action notification. The contact persons have 30 days to respond to the comments of the EC. Make sure to provide a point-by-point response and adjust the study documents (with and without track changes) where necessary. Using the link in the action notification you can upload the adjusted documents to the Research Dashboard.

The UHasselt EC will review the point-by-point response and the adjusted documents. If not all issues are resolved, the study submission contact persons will receive a new action notification to respond

to the additional comments. If the EC concludes that all comments have been resolved, the final advice letter will be provided. An email notification will be sent out to the contact persons for study submission, the FAGG and the local ECs (if applicable).

NOTE: The status of the EC approval flow can be checked in the 'Overview' tab under 'Current step EC'.

9.4.2. Approval of participating departments

The UHasselt CTU will start the necessary approval requests to the participating departments in the tab 'Control panel'. Automatically, the status is set to 'started', with a corresponding deadline. The respective departments will receive an email notification to process the request and approve or give comments within two weeks. This process is explained further in section 8.

### 9.5. Waiting for contract to be signed

When all necessary approvals have been received, the CTU will start the contract signing procedure and update the phase of the study. The CTU will send an email notification to the sponsor/CRO contract person(s) contract negotiation to request the preparation of the final clean version of the approved contract. The preferred signing method is already indicated in the subsection 'Legal department' of the tab 'Contract and budget' and can be initiated.

When the signing process is complete, the CTU will upload the signed contract in the Research Dashboard and approve the start of the study (see section 9.6).

9.6. Study approved – open for enrollment

After the contract is signed, the study will automatically proceed to phase 'Study approved – open for enrollment', indicating that screening and enrollment of study subjects can start at UHasselt.

ATTENTION: Please enter the definite start date (date first screening/inclusion) of your study directly after the start of the study. Take into account that the study needs to start within one year after EC approval (see section 10.2). The start date can be entered using the action form 'Follow-up study' which can be found using the arrow next to the header of the study or de 'Follow-up study' button next to the header of the study. Upon entering the definite start date of your study, the phase will automatically be updated to 'Study approved – enrollment ongoing'. For more information, see section 10.1.
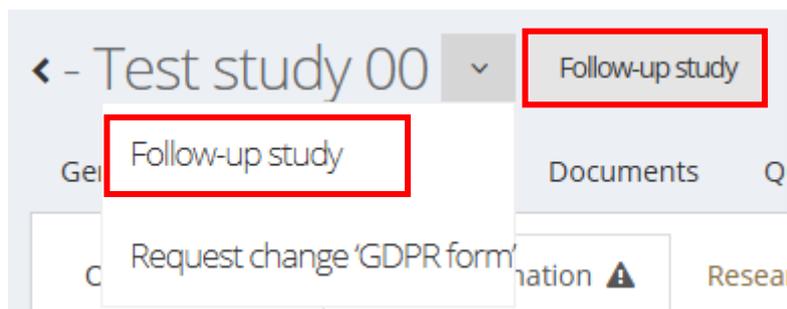
10. Follow-up of an approved study request

10.1. Updating the status of the study using the action form 'Follow-up study'

After approval of your study request, the phase of the study should be updated continuously as the study proceeds. Therefore, select the action form 'Follow-up study' using the arrow next to the header of the study and select one of the actions described below resulting in a change in study phase.
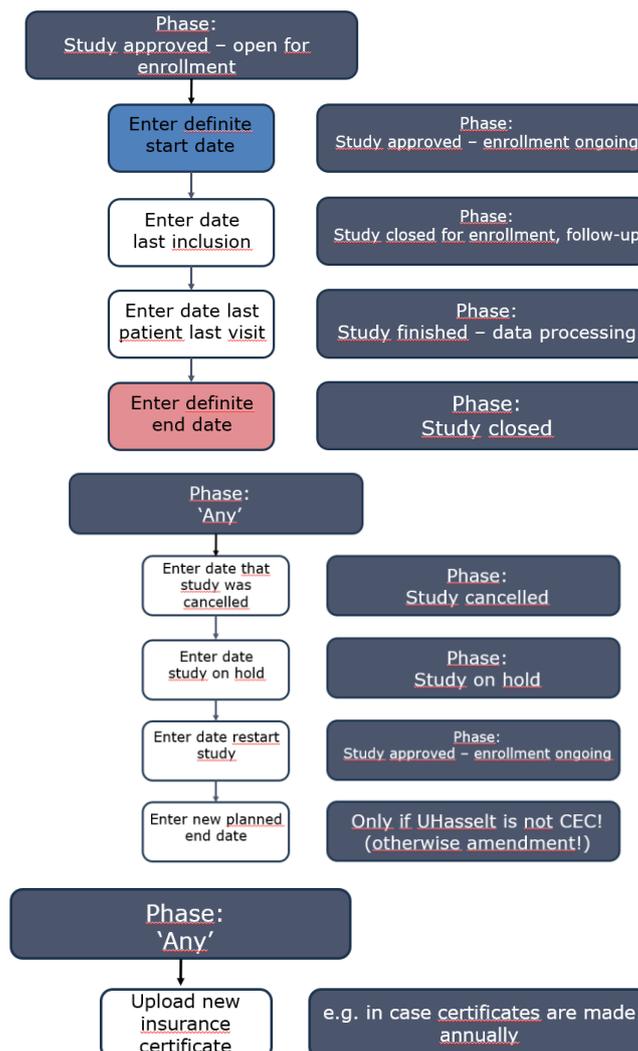
10.2. Life cycle processes related to the start and end date

In accordance with the applicable legislation, approvals of an EC are valid for one year. If the study has not been started within one year of approval, the positive advice will expire. For all studies with UHasselt as central EC, the Research Dashboard will follow up on this requirement. If the definite start date is not filled 11 months after the positive advice (through the action form 'Follow-up study', described in section 10.1), an email notification is sent to the contact persons of the study submission. If one month later the definite start date is still not filled, this will be escalated to the UHasselt EC. The positive advice of the EC will expire and the local PI will be informed that a new request will have to be submitted.

Similarly, a study is approved with a specific planned end date. One month before the planned end date, the Research Dashboard will send an email notification to the contact persons for the study submission, mentioning that - according to the study details provided - the study will end within one month at UHasselt. When the study is proceeding according to the original plan, the contact persons are asked to enter the definite end date as soon as possible and to upload a final study report within one year after the end of the study. This can be done through the action forms 'Follow-up study' and 'Upload reports' which can be found next to the header of the study using the arrow (see sections 10.1 and 10.3).

However, if the study needs to be prolongated, one of the following actions is necessary:

- o If UHasselt is the central EC, please submit an amendment using the tab 'Amendments' to prolongate the study (see section 10.4).
- o If UHasselt is not the central EC, please follow the rules of the central EC and only change the planned end date in the Research Dashboard when the central EC approved to prolongate the study. The planned end date can be updated through the action form 'Follow-up study' which can be found next to the header of the study using the arrow. If applicable, a new insurance certificate can also be uploaded using the same action form 'Follow-up study' (see section 10.1).

In case at the time of the planned end date no action has been taken by the research team, the Research Dashboard sends a reminder to the contact persons and the CTU. This may have important implications for the validity of the insurance. The UHasselt CTU will contact the PI, but in case no action is taken, the study will be closed in the Research Dashboard.

10.3. Upload an annual progress or end report

Uploading annual progress reports and a final end report for EC review is obligatory when UHasselt is the central EC of the study. Throughout the course of the study, notifications will be sent when the deadline for a progress or end report is approaching.

IMPORTANT: the automatic notifications only function when the study is submitted in the Research Dashboard, not when the study was previously submitted. In the latter case, manual follow-up remains necessary.

In case UHasselt is not the central EC for your study, uploading annual progress reports or a final end report is not obligated but optional.

To upload annual progress reports and an end report, select the action form 'Upload reports' which can be found by selecting the arrow next to the header of the study. In the 'Templates' tab in the left-

hand column of the Research Dashboard, templates for an annual progress report and end report can be found under category J. The use of these templates is optional.

10.4. Submit a study amendment

When changes are necessary to an approved study request, a (non-)substantial amendment can be filed in the Research Dashboard. The tab 'Amendments' automatically appears in the study upon approval. Amendments must be submitted and approved by the central EC and notified to the local EC(s). The 'Amendments' tab automatically adapts according to the situation of the study (UHaselt EC as local versus central EC).

When the UHasselt EC acts as central EC, the submission of the amendment will start an approval process. The UHasselt EC can give comments and change the status of the amendment (approved / waiting for insurance / comments sent / denied). The Dashboard will send notifications to the contact persons for study submission and the participating departments that are affected by the amendment. In case of comments, the contact persons will receive an email notification to adapt and resubmit the amendment through the tab 'Amendments'. The process can repeat itself up to approval of the amendment by the UHasselt EC.

When submitting an amendment, a cover letter needs to be included, signed by the PI. An optional template is available in the left-hand column of the Research Dashboard in the section 'Templates' under A2. The UHasselt EC needs to receive complete descriptions of the amendment, including the rationale(s) for the amendment and the anticipated impact on current and future subjects, as well as revised versions (with and without track changes) of affected documents (e.g., informed consent documents, questionnaires, protocol, ...). In case an additional site is added, the UHasselt EC will send an advice request to the EC of the new site if applicable. Please be aware that you are responsible to submit the complete study file to the additional site on the same day as you submit the amendment request to the UHasselt EC.

The changes described in the amendment can only be implemented after approval of the UHasselt EC. The central EC will send the approval letter to the local ECs and the FAMHP. After approval, please also provide the adjusted documents to the local ECs.

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When the UHasselt EC is local EC, the submission of the amendment will be handled as a notification to the UHasselt EC. The new documents should be uploaded using the 'Amendments' tab as soon as approved by the central/independent EC. When adding an amendment, the dashboard will collect information concerning the amendment, all updated documents and the approval letter and approval date from the central/independent EC. The status of the amendment will automatically change into 'approved'.

10.5. Submit a contract amendment

Contract amendment requests are handled through the control panel in the Research Dashboard. In the 'Control panel' tab, the 'type' can be set to 'Amendment'. As for the initial approval requests, contract amendment requests can only be initiated by the UHasselt CTU. All persons with access to the study, can follow up the status of the approval requests and communicate with the departments involved once they are started. The usage of the control panel is identical to the initial legal approval flow and is described in section 8.

The documents concerning the contract amendment can be added through the 'Documents' tab in your study request. Please make sure to select the appropriate document category and to enter version details (see Table 4, separate pdf document).

To start a contract amendment approval request, please send an email to the UHasselt CTU through ctu@uhasselt.be with all the necessary information (proposal of the contract amendment, affected participating departments, ...).