Sheffield Hallam University

Converis Ethics Review
Academic User Guide

Contents

1.   Introduction

1.1   What is Converis?

Converis is the University's Research Management System and is used to record Pre-Award Funding Applications and Ethics Reviews.

1.2   Ethics Review in Converis

Completing the Ethics Review application in Converis enables the University to record that research conducted has been subjected to ethical scrutiny.

The SHU Research Ethics Policy should be consulted before completing the Ethics Review application in Converis.

1.3   Responsibilities

Collecting data without ethical approval or ethical scrutiny constitutes research misconduct under the University policy. Studies can only begin once ethics approval has been received.

The final responsibility for ensuring that ethical research practices are followed rests with the supervisor for student research and with the Principal Investigator for staff research projects.

Note that students and staff are responsible for making suitable arrangements for keeping data secure and, if relevant, for keeping the identity of participants anonymous. They are also responsible for following SHU guidelines about data encryption and research data management.

Converis Role	Responsible for
Staff Researcher/Student	Creating the application in Converis
Director of Study	Signing off Students' application as ready for review
Ethics Reviewer	Undertaking ethical review of applications and making recommendation. Lead Reviewer responsible for making overall approval decision or escalating to FREC. Responsible for reviewing amendments.
FREC	Making overall approval decision when applications/amendments are escalated.

1.4   Timescales

The target for completing Ethics Reviews is 2 weeks, from date of submission.

2.   Accessing the system

Converis is part of single sign-on (SSO). You can use your existing SHU username and password to access the system.

To access Converis click on the following link https://shu.converis.clarivate.com

If you are signed in to SSO, you will be taken straight to your Converis dashboard.
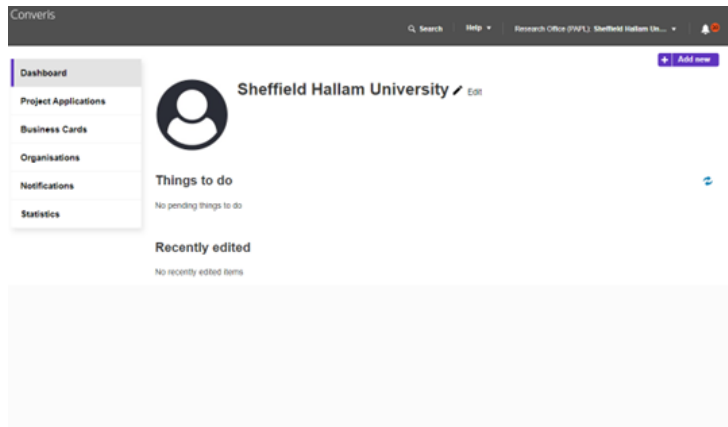
If you are not signed in to SSO, you will be redirected to the SHU authentication portal when you click the link.

Enter your SHU email address in the following format username@hallam.shu.ac.uk and click **Next**
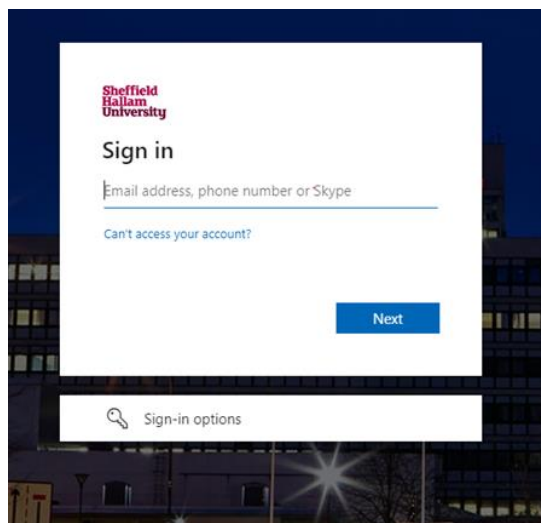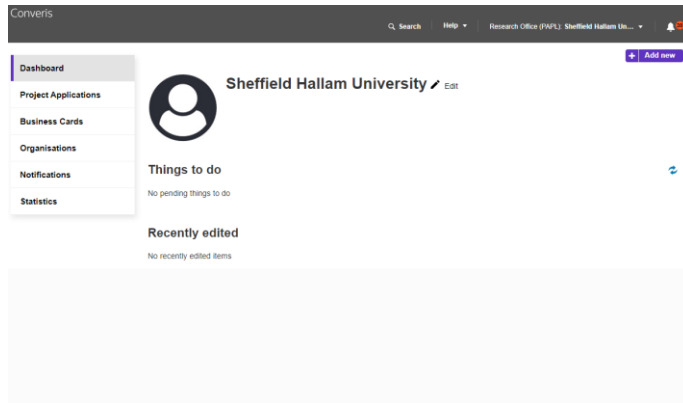
You will be redirected to the following page and asked for your SHU login username and password.

Enter your SHU **username** in the format username@hallam.shu.ac.uk and **password** and click **Sign In**.

Once authenticated, you will be logged in to Converis.
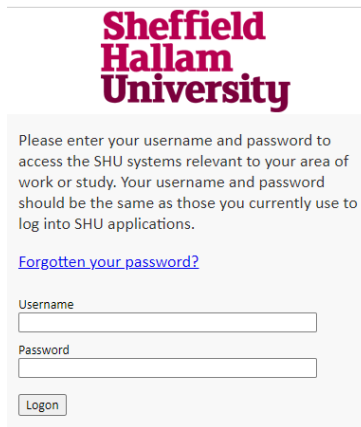
3. Accessing help

3.1 Technical Help

The self-service portal (Assyst) is used to manage requests for help.

You can access the portal at: http://itservicedesk.shu.ac.uk/

Enter your SHU username and password and click **Logon**

To request help, go to **Request a Service – Staff** in the bottom right corner of the screen, or **Request a Service – Students**
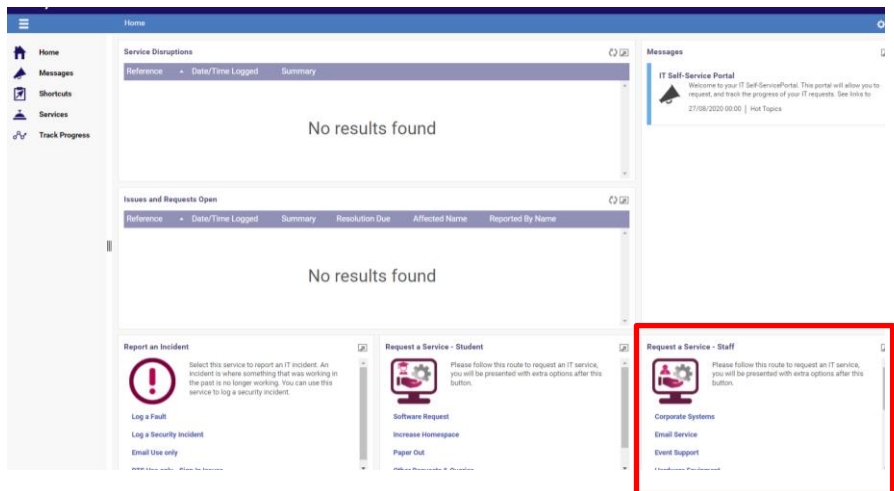
For staff requests, click **Corporate Systems,** then click **Converis**

For student requests, click **Converis**
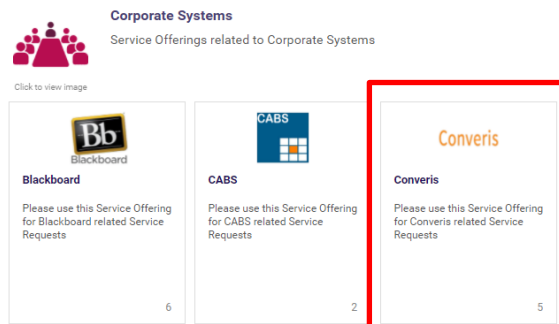
Select the required service
e.g. Activate Account
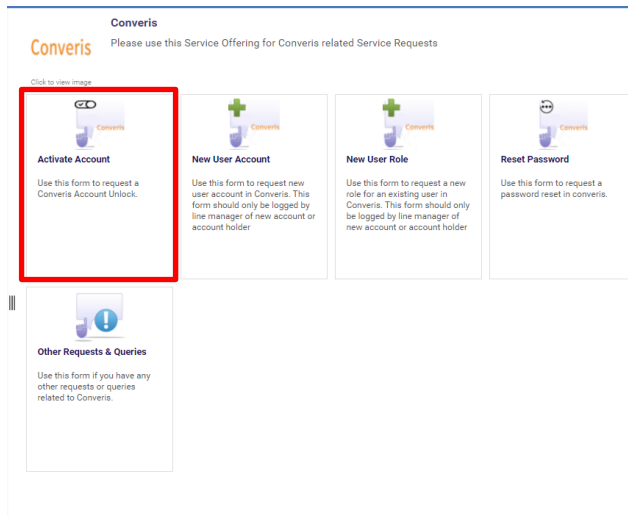
Complete the form and
click **Submit**
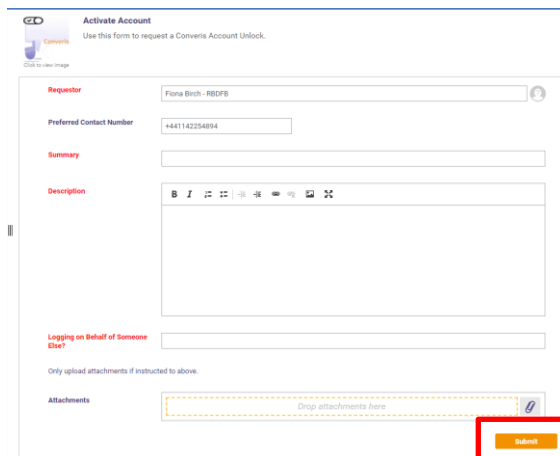
3.2   Application Specific Queries

Health   Research Institute Ethics
                Admin

[! RIS Health Industry & Innovation Ethics](#)

                Research Institute Ethics
                Lead

Dr Mayur Ranchordas

Industry &   Research Institute Ethics
Innovation   Admin

[! RIS Health Industry & Innovation Ethics](#)

                Research Institute Ethics
                Lead

Professor Simon Andrews

Culture &   Research Institute Ethics
Creativity   Admin

[! RIS Social & Economic Culture & Creativity Ethics](#)

                Research Institute Ethics
                Lead

Dr Ruth Deller

Social &   Research Institute Ethics
Economic   Admin

[! RIS Social & Economic Culture & Creativity Ethics](#)

                Research Institute Ethics
                Lead

Dr Jake Philips

3.3   Ethics Policy and Procedure Queries

Research and Innovation Office   ethicssupport@shu.ac.uk

4. Ethics Process Overview

Ethics Review Process

Legend:
- Reviewer action
- System action
- FEA – Faculty Ethics Administrator action
- Applicant action
- Doctoral supervisor action

Staff researcher determines pathway and completes application → Supervisor approval ← Doctoral researcher determines pathway and completes application

→ Pathway

Pathway branches:
- No human participants, human tissue or personal data
- Approval given elsewhere – another UK HEI
- Very low risk human participant studies
- All other research with human participants
- IRAS – projects requiring NHS or HMPPS ethics

No human participants, human tissue or personal data → FEA to answer question on Admin tab

If involves human participants, template type needs to be changed by Converis Support Team

FEA to answer question on Admin tab → Application recorded as Approved by FEA

Approval given elsewhere – another UK HEI → Application recorded as Approved by Applicant

Very low risk human participant studies → FEA assigns 1 Reviewer

All other research with human participants / IRAS – projects requiring NHS or HMPPS ethics → FEA assigns 3 Reviewers

FEA assigns 1 Reviewer / FEA assigns 3 Reviewers → Ethics review by Reviewer

If reviewer declines, FEA receive email to notify and reallocate review

Ethics review by Reviewer → FEA uses lead reviewers decision and moves workflow status on accordingly

Outcomes:
- Application recorded as Approved
- Application recorded as Approved with Advisory Comments
- Resubmission of Ethics Review is required
- Project not approved

Resubmission of Ethics Review is required → FEA move status of the application back to "Application Referred back for Resubmission" and Researcher notified by email

Project not approved → Researcher notified by email

Application recorded as Approved / Application recorded as Approved with Advisory Comments → Approval communicated to Researcher. All logged, and can be reported on and audited

Approval communicated to Researcher → Post approval amendments recorded on Converis record * → Amendment reviewed by Reviewer

*
Amendments to IRAS template should be submitted through the NHS system not the SHU Converis System
Amendments to Other UK HEI template should be submitted through the approving institutions system, not the SHU Converis System
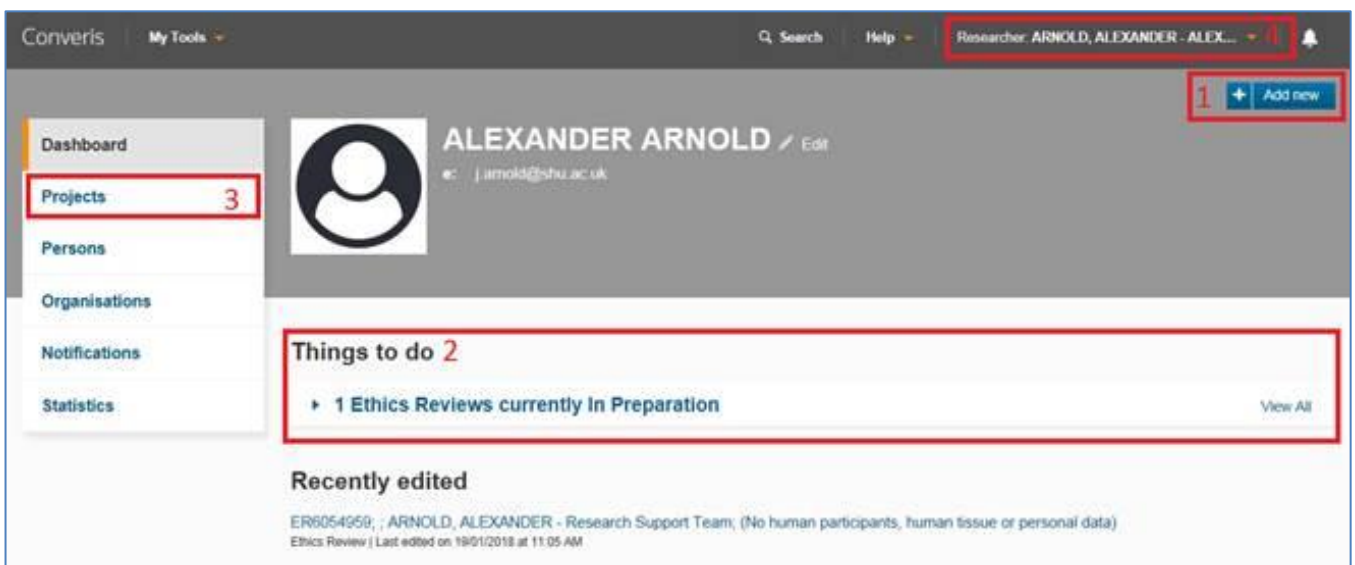
5. Creating an Ethics Review

After you log in to Converis you will arrive at the **Dashboard.**
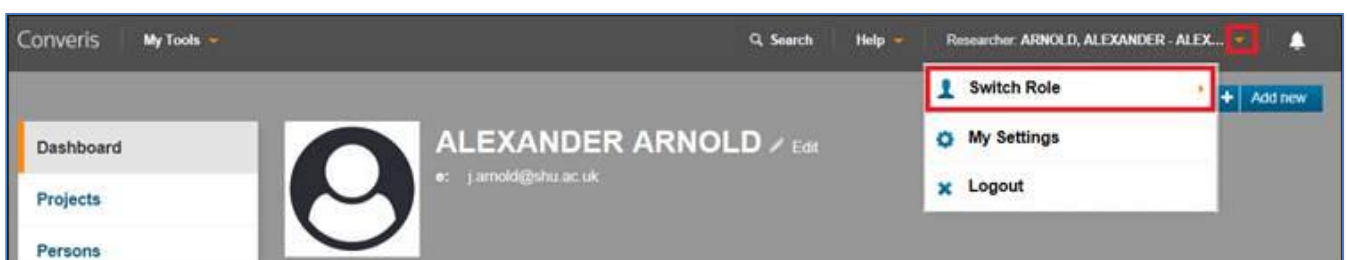
From this screen you can:

1. Create a new Ethics Review
2. Access Ethics Reviews you are currently preparing
3. View all of your Ethics Reviews
4. Switch roles and logout

You must be logged in as **Researcher** for staff research or for PhD/MRes/MbyRes applications you should be in your **Student** role.
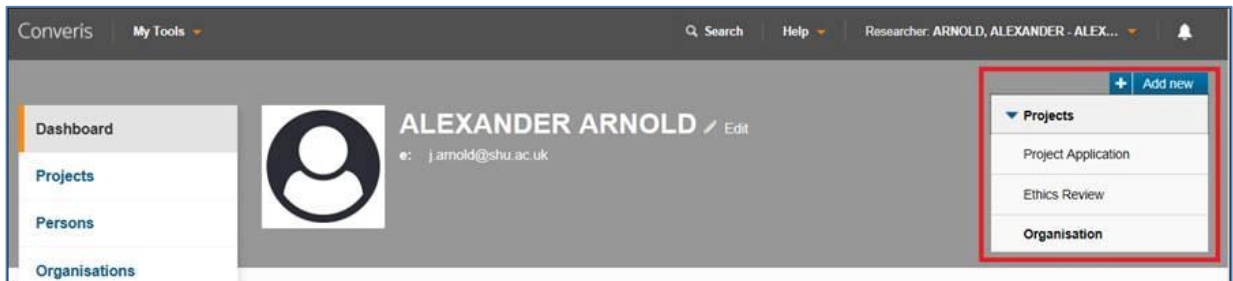
Click on the arrow in the top right of the screen and select **Switch Role**.

You will be returned to the Dashboard of your selected role.

5.1 Starting a new application

1. Click Add New

2. Select Projects / Ethics Review

3. You will then need to select the **Ethics Review Type.**

   There are five pathways (Ethics Review Types) to choose from. Each one reflects the level of risk associated with the research.

   Click on a template to create a new blank application.
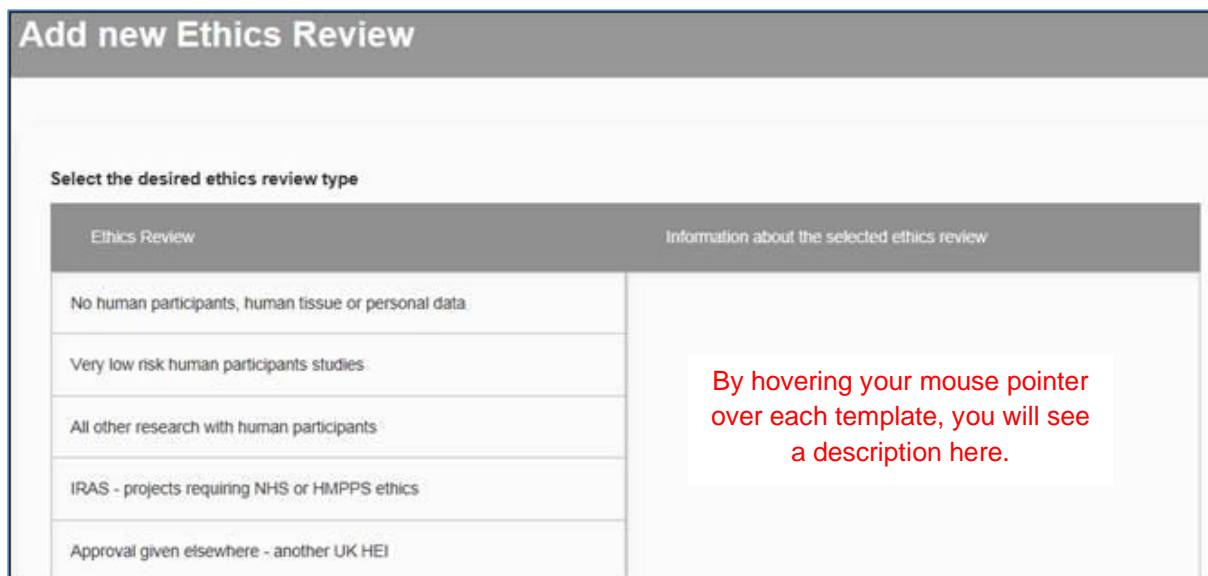
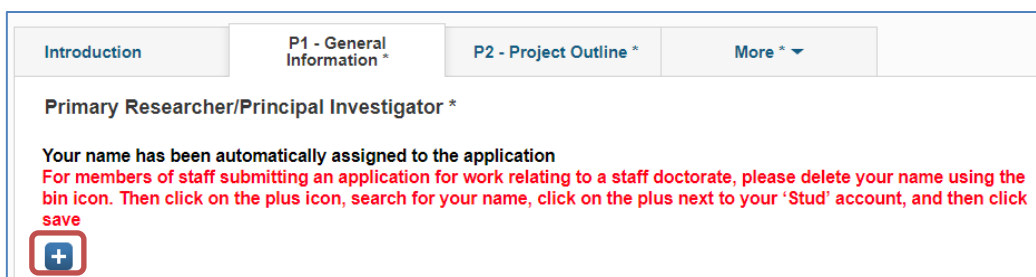Further information about each template can be found on the next page.

Name of pathway (template in Converis)	Description/to be used for	Is review required?	Process
No human participants, human tissue or personal data	• Desk based reviews. • Analysis of anonymised secondary data. • No interaction with human participants. • Typically only in areas such as humanities, engineering and physical sciences; although not all research in those areas has no participants.	No	Application created in Converis by Researcher and marked as approved by Faculty Ethics Admin.
Very low risk human participants studies *	• Participants not vulnerable; • No foreseeable risk of physical or emotional harm; • No potential pain; • Not a sensitive topic; • All participants giving informed consent; • No covert observation; • No drugs, food substances or invasive procedures being administered.	Yes by 1 reviewer	Application created in Converis by Researcher. Reviewer assigned by Faculty Ethics Admin. Reviewer responsible for responding.
All other research with human participants *	This is the standard ethics proforma and includes: • Bioscience; • Food science; • Sport science • And most social science research.	Yes by 3 reviewers	Application created in Converis by Researcher. Reviewers assigned by Faculty Ethics Admin. Lead Reviewer responsible for collating Reviewer's responses.
IRAS – projects requiring NHS or HMPPS ethics *	Project is being submitted to NHS or HMPPS (prisons and probation) ethics through IRAS	Yes by 3 reviewers	Application created in Converis by Researcher. Reviewers assigned by Faculty Ethics Admin. Lead Reviewer responsible for collating Reviewer's responses.
Approval given elsewhere - another UK HEI	In the case of collaborations reviewed under another UK university's approval process.	No	Application created in Converis by Researcher and recorded as approved.

* In studies with human participants, the online form includes health and safety risk assessment for the researcher as before. However, please note if it may be necessary to conduct a further health and safety risk assessment for the proposed research, for example for laboratory based studies. Further information can be obtained from your Faculty Safety Co-ordinator. Any further risk assessment can be uploaded to Converis alongside your other documents.

Your name will be automatically assigned to the application as the **Primary Researcher/Principal Investigator**.

If you are a member of staff submitting an application for work relating to a doctorate, follow these steps to remove your staff account and assign your student account to the application.

1. Delete your name by clicking on the bin icon.

2. Click on the blue plus icon.

3. Search for your name.

4. Click on the blue plus next to your student account (STUD)

Your student account will be added to the application.

5. Click **Save** at the bottom of the screen.

   This will save your new application to your account and you can then continue to work on it.
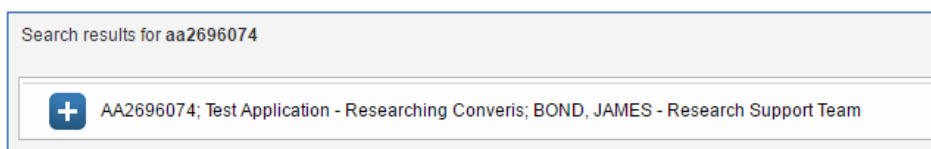
5.2 Completing the rest of the application

- You can move backwards and forwards between tabs.

- Information entered into fields *is not* automatically saved. Click on the **Save** button at the bottom of the screen at regular intervals to avoid losing information.

- The **Save and Close** button will close the record you are working on as well as saving the data that has been entered. Leave the record in the In Preparation status so that you can return to edit it.

- Mandatory Fields have an * next to them; this means they must be completed before the status of the application can be submitted.

- If your review is linked to a project application in Converis, use the **Converis Project Application** field to link the records.

  Click on [+].   Enter the **Title** or **Project ID** of the application and click the magnifying glass icon.

  Select the record by clicking on [+].

  Search results for **aa2696074**

  [+] AA2696074; Test Application - Researching Converis; BOND, JAMES - Research Support Team

- If the project is <u>**Doctoral research**</u> you will need to add your Director of Studies**.** This can be done in the same way as when adding yourself as the Principal Investigator.

If Doctoral research, please name your Director of Studies

Click on the blue plus icon below to add the Director of Studies. Another member of your supervisory team may be nominated to undertake this on behalf of your Director of Studies.

If the Director of Studies cannot be found in the system please email converis@shu.ac.uk

[+]

- If the project is <u>**Doctoral research**</u> you can also add all the members of your Supervisory Team. This enables them to view your application. If a supervisor is from an external institution please add them to the text box under **Q3b. External Investigator Details** (they will not be able to view your application but you could download a PDF copy and send this via email.)

If Doctoral research, please name all members of your Supervisory Team

Click on the blue plus icon below to add the members of your Supervisory Team.

If members of your Supervisory Team cannot be found in the system please email converis@shu.ac.uk

- If you are carrying out **Staff Research** and would like to add a Co-Investigator please add Co-Investigators in **Q3a. Other SHU Investigator.** Co-Investigators can edit the application while it is "In Preparation". They cannot sign off the application on behalf of the Principal Investigator.

Q3a. Other SHU Investigator

For staff projects, add any SHU collaborators here

- If your research is funded but you can't find the **Funder** on the system you can add a new record for them by clicking on the icon highlighted in the picture below.

Q8b. If the research is externally funded, who is the Funder?

- To upload documents click on this icon 📁 .
    o Select your document and click **Open**.
    o Complete the **Document Type** and **Description**.
    o To open documents in Converis, click on the file type Icon.

Upload Documents Here

	Name	Document Type	Description	
W	Health and safety plan.docx	Select document type ⌄		🗑

5.3   Principal Investigator Sign-off

Once all fields are complete the application needs to be signed-off before submitting into the system.

Click on the **P9 - Adherence to SHU Policy and Procedures** tab and complete the Principal Investigator Sign-off.

Please note only the Principal Investigator can sign off an application.

5.4 Moving your application on to the next stage

When you have completed your application, click on the **Save & Close** button at the bottom right of the Converis screen.

The status box will pop up. Select the appropriate workflow status for your role then click **Done**.

For Staff Research
On All Other Research, Very Low Risk, No Human Participants or IRAS

This will generate an email to your Faculty Ethics Admin Team whowill then process your application.

For Student Research
On All Other Research, Very Low Risk, No Human Participants or IRAS

This will generate an email to your Director of Study to ask them to sign-off your application before submitting it to the Faculty Ethics Admin Team to process.
They may return the application to you, to edit, if they consider revisions are needed before the application can be submitted for review.

For Staff /Student Research
On Approval given elsewhere - another UK HEI

This will generate an email to you to confirm the approval has been registered

5.5   What happens next?

If you have responded yes to any of the following questions, an email will be sent to the appropriate contact:

i) Participants under 5 years old	P1 Tab	Insurance Team
ii) Pregnant women	P1 Tab	Insurance Team
iii) 5000 or more participants	P1 Tab	Insurance Team
iv) Research being conducted in an overseas country	P1 Tab	Insurance Team
Q4. Are you likely to be generating potentially security-sensitive data that might need particularly secure storage?	P2 Tab	IT Help
Q3. Is this a clinical trial?	P3 Tab	Insurance Team
Are you uploading a Risk Assessment Form?	P8 Tab	Health and Safety
Are you uploading a Data Management Plan?	P8 Tab	Library Support Team

Pathway
- No human participants, human tissue or personal data;

If the correct template has been selected and completed, your application will be recorded as 'Approved' and you will receive email notification to this effect.

- Approval given elsewhere - another UK HEI

Once you have completed the application and save and closed it, you should set the status to 'Approved'.

- Very low risk human participants

Faculty Ethics Administrators will assign a reviewer and it will be their responsibility to make a final decision.

- All other research with human participants
- IRAS - projects requiring NHS or HMPPS ethics

Faculty Ethics Administrators will assign three reviewers. One of the Reviewers will be assigned as Lead, and it will be their responsibility to collate all comments and make a final decision.

Where there has been a difference of opinion between the three Reviewers that cannot be resolved, the Lead Reviewer may ask the Faculty Research Ethics Chair (FREC) to arbitrate.

5.6   Notification of outcome

When a decision has been made, you will receive an email to notify you of the outcome. There are five possible decisions that Reviewers can make:

1. Application Approved
2. Application Approved with Advisory Comments
3. Application Referred back for Resubmission
4. Application Not Approved
5. Second Resubmission Required (where application has already been resubmitted once)

Comments collated by the lead reviewer will be provided in the email.

5.7   If you have to resubmit

If your Ethics Review application has been "Referred back for Resubmission" you will receive an email notification containing collated comments from the Lead Reviewer/FREC.

Doctoral Students are encouraged to seek the advice of their Director of Studies before resubmitting the application for further full review.

You should then amend your application based on these comments.

If you need to change your response to any of the questions below, please email the Converis Support Team (converis@shu.ac.uk) with the relevant details.

i) Participants under 5 years old	P1 Tab
ii) Pregnant women	P1 Tab
iii) 5000 or more participants	P1 Tab
iv) Research being conducted in an overseas country	P1 Tab
Q4. Are you likely to be generating potentially security-sensitive data that might need particularly secure storage?	P2 Tab
Q3. Is this a clinical trial?	P3 Tab
Are you uploading a Risk Assessment Form?	P8 Tab
Are you uploading a Data Management Plan?	P8 Tab

After you have completed your changes, you should fill in the box at the bottom of the P10 tab called "Applicants Comments to Reviewers (following resubmission)" summarising your changes. Please ensure you complete this summary so the Reviewer can see where your changes are on the application.

When you are finished, click on save and close and set the status to "Send for approval by reviewers", then click on done. This sends an email to the lead reviewer/FREC to review the application again and amend their final decision.

5.7.1 Resubmission Process Map
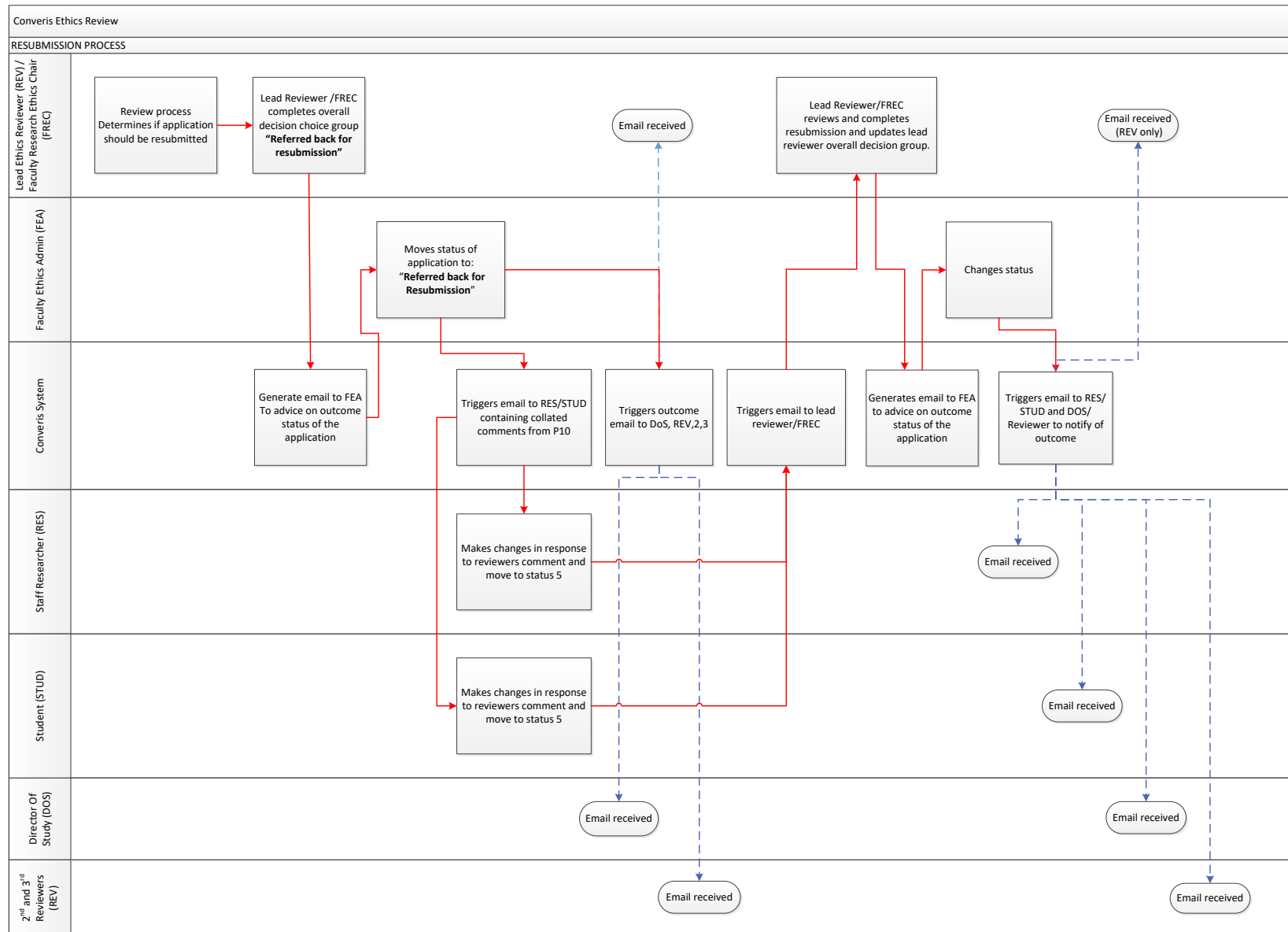
5.7.2 If you have to resubmit on a different template type

If the reviewer's recommendation is to submit on a different template type, you will need to contact the Converis Support Team (converis@shu.ac.uk) with the following information:

- The Ethics ID number (beginning ER)
- The template type the application needs to be changed to
- The reason for the change in template type

The team will then arrange for the template to be changed to the correct type and the application will be returned to "In Preparation", where it can be further edited by you. You will receive an email to notify you when this has happened.

When you have finished editing your application, click on Save & close and move the status on as indicated in the table below.

Template Type	Staff Researchers Move the status of the application to:	Doctoral Researchers Move the status of the application to:
For No Human Participants templates	Send for Admin Check	Send for Director of Studies Approval
For All Other Research templates	Send for Admin Check	Send for Director of Studies Approval
For IRAS templates	Send for Admin Check	Send for Director of Studies Approval
For No Human Participants	Send for Admin Check	Send for Director of Studies Approval
For UK HEI	Application Approved	Application Approved

5.8   If your application is not approved

In cases where the application is not approved, you have the right to appeal to the University Research Ethics Committee (UREC) by contacting the Head of Research Ethics, Professor Ann Macaskill (a.macaskill@shu.ac.uk)
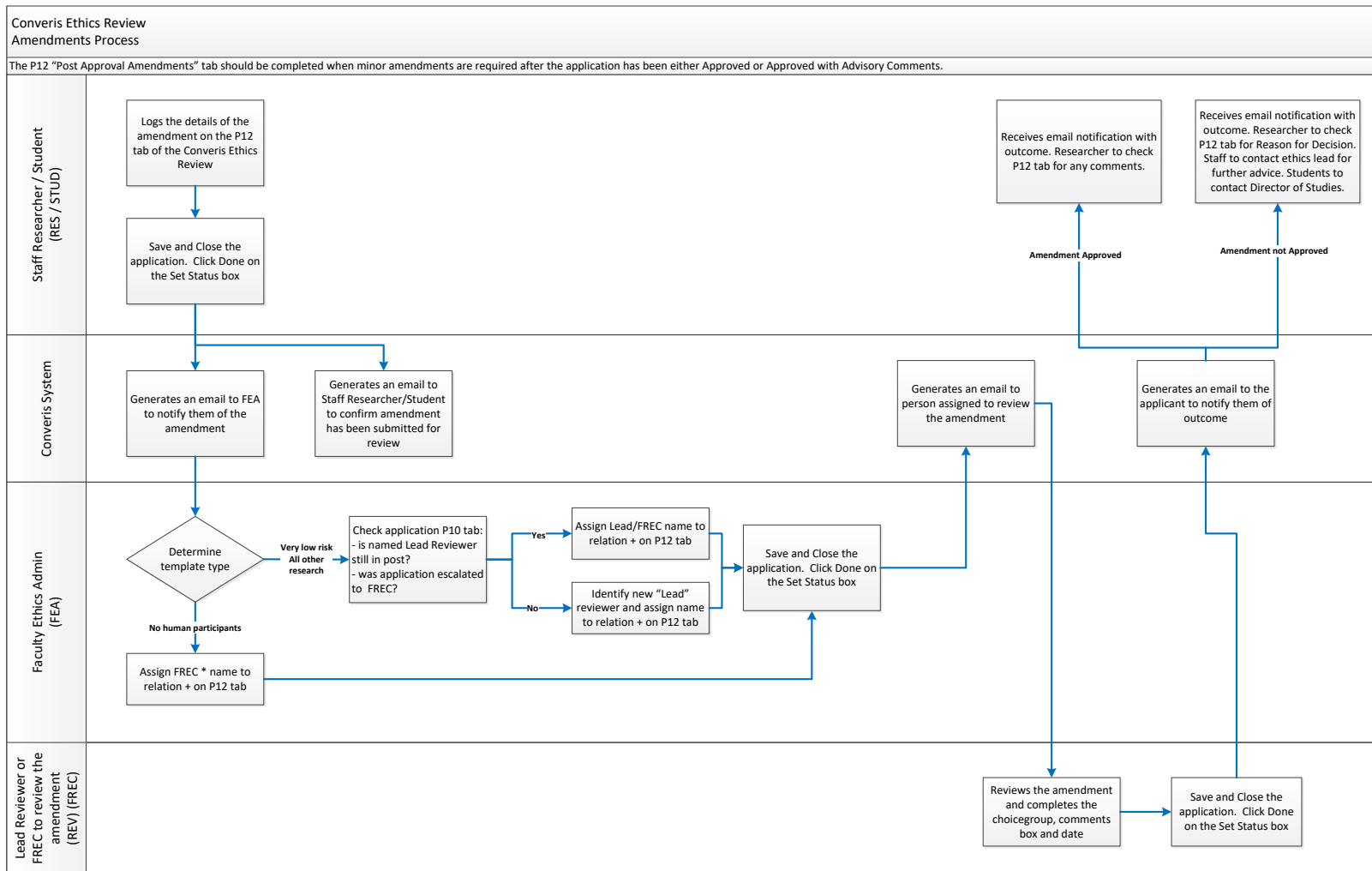
5.9   Your responsibilities post-approval

Once ethics approval has been granted, you are expected to deliver the project in accordance with the University's research ethics and integrity policies and procedures: https://www.shu.ac.uk/research/excellence/ethics-and-integrity/approvals1.

As the Principal Investigator you are responsible for monitoring the project on an ongoing basis and ensuring that the approved documentation is used. The project may be audited by the University during or after its lifetime.

The email confirming approval should be kept and stored in your project research files.

5.10 Post Approval Amendments

If amendments to your study are required after approval has been granted, these should be recorded on the tab called "P12 - Post Approval Amendments" and the following process followed.

Converis Ethics Review
Amendments Process

The P12 "Post Approval Amendments" tab should be completed when minor amendments are required after the application has been either Approved or Approved with Advisory Comments.

Staff Researcher / Student (RES / STUD)

- Logs the details of the amendment on the P12 tab of the Converis Ethics Review
- Save and Close the application. Click Done on the Set Status box
- Receives email notification with outcome. Researcher to check P12 tab for any comments.

  Amendment Approved
- Receives email notification with outcome. Researcher to check P12 tab for Reason for Decision. Staff to contact ethics lead for further advice. Students to contact Director of Studies.

  Amendment not Approved

Converis System

- Generates an email to FEA to notify them of the amendment
- Generates an email to Staff Researcher/Student to confirm amendment has been submitted for review
- Generates an email to person assigned to review the amendment
- Generates an email to the applicant to notify them of outcome

Faculty Ethics Admin (FEA)

- Determine template type
  - Very low risk / All other research → Check application P10 tab: - is named Lead Reviewer still in post? - was application escalated to FREC?
    - Yes → Assign Lead/FREC name to relation + on P12 tab
    - No → Identify new "Lead" reviewer and assign name to relation + on P12 tab
    - → Save and Close the application. Click Done on the Set Status box
  - No human participants → Assign FREC * name to relation + on P12 tab

Lead Reviewer or FREC to review the amendment (REV) (FREC)

- Reviews the amendment and completes the choicegroup, comments box and date
- Save and Close the application. Click Done on the Set Status box

Notes:
Amendments to IRAS template should be submitted through the NHS system not the SHU Converis System
Amendments to Other UK HEI template should be submitted through the approving institutions system, not the SHU Converis System
* If FREC unavailable, another member of Faculty Research Committee can be assigned

6. Director of Study Approval

6.1 Accessing the Application

1. When a Doctoral Student has completed an Ethics Review Application you will receive an email notifying you it is ready for you to approve and sign-off as ready for review.
   Please note that applications on the Approval given elsewhere - another UK HEI template are not sent to the Director of Study for sign-off.
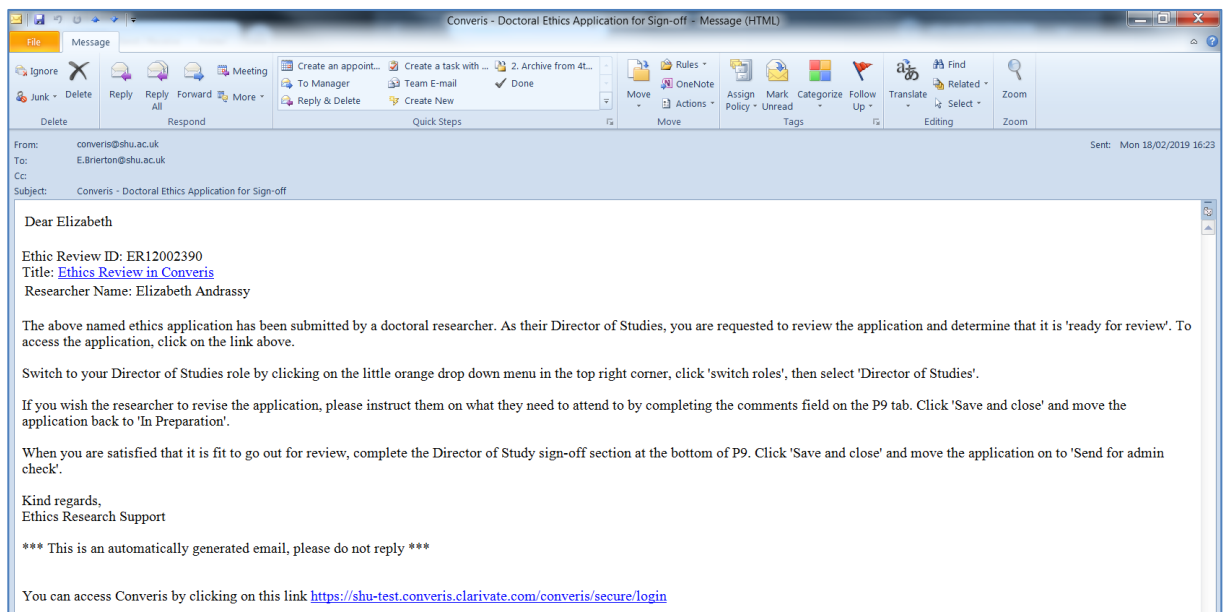
2. Click on the blue hyperlinked title to access the application.
3. Login to Converis.
4. Important: If after logging in, you get the following **Access denied** message you will need to switch to your Director of Study role.
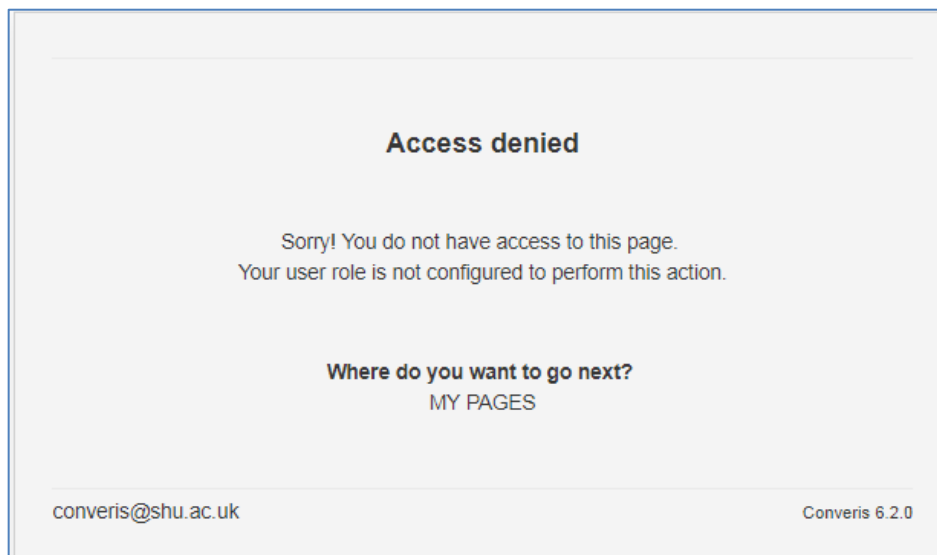
5. Click on the arrow in the top right of the screen and select **Switch Role**, then choose **Director of Study**.
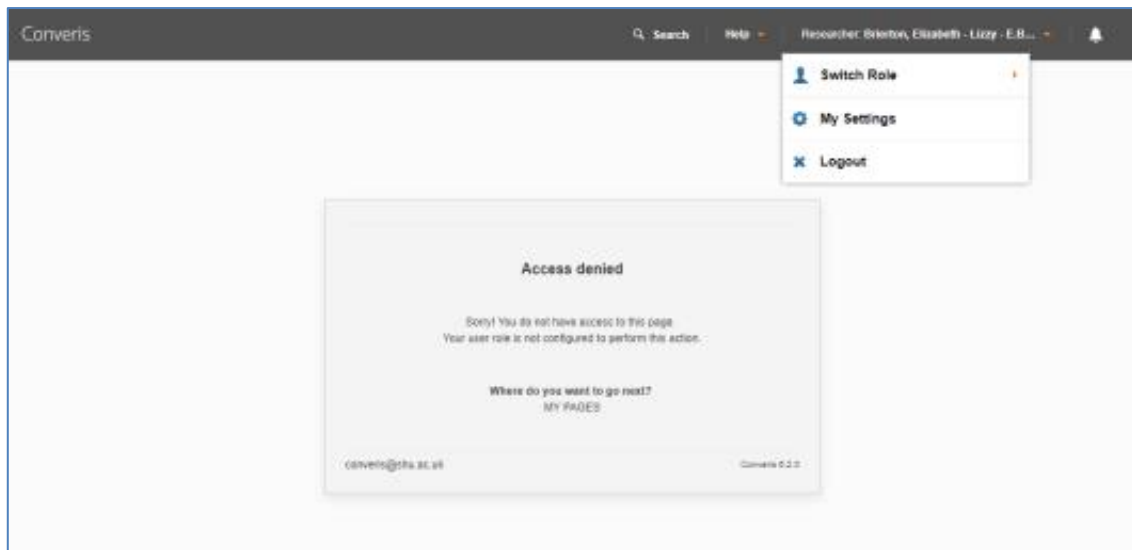
6. You will be returned to the Dashboard for your Director of Study role.
7. Click on the application listed in your **Things to Do** section this will take you into the application.

8. Read through the Ethics Review application by clicking through each tab.

6.2 Sending the Ethics Review back to the Student

If the application is not yet ready for you to approve then it should be returned to the Student for amendments to be made.
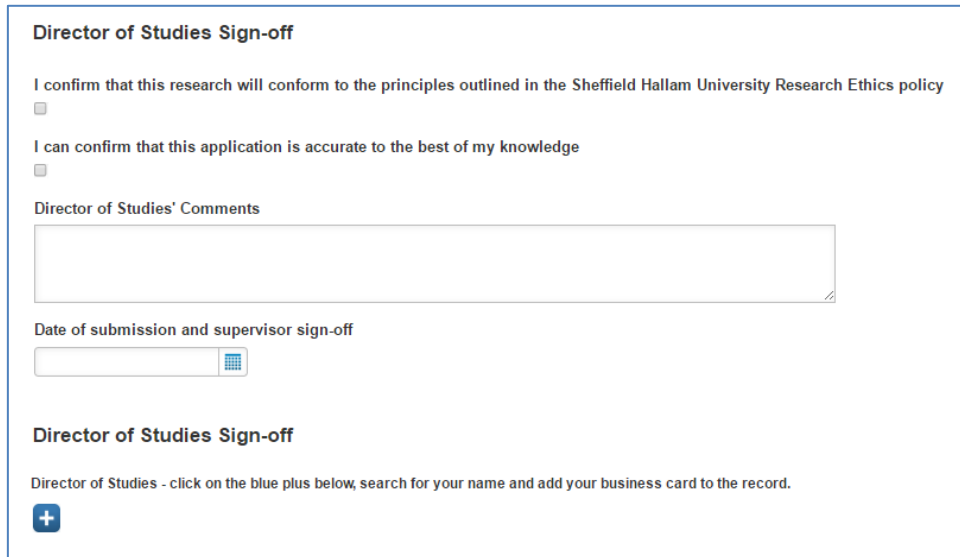
1. Complete the comments field on P9.
2. Save and Close the Application.
3. Change the Status to **In Preparation** and click **Done**.

* The Student will now receive an email notifying them of your comments.

6.3   Signing off the application

If the application is ready for you to approve:

1. Navigate to the "P9 - Adherence to SHU Policy and Procedures" tab.
2. Underneath the Principal Investigator Sign-off section you will see a section called, Director of Studies Sign-Off.
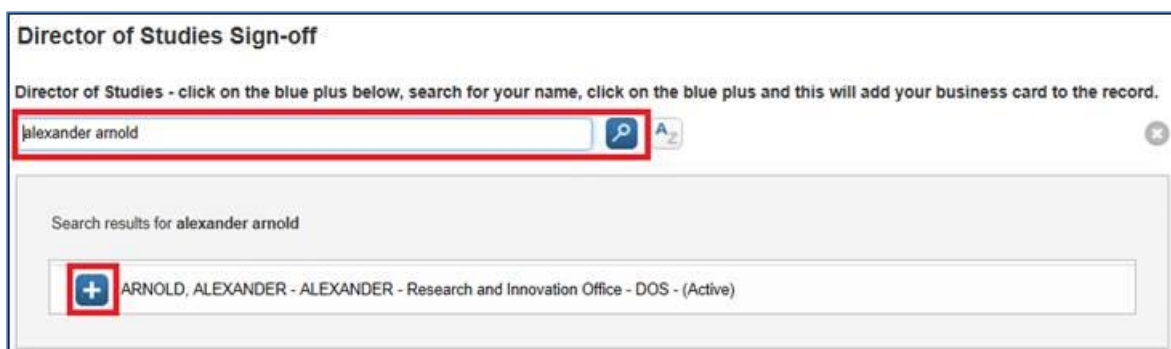
3. Complete all fields in this section ensuring that you add your name to sign-off the application. To do this you need to search for and apply your Director of Studies Business Card.

4. Click on the blue plus.

5. Type in your name and click on the magnifying glass to search. This will bring up your Director of Study Business Card. Click on the blue plus next to your name.

6. Now click on Save and Close

7. The Set Status box will then appear - select **Send for Admin Check** - click on Done.

6.4   What happens next?

Once you have Saved & Closed the application after signing-off the application, Converis will notify the Faculty Ethics Administrator that there is an application for them to check.

The Administrator is then responsible for assigning reviewers (where the application requires review), sending the application onto Reviewers and in turn changing the workflow status of the application to reflect the decision made.

When a final decision has been made, Converis will notify you and the Student of the outcome of their application.

7.   Ethics Reviewers

Ethics Review applications on the All Other Research and IRAS templates are assigned three reviewers:

- The Lead Reviewer generally being an experienced researcher with cognate subject expertise
- 2nd and 3rd Reviewers, who may be subject experts, have methodological overlap, can be lay Reviewers (lay members or Researchers with no natural research connections).

Ethics Review applications on the Very Low Risk template are assigned one reviewer.

7.1   Accessing the Application

1. You will be notified by email when you have been assigned to review an Ethics Review application. The email notification will inform you whether you have been allocated as Lead, 2nd or 3rd Reviewer.

2. Click on the blue hyperlinked title to access the application.

3. Login to Converis.

4. Important: If after logging in, you get the following **Access denied** message you will need to switch to your Ethics Reviewer role.
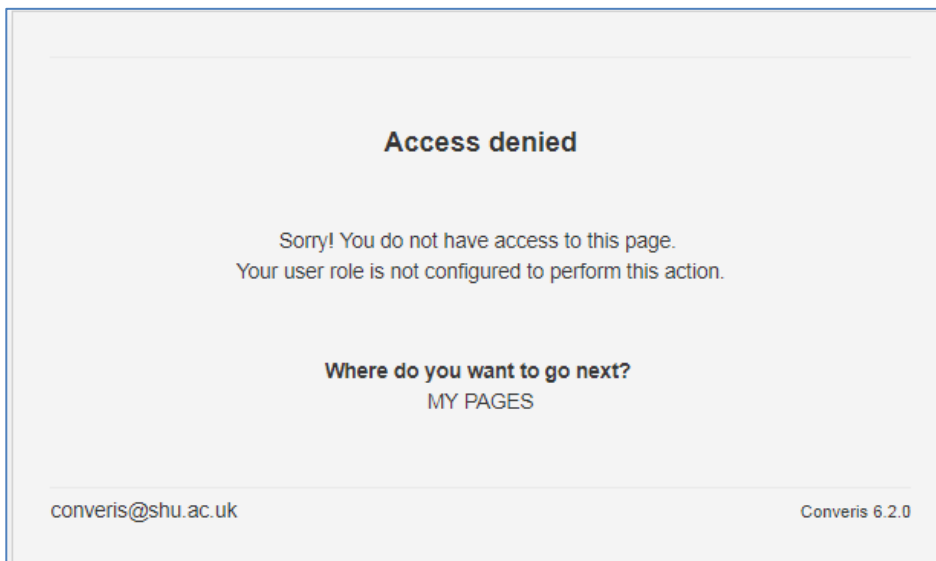
5. Click on the arrow in the top right of the screen and select **Switch Role**
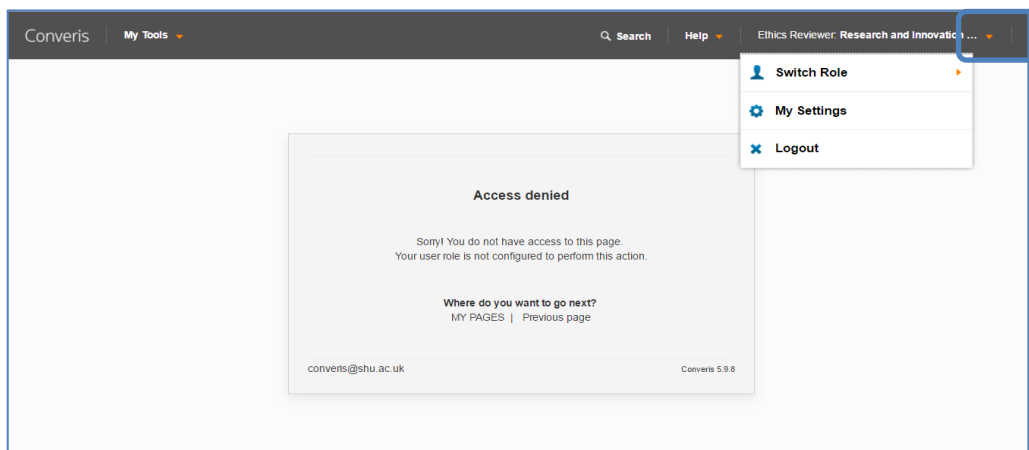
6. You will be returned to the Dashboard for your Ethics Reviewer role.
7. Click on the application listed in your **Things to Do** section this will take you into the application.

7.2   Declining to review the application

To decline to review an application, please follow these steps:

1. Navigate to the P10 Review tab and go to the section where your name is listed.
2. Tick the check-box below your name to decline.
3. Provide a reason for declining the review in the comments box.

I am unable to review this application (tick box below)
☐

Please provide a reason why you are declining to review the application

4. Click on Save and Close at the bottom of the screen.
5. The Set Status box will then appear - click on Done.

An email will now be sent to the Faculty Ethics Admin to inform them you have declined to review the application and the reason why, so that they can reallocate reviewers to the Ethics Review.

7.3 Reviewing the application

1. To review the application, navigate to the P10 Review tab and go to the section where your name is listed.

2. Complete all required fields in this section. If you have substantial comments please upload as a word document and write "see attached document" in the comments box.

In my judgement the application should be:

Select Ethics Approval De ⌄

Reason for decision

If your decision is that the application requires amendments, resubmission or shouldn't be approved, please provide details here.

Upload

📁

I confirm that I do not have a conflict of interest with the project application
☐

Date of review

▦

3. Click on Save and Close at the bottom of the screen.

4. The Set Status box will then appear - click on Done.

7.4　Lead Reviewers Responsibilities

In addition to reviewing the ethics application, the lead reviewer is also responsible for collating the comments of all reviewers and making an overall decision. They can escalate the application to the Faculty Research Ethics Chair for their input.

Once all reviewers have reviewed the application:

1. Navigate back to the tab "P10 - Review".
2. Review the decisions and comments made by all reviewers.
3. **If there is consensus or you are confident to make a decision:**

   a) Scroll down to the bottom of the page to the following section - "**This section to be completed by Lead Reviewer (or FREC if escalated)**".

   b) Complete the following fields:
      - Comments collated by Lead Reviewer (or FREC if escalated) or upload your feedback as an attachment. In the upload section, click on the blue folder icon and upload your document.
      Please note that the applicants will be able to view the comments in this field.

      Note: If you upload your feedback as an attachment make a note in the collated comments box above to say "See attached feedback".

      - Final Decision to be completed by Lead Reviewer (or FREC if escalated)

         - Application Approved
         - Application Approved with Advisory Comments
         - Application Referred back for Resubmission
         - Application Not Approved.
         - ((Second Resubmission Required))

      - Date of Final Decision

   c) Now click on Save and Close

   d) The Set Status box will then appear - click on Done.

4. **If there isn't consensus or you aren't confident to make a decision:**

a) Scroll down to the bottom of the page to the following section - "**This section to be completed by Lead Reviewer (or FREC if escalated)".**

b) Click on the blue plus

c) Type in the Faculty Research Ethics Chair (FREC) surname and click on the magnifying glass icon.

d) You will be presented with a list of Faculty Research Ethics Chairs that match your search criteria.

e) Click on the blue plus icon next to the correct Faculty Research Ethics Chair to add them to the record.

f) Now click on Save and Close.

g) The Set Status box will then appear - click on Done.

7.5   What happens next?

7.5.1   If outcome decision made by Lead Reviewer

Once you have Saved & Closed the application after making your judgement, Converis will notify the Faculty Ethics Administrator of the Final Decision.

The Administrator is then responsible for changing the workflow status of the application to reflect the decision made.

Converis will then notify the applicant of the decision.

7.5.2   If escalated to FREC Chair for outcome decision

Once you have Saved & Closed the application, after adding the FREC business card to the record, Converis will notify them that they have been asked to review an application.

The Faculty Research Ethics Chair is then responsible for reviewing the application, collating the comments and making a final decision.

7.6   Reviewing a Resubmitted Application

You will receive an email notification with instructions (as below) when an applicant has resubmitted an application that has previously been 'Referred back for Resubmission'.

Only the Lead Reviewer is required to review applications that are being resubmitted. The second and third reviewers will not receive an email notification.
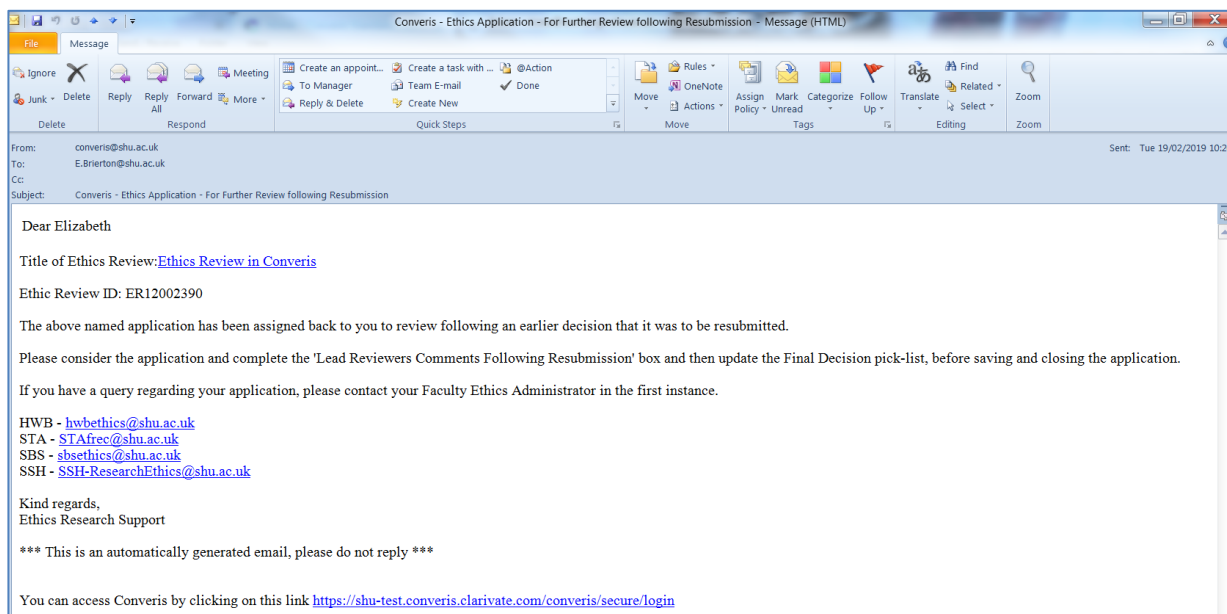
7.7   Reviewing Amendments

When an amendment for an approved (or approved with advisory comments) ethics review is submitted, a reviewer will be assigned to review the amendment.

The reviewer will receive an email notifying them of what to do.
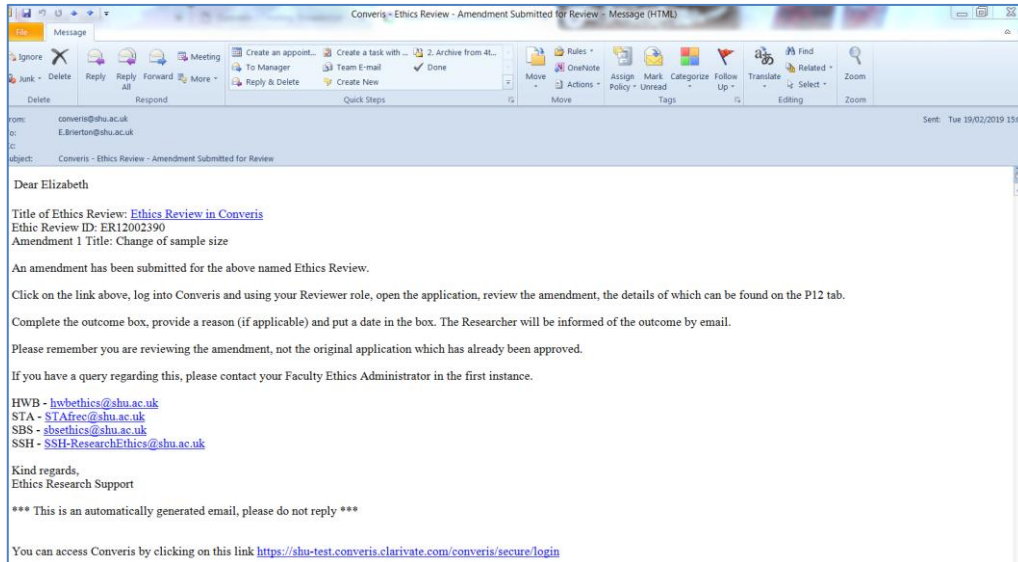
The following steps should be followed:

1. Log into Converis.
2. Navigate to the P12 tab and review the amendment.
3. Complete the decision choice group for the relevant amendment, provide a reason if required and date the amendment.

4. Then save and close the application, and click done when the set status box appears.

The applicant will then receive an email notifying them of the outcome.

8. Faculty Research Ethics Chair (FREC)

8.1 Reviewing an application

1. You will be notified by email if a Lead Reviewer escalates an ethics review to you.
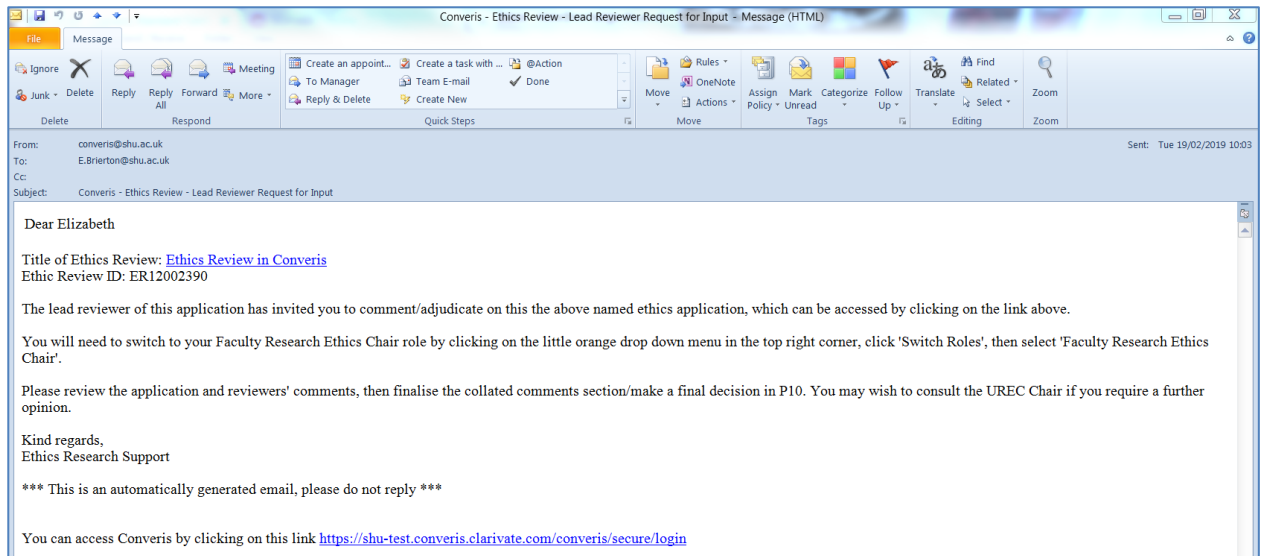
2. Click on the blue hyperlinked title to access the application.

3. Login to Converis.

4. Important: If after logging in, you get the following **Access denied** message you will need to switch to your Faculty Research Ethics Chair role.
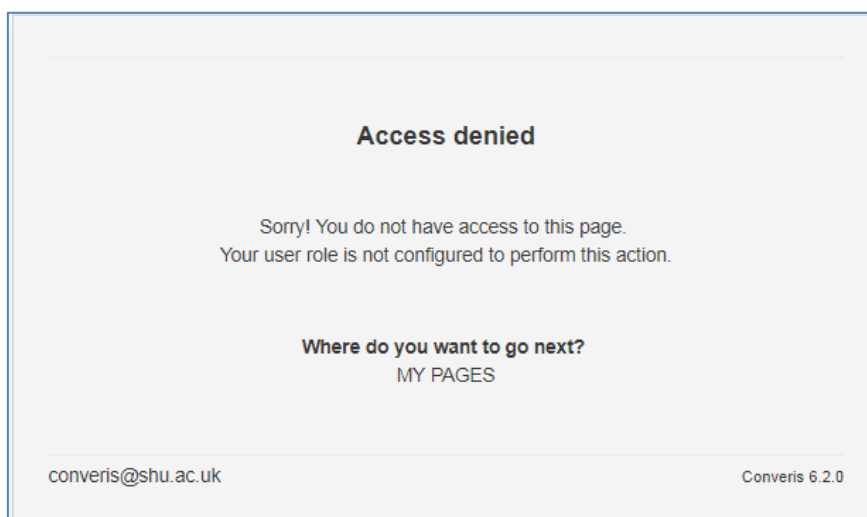
5. Click on the arrow in the top right of the screen and select **Switch Role**
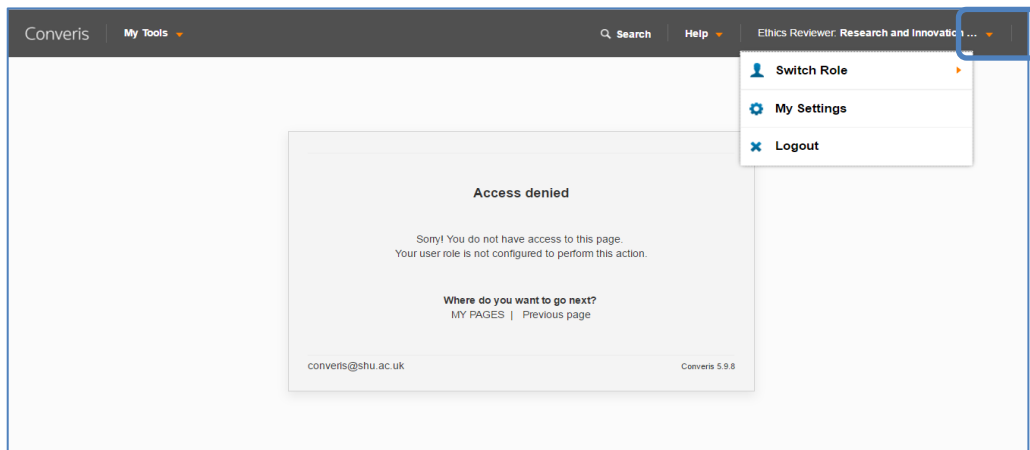
6. You will be returned to the Dashboard for your Faculty Research Ethics Chair role.

7. Keep Converis open and click on the link contained within the email again and you will be able to access the Browse template.

8. Click on edit to access the detail of the application.
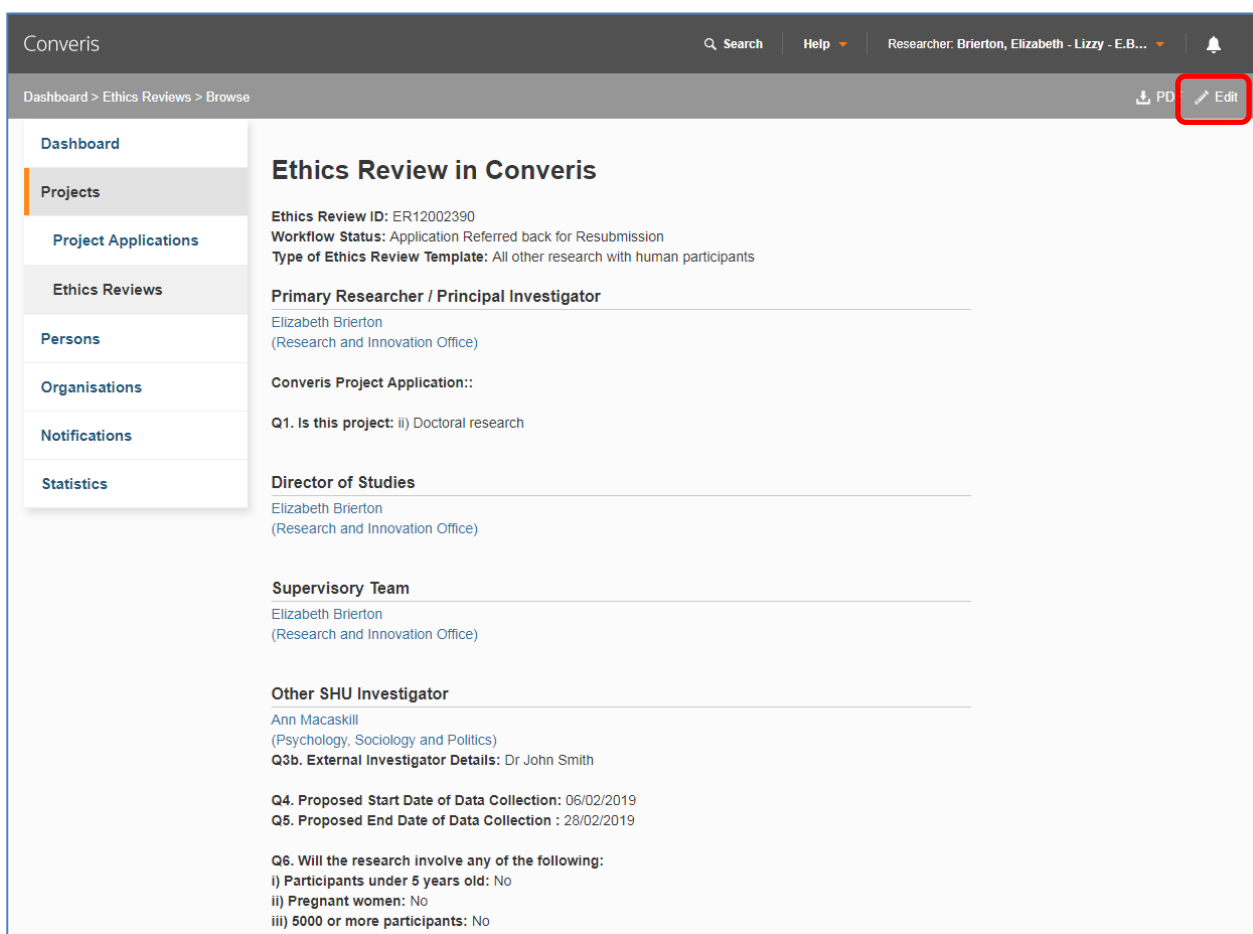
9. You should now read through the Ethics Review application by looking through each tab.

   Once you have read through the information contained in Converis, you can proceed to make your decision.

10. Navigate to the tab called "P10 - Review".

11. You can now review the comments made by the Lead, 2nd and 3rd Reviewer.

12. Next, scroll down to the bottom of the page to the following section - "**This section to be completed by Lead Reviewer (or FREC if escalated)**".

13. You will see your name added as the Faculty Research Ethics Chair.

14. Complete the following fields:
    a. Comments collated by Lead Reviewer (or FREC if escalated) or upload your comments as an attachment you can do this by clicking on the folder icon under Upload. Please make a note in the comments box to say "Please see attached document".
       Please note that the applicants will be able to view the comments in this field.

    b. If the application is being reviewed following Resubmission then complete the "Lead Reviewers Comments following Resubmission" box.
    c. Final Decision to be completed by Lead Reviewer (or FREC if escalated)

       ▪ Approved
       ▪ Application Approved with Advisory Comments
       ▪ Application Referred back for Resubmission
       ▪ Not Approved for the reasons listed below
       ▪ ((Second Resubmission Required))

d. Date of Final Decision

15. Now click on Save and Close

16. The Set Status box will then appear - click on Done.

8.2 What happens next?

Once you have Saved & Closed the application after making your decision, Converis will notify the Faculty Ethics Administrator of the Final Decision.

The Faculty Ethics Administrator is then responsible for changing the workflow status of the application to reflect the decision made.

Converis will then notify the applicant of the decision.

9.   Cloning a record

To clone a record:

1. Click on Ethics Review

2. You will see all the Ethics Reviews you have access to

3. Find the Ethics Review you wish to clone

4. Click Clone
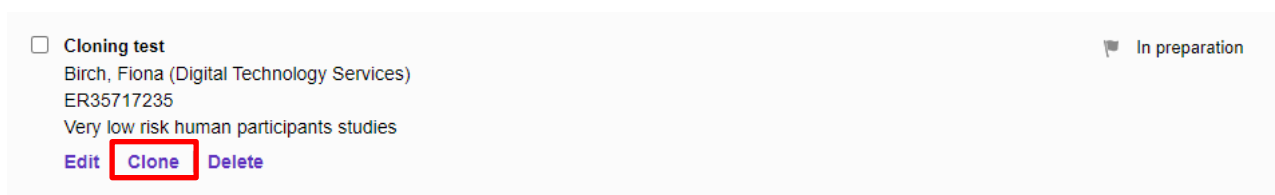
5. Then click Save without editing

6. A new Ethics ID is populated

7. You can now edit the record

10.   Producing a PDF of an Ethics Review

1. Click on Projects

2. Click on Ethics Reviews

3. You will see all the Ethics Reviews you have access to

4. Find the Ethics Review you would like to PDF

5. Hover anywhere over the light grey box of that application
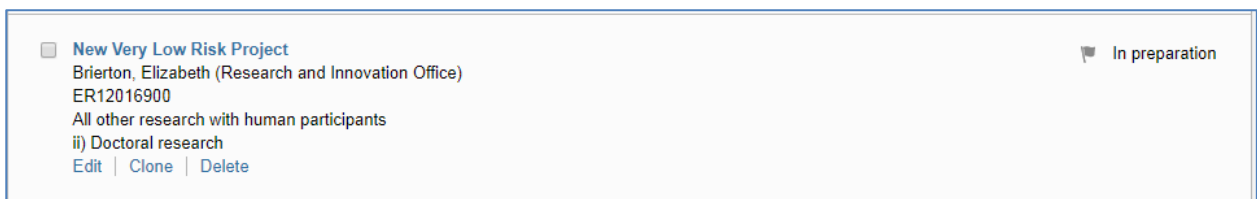
6. The colour will change to a darker grey

7. Click anywhere except on the Edit button

8. Allow a few seconds for the Browse Template to load

9. On the new window click PDF in the top right

IRAS Application Process

Informed by NHS or HMPPS partner that an IRAS application is required and that SHU would be the appropriate sponsor. Contact with the partner R&D office and the HRA decision tool will inform this

http://www.hra-decisiontools.org.uk/research/

https://www.myresearchproject.org.uk/

Complete draft of IRAS form

FAQs on Completing the IRAS Form

9) This project filter section is key. Doctoral researchers should tick that their work 'is an educational project'

A4) The contact for sponsor should be: Dr Keith Fildes, Research and Innovation Office, researchsupport@shu.ac.uk; not the researcher

A64) The contact for sponsor should be: Dr Keith Fildes, Research and Innovation Office, researchsupport@shu.ac.uk; not the researcher

A76-1, -2 and -3) If the logical answer isn't NHS (first box), tick other (second box) and write 'Sheffield Hallam University indemnity will apply'
The University's three insurance certificates can be found at https://staff.shu.ac.uk/enterprise/research/support_shuinfo.asp#insurance, and should be uploaded to IRAS

D1 and D3) The PI should sign D1. For doctoral studies the supervisor should sign D3

Upload draft IRAS form and all supporting documents to the IRAS pathway in Converis

Scientific Review occurs in Converis

https://shu.converis.clarivate.com/converis/secure/login

Make required changes to IRAS form and submit it

Undertake necessary insurance checks and confirm SHU sponsorship

Ethical Review

Engage with the REC and respond to their requests and queries. Attendance in person is encouraged

Researcher action

NHS or HMPPS action

RIO action

SHU reviewer action

https://www.hra.nhs.uk/documents/1006/statement-activities-word-template.docx

If requested to, complete a Statement of Activities (with input from RIO contracts team)

FAQs on Completing the Statement of Activities Form

Page 1: Researcher to complete

Question 1: Yes, but SHU will be guided by the NHS regarding this - please liaise with your NHS research partner to get their view on whether this should be the sole agreement or whether the NHS require a model non-commercial agreement to be signed in addition to this. SHU would generally prefer to just use this Statement of Activities form, other than for clinical trials, where more comprehensive agreements may be required

Question 2-3: Participating organisation to confirm

Question 4-5: RIO - but the answer will depend very much on what the NHS partner wish to do regarding contracts

Question 6-15: Researcher to complete

Schedule 1: If no funds are being transferred to the NHS partner this can be left blank. If funds are being transferred, this should be completed by Wen Ye (w.ye@shu.ac.uk) in Finance

Schedule 2: Researcher and RIO in discussion (Michelle Hayward in Contracts Team - m.hayward@shu.ac.uk - to check clauses)

Schedule 3: Researcher and RIO in discussion (Michelle Hayward in Contracts Team - m.hayward@shu.ac.uk - to check clauses)

Appendix 1: Researcher to complete delegation log and study tasks

Approval given

Upload approval documents to the 'Post IRAS Approval' tab on Converis

Acronyms

IRAS - Integrated Research Application System - the online ethics application system for projects involving health, social care, prison and probation services

Converis - Sheffield Hallam's online ethics application system

HMPPS - Her Majesty's Prison and Probation Service

RIO - Research and Innovation Office - Sheffield Hallam's research office

REC - Research Ethics Committee - a body that receives IRAS applications and undertakes the ethical review