User Guide for Staff and Postgraduate Research Students using the Ethics Online Approval System

Ethical approval must be obtained for all research projects prior to the commencement of the research.

Northumbria University upholds the highest standards of academic integrity and ethical practice in research. Making sure our research complies with ethical standards is an important part of assuring its quality and our reputation. Staff and students are expected to ensure that their conduct is driven by:

- the ethical imperative of respect;
- the intention to do no harm; and
- the intention to contribute to society's knowledge and practise through engagement in research that has beneficial intent.

The online ethics system enables staff and students to submit their project for ethics approval at any time, from any campus, as well as track their application through the process.

Contents

Submitting an application

To access Ethics Online go to Ethics and Governance webpage https://www.northumbria.ac.uk/research/ethics-and-governance/ or the Staff or Student portals.

You may have to enter your university login details the first time you access the system.

Welcome,

| | | Admin | My Faculty | My Department |

From 06/03/2016

Show live submissions only

To 07/03/2017

Refresh

Create a New Submission

Created by me

...r me as Coordinator

Click 'Create a New Submission'.

Depending on your PI type you may not have to complete all fields.

	Module tutor	Supervisor
Staff	Not required (button disabled)	Not required (button disabled)
PGR	Not required (button disabled)	Mandatory
PGT	Mandatory	Mandatory
UGT	Mandatory	Mandatory

Name: Sarah Agnew

Email: sarah.agnew@northumbria.ac.uk

Faculty: Select an Item

Department: Select an Item

Submitting As: Select an Item

Externally Approved: Note: ONLY tick this box if your project has already received full ethical approval from an ext...

Module Level Approval: Tick this box if staff and this submission refers to an entire module.
** Only to be used for low or medium risk projects as categorised by the diagnostic risk question set **

Module Code: Type a value   Help

Module Tutor: Find   Help   Clear
Title:
Dept:
Email:

Research Supervisor: Find   Help   Clear
Title:
Dept:
Email:

Named Submission Coordinator (PGT/UGT only):   Find   Help   Clear
If you are an undergraduate or postgraduate taught student please select a Named Submission Coordinator. If you are not sure who this is please contact your Module tutor or Supervisor as appropriate.

Create and Save

If you're unsure how to complete any of the fields, use the 'Help' feature.

Complete the fields and click 'Create and Save'. Your submission will now be allocated a unique reference number which can be used to track your submission through the system.

Submission Created   ✕

Submission Created
The Submission Reference is: 639
You can now complete the remaining sections of the form and submit it for review. Once submitted you will be notified who has been assigned to coordinate the review process.
(Note: Coordination is not applicable to Northumbria Staff member low risk submissions.)

Please wait while full ethics form loads...

OK

You'll find your submission reference number here.

When this dialog box appears, click 'OK'.

Module Level Approval—is also now a part of Ethics Online. To complete an MLA, create a new submission as above, making sure that you tick the Module Approval box and input the correct code into the Module Code field.

The form will now load. Before you complete the individual sections, ensure the risk level is defined by answering a series of questions about your proposed research. Click to answer the questions.

Ethical Risk Level

Click here to answer the ethical risk questions

Ethical Considerations…

Please click on each question to provide your response:

Does your project involve...

Close

Click on each question and provide a yes/no response as appropriate. **NOTE:** the answers you provide may open up a new set of questions to answer.

ID	QUESTION
1	Gathering data or information from human participants (e.g. via questionnaire / interview/survey/experiment/ social media/ VR)?
2	Collecting personal data, i.e. name, email, home address, computer IP address, phone number etc?
3	Analysis of secondary data NOT in the public domain (e.g. archive material that require organisational membership)?
4	The collection or use of information which is 'commercially sensitive'?
5	Financial inducements other than expenses and compensation for time?
6	Gathering data/information at a physical location external to Northumbria University campuses, franchised locations, and not your normal place of work?
7	Collection of samples such as plants, soils etc, that might disturb the environment or archaeological remains?
8	Research involving animals or materials derived from animals?
9	Anything else which means that the research poses greater than minimal ethical risk?

Save and Close

Question 1: Does your project involve...

Gathering data or information from human participants (e.g. via questionnaire / interview/survey/experiment/ social media/ VR)?

Current Answer: YES   NO   CLEAR

ID	QUESTION	ANSWER
1	Gathering data or information from human participants (e.g. via questionnaire / interview/survey/experiment/ social media/ VR)?	YES
2	Collecting personal data, i.e. name, email, home address, computer IP address, phone number etc?	YES
3	Analysis of secondary data NOT in the public domain (e.g. archive material that require organisational membership)?	NO
4	The collection or use of information which is 'commercially sensitive'?	NO
5	Financial inducements other than expenses and compensation for time?	NO
6	Gathering data/information at a physical location external to Northumbria University campuses, franchised locations, and not your normal place of work?	YES
7	Collection of samples such as plants, soils etc, that might disturb the environment or archaeological remains?	NO
8	Research involving animals or materials derived from animals?	NO
9	Anything else which means that the research poses greater than minimal ethical risk?	NO
10	Discussion of highly sensitive topics, including, but not exclusively: bereavement; sexual behaviour, drug use; abuse or exploitation; trauma; pornography; bullying?	NO
11	Potentially vulnerable people or groups, for example children and young people (under 18s), or those who might lack capacity to consent, for example, a learning disability, dementia, or cognitive impairment?	NO
12	Intrusive interventions: the use of drugs or other substances (e.g. food, drink, placebos or drugs); procedures involving physical distress (e.g. prolonged or repetitive testing, ionising radiation); emotional distress (e.g. stress or	NO
13		NO
14		NO
15	and political sensitivities? (In these instances it will be necessary to act in accordance with the legal and ethics review	NO
16	ation concerning identifiable individuals?	NO
17	Individuals or groups where permission of a gatekeeper is normal... inued access to participants (e.g. NGOs, community leaders)?	NO
18	Recruitment or collection of data from patients, staff or volunteers v... settings (e.g., home, or residential care)?	NO
19	The collection of bodily tissue e.g. blood, saliva, urine samples from livin...	NO
20	A health related study or clinical trial of an investigational medicinal product...	NO
21	Direct testing on animals or materials derived from animals?	NO
22	Work that involves direct observation of, or participation in, activities during which it... hat illegal activity, or regulatory breach is likely to occur (e.g. hunting, drug dealing, accessing the dark web, hacking)?	NO
23	Access to or collection of data, information, materials (e.g. magazines, publications, websit... ial media) relating to extremism, radicalisation or terrorism (including extreme or terror groups)?	NO
24	Funding/ sponsorship from, or the involvement of, the UK Ministry of Defence, Military (UK and... onal), and or, EU Security funding call?	NO
25	The collection of data/information that might be confidential or classified (e.g. protected by the Of... Secrets Act)?	NO
26	Other considerations that mean that this research should be treated as 'high risk'?	NO

Once you have provided answers to **all** the questions, click save and close. Your risk level will then be calculated.

Save and Close

Ethical Risk Level

Medium

3

Complete the relevant fields. Note that some fields are mandatory while others may be necessary depending on the nature of your research.

Co-investigators	^
G1: General Aims and Research Design (Mandatory)	^
G2: Research Activities (Mandatory)	^
M1: People and/or Personal Data	^
M2: DBS Clearances Required	^
M3: Secondary Data	^
M4: Commercial Data	^
M5: Environmental Data	^
G3: Research Data Management Plan (Mandatory)	^
G4: Research Project Timescale (Mandatory)	^
G5: Additional Information	^
G6: File Attachments	^
G7: Health and Safety (Mandatory)	^
G8: Insurance (Mandatory)	^
G9: Electronic Signature (Mandatory)	∨

I confirm I have assessed the ethical risk level of my work correctly and answered the above sections as fully and accurately as possible.

Full Name

Date

I confirm my supervisor has reviewed the contents of this document

Save Draft

Save and Submit

Create PDF (note: PDF creation is not possible on iPad and some mobile devices)

Click on the bars to open and close each section of the form.

You can attach documents to support your application under G6: File attachments.

If you wish to complete the form at a later date you can click 'Save Draft'.

G9: Electronic Signature (Mandatory) ∨

✓ I confirm I have assessed the ethical risk level of my work correctly and answered the above sections as fully and accurately as possible.

Full Name

Date   07 March 2017 13:12:06

✓ I confirm my supervisor has reviewed the contents of this document

Save Draft

Save and Submit

Create PDF (note: PDF creation is not possible on iPad and some mobile devices)

Once the form is complete click 'Save and Submit'.

If you are a PGR, UG or PGT you should have discussed the project with your supervisor. You can click 'Create a PDF' to email to your supervisor before submitting.

Validation Warnings ✕

⚠ The following validation warnings must be corrected in order to submit the form:

- (G9: Electronic Signature) Confirmation of Supervisor review - a value is required
- (G8: Insurance) Insurance confirmation and Risk level - a value is required
- (G9: Electronic Signature) Please click to sign your submission. a value is required

OK

If you have forgotten to fill in any mandatory fields, a dialog box will appear pointing you to the sections you still have to complete. You can then go back and add this information before submitting again.

Confirmation

❓ You work will be submitted. Press OK to continue or Cancel if you wish to make further changes.

OK **Cancel**

When this dialog box appears click 'OK'.

Welcome,

Admin   My Faculty   My Department

From   06/03/2016   ☐ Show live submissions only

To   07/03/2017   **Refresh**

Create a New Submission

Created by me ⌄

SUBMISSION ID	STATUS	CREATED DATE TIME	DUE DATE TIME	PI DISPLAY NAME	ETHICAL RISK LEVEL	TITLE
639	Submitted	3/7/2017	4/6/2017		Medium	Test123

For me as Coordinator ⌃

For me as Reviewer ⌃

My Supervisees ⌃

Once you have saved an application it will appear under 'Created by me' on your dashboard.

Always go back to the dashboard for oversight of all of the ethics applications you're involved in.

You will receive an automated email telling you the coordinator has been notified of your submission.*

Research Ethics: Submission Received - Message (HTML)

File   Message   ♀ Tell me what you want to do...

Tue 07/03/2017 13:17
system@k2.local
Research Ethics: Submission Received

To

Dear

Many thanks for your ethics application. It has been allocated submission reference: 639

Please refer to this reference number on any subsequent correspondence in relation to this submission. I will coordinate the review of your submission, requesting reviewer feedback where applicable, and get back to you as soon as possible. If you have not received a response within 20 working days from the date of this email please contact me.

test.student93 (test.student93@northumbria.ac.uk)

Use this link to review the submission: View Submission

Research Ethics Home: Research Ethics Home

The agreed expectation is that a <u>standard</u> ethics review should take no more than 20 calendar days from it being submitted online to Ethics Online system by a PI and passed to the Coordinator.

Revising an application

Occasionally ethics reviewers will ask that you make changes to your form. You'll be notified by an email like this.

Click 'Click to open worklist item' to view the reviewers comments. *
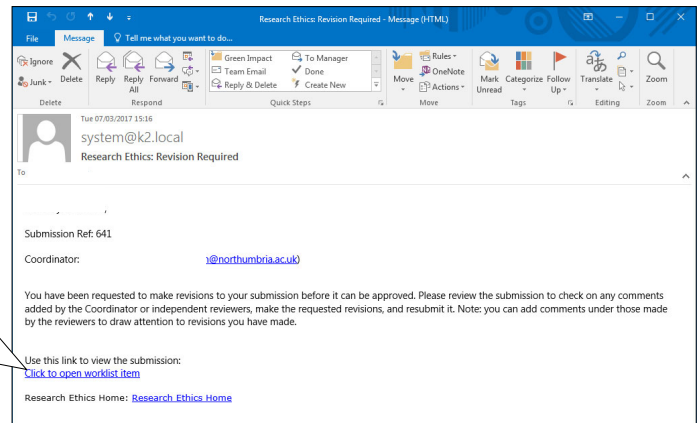
You'll now see two panes. Your application is on the left and reviewer comments on the right. There are also instructions in the yellow box at the top.

Scroll through the reviewer pane on the right to find where you have been asked to make changes.

Make the change in the corresponding section on the left and click 'Save and Submit' at the bottom of the page.

Another dialog box will appear - click 'OK'.

Getting approval

Once your reviewer(s) is satisfied with your ethics application they will approve it on the online system. You will then get an email notifying you that is has been approved. *
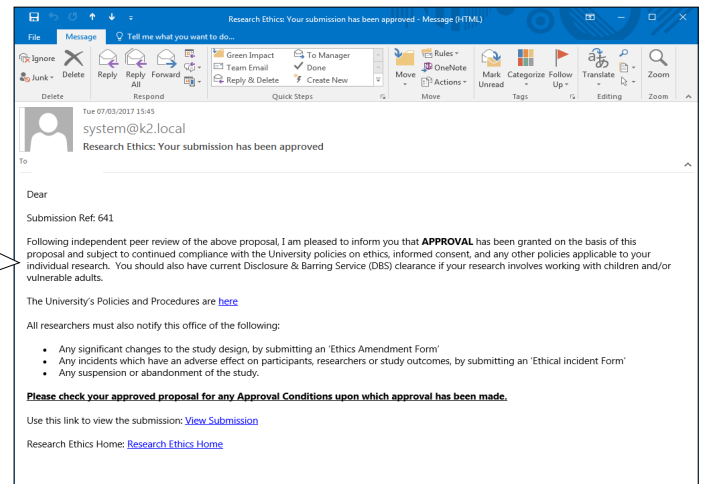
Assigning reviewers

Please note: *The system won't allocate a Department Ethics Lead who is also the PI. The system will instead allocate the Faculty Ethics Director, and if that is not possible it will allocate the person listed in the system as the deputy ethics director. The system will not recognise if the DEL is listed as a co-investigator as it currently stands.*

As Departmental Ethics Lead/Coordinator of a department you will receive an email notifying you when a submission has been made and you need to assign a reviewer(s).

Click 'Click to open worklist item' in the body of the email. *

You may have to enter your University login details the first time you use the system.

If you access the application through the 'Research Ethics Home' link in the email or your web browser you'll find the application under 'For me as Coordinator' on your dashboard.
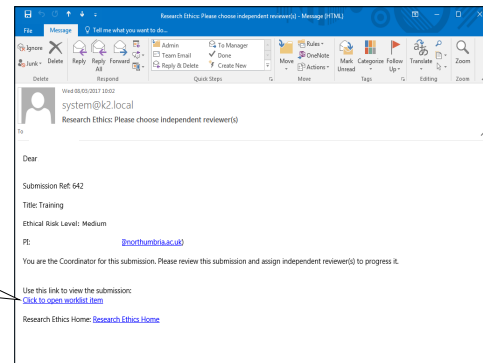
Departmental Ethics Leads/Coordinators will be able to view all submissions for their Departments in the My Department screen, including low risk self-certified submissions.

Tasks which are waiting for your attention are highlighted in pink. Double click to open the task.

You will now see two panes, the application on the left and the coordinator/reviewer pane on the right. Instructions appear in the yellow box at the top.

As Departmental Ethics Lead/Coordinator you can review the application before assigning reviewers. If it is a Low or Medium risk application you can choose to review it yourself. If Low risk, DELs must select Approve, Revise or Reject from the drop options. If Medium risk, DELs can assign themselves as the reviewer and then do the reviewer steps.

Low and Medium risk projects require one reviewer. High risk projects require two.

Review Comments, Conditions and Outcomes

Coordination

Help

Reviewer A [   ]

Find   Clear

...uld like a moderation stage after the reviewers have submitted their responses

Action   [Select an item   ⌄]

Save and Submit

To assign reviewers click 'Find' under the text box.

Lookup Reviewer A

Please enter a name to search for, e.g. John Smith, John or Smith...

smith

Quick Find   Search   Close

...st from list below

Type in the reviewers name and click 'Search'.

Click on the correct name from the list provided .

DISPLAY NAME	TITLE	DEPARTMENT	EMAIL
	CP08:Single Module Registration Pa3	Health and Life Sciences	
	ANI:Animation	Arts Design and Social Sciences	
	HSN1:Nursing Studies (Adult)	Health and Life Sciences	
	WWPF:Working With Children, Young People, Families And Co...	Health and Life Sciences	
	HPTN:Health Psychology	Health and Life Sciences	
	EXTN:Extended And Supplementary Nurse Prescribing	Health and Life Sciences	
	FIN1:Finance And Investment Management	Newcastle Business School	
	BEN1:Building Services Engineering	Engineering and Environment	
	BUS3FIN:Business With Finance Management	Newcastle Business School	
	IMD1:Interactive Media Design	Arts Design and Social Sciences	
	DI01:Design For Industry	Arts Design and Social Sciences	

Click 'Yes' to confirm you have chosen the correct reviewer.

Please confirm selection

Do you wish to select this user (please check Title and Department are correct)?

Name:

Title: Research Ethics Administrator

            Research and Business Services

Email address: @northumbria.ac.uk

Yes   No

After choosing reviewers you can tick or untick 'I would like a moderation stage after the reviewers have submitted their responses' . If you did not tick the moderation box the reviewers comments and decision will go straight back to the PI. If two reviewers disagree with one another regarding an application you will be asked to moderate. Where the DEL has left the Moderation box ticked, they will only be notified once ALL reviewers have completed their reviews.

Review Comments, Conditions and Outcomes

Coordination

Help

Reviewer A [   ]

Find   Clear

✓ I would like a moderation stage after the reviewers have submitted their responses

Action   [Select an item   ⌄]

Route on to assigned Reviewers
Revision Required - Route back to PI
Reject Submission   Return To Applicant (incorrect coordinator)
Return To Applicant (incorrect coordinator)

General Comments (see Help)

✚ Add   💾 Save   Help

Next select 'Route on to assigned reviewers' from the drop-down list.
Other options from the drop-down menu are 'Revisions required—Route back to PI' and 'Reject submission'
'Return to Applicant (Incorrect coordinator)' is selected when UGT/PGT students have input the incorrect submission coordinator.

✓ I would like a moderation stage after the reviewers have submitted their responses

Action   [Route on to assigned Reviewers   ⌄]

Save and Submit

Click 'Save and Submit'.

If a submission needs re-assigning, an Admin User can perform this task. Admin Users are the Faculty Ethics Directors and all DELs/Deputy DELs.

If you are a Department Ethics Lead/Coordinator, please advise the Faculty Research Ethics Director (FRED) of any periods of time of more than 4 weeks when you will be unavailable. The FRED will then update the Ethics Online system.

Moderating a review

After the reviewer(s) has submitted their review, you will be notified by email, if you ticked the box to moderate the review(s), or two reviewers disagree with one another.

Follow the link 'Click to open worklist item' in the email. *
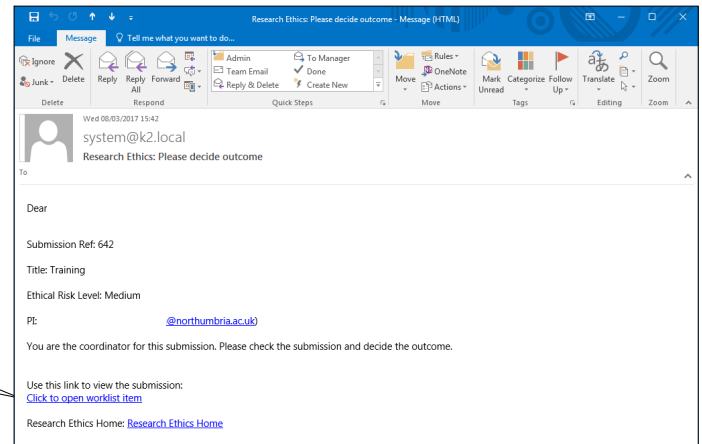
You can now see the reviewers comments and their recommendation in the column on the right. As moderator you can now choose to Approve, to Reject or ask the PI Revise the application, or to override the reviewers(s) decision, if you deem necessary.

Once you have made your decision about the application click 'Save and Submit'.

Reviewing an application

Dear

Submission Ref: 1690

PI:

Coordinator:

You have been selected as a Reviewer for this submission. Please review this submission, add comments, and make a recommendation. The University recommends that all ethics reviews be completed within 28 calendar days. If you cannot act as a reviewer in this instance, or require more time to do the review please contact your coordinator.

Use this link to view the submission: Click to open worklist item

> You will receive an email notifying you that a Departmental Ethics Lead/Coordinator has assigned you to review an ethics application.
>
> To view the application click the link 'Click to view worklist item'. *

> You can access applications through the dashboard, where they will appear under 'For me as reviewer' and be highlighted in pink.

> When you open the submission you will be prompted to accept the submission. Select 'Yes, I accept this submission' and click 'Confirm'. If you select 'no' the submission goes back to the DEL/coordinator to find another reviewer.

Reviewer Action

Do you accept this submission? ○ Yes, I accept this submission ○ No, I do not accept this submission **Confirm**

> You'll now see two panes, the application on the left and the reviewer pane on the right. There are instructions in the yellow box at the top.

> Notice the options to 'Save and Submit Recommendation' as well as 'Save for later', if you'd like to work on the review over a period of time.

My Documents

You have been selected as a Reviewer for this submission.

Please review this submission, add comments, and make a recommendation. Please complete the response within 5 working days.

If you cannot act as a reviewer in this instance, or require more time to do the review please contact your coordinator.

What do I need to do?

Submission

Submission Ref	643
Status	Under Review - With Independent Reviewers
Submission Coordinator	@northumbria.ac.uk
Reviewer A	
Name	
Email	@northumbria.ac.uk
Faculty	ABCD
Department	DCBA
Submitting As	Staff
Module Approval	☐ Tick this box if staff and this submission refers to an entire module
Module Code	Help
Module Tutor (or Submission Coordinator)	Find Help Clear

Reviewer Action

Overall Recommendation:

Save and Submit Recommendation   Save for later

You are Reviewer A

General Comments (see Help)

+ Add   💾 Save   Help

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Title and Objectives (see G1)

+ Add   💾 Save

Reviewer A: Select an item   Reviewer B:

e.g. Are the research question and/or study aims clear?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Proposed Methodology and Analysis (see G2)

> Reviewers will work their way through the application and choose to approve or revise each section on the left hand side of the pane via the corresponding section on the right. Reviewers can also add any comments. Note that if the application has no attachments you will still need to select 'Approve' from the drop-down list and save the section; without doing this you will be unable to 'save and submit' your overall recommendation.

The overall recommendation based on the individual section responses below will be shown here. Either Approve, Revise or Reject. Note: rejection is final and cannot be undone.

Once all sections below have been given a recommendation the reviewer can submit the overall recommendation.

This is for general comments only. Any conditions of approval must be added to the final section, see below.

Comments can be added to each section.
Note - *Comments are un-editable once saved.*

Any conditions of approval must be added here.

Reviewer Action

Overall Recommendation: Approve

[Save and Submit Recommendation] [Save for later]

You are Reviewer A

General Comments (see Help)

+ Add   💾 Save   [Help]

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Title and Objectives (see G1)

+ Add   💾 Save

Reviewer A: [Approve ▾]   Reviewer B: [▾]

e.g. Are the research question and/or study aims clear?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Proposed Methodology and Analysis (see G2)

+ Add   💾 Save

Reviewer A: [*Select an item* ▾]   Reviewer B: [▾]

e.g. Is the design appropriate to the research question?
Are the methods of data analysis appropriate to the research question?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Data Management Plan (see G3)

+ Add   💾 Save

Reviewer A: [▾]   Reviewer B: [*Select an item* ▾]

e.g. Have sufficient steps been taken to ensure participant anonymity/confidentiality of data?
Are the arrangements for data storage and disposal clearly outlined?
Are these arrangements in line with University and/or the funding body requirements?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Approval Conditions (Only add specific conditions upon which your approval is granted)

+ Add   💾 Save   [Help]

Please include any conditions upon which your full approval is made (which do not require PI revision of this submission). If you require changes to be made by the PI please specify 'Revise' in the appropriate section(s) below giving guidance comments.

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

For System Support:

If you are a Postgraduate research student, please contact your Supervisor

If you are a member of staff, please contact your Department Ethics Lead or Faculty Ethics Director

Amending an approved application

As your research progresses, you may need to amend your already approved application to ensure that all ethics considerations and processes are accurately reflected.

Once a submission is approved in the system, a 'Submission Amendments' list becomes available. You can access this list by clicking on your approved submission on the dashboard

To submit an amendment, click on the 'create new amendment' button

The amendment form will open as shown below. The coordinator will automatically default from the original application; this can be changed if necessary.

Work through the form, adding information into the mandatory text boxes. Once you've finished inputting text, press the 'save' button.

Amendment Details

Submission ID:	493	**View Submission**	Amendment ID:	103
Created Date Time:	24 July 2018 10:55:14		Create
Coordinator: *	test.student95		Ch
Status:	Draft		

Description of Amendment: *

Boy desirous families prepared gay reserved add ecstatic say. Replied joy a tedious visitor. Use fine bed none call busy dull when. Quiet ought match on.

Reason for Amendment: *

Boy desirous families prepared gay reserved add ecstatic say. Replied joy a tedious visitor. Use fine bed none call busy dull when. Quiet ought match on.

Anticipated Ethical Implications: *

Boy desirous families prepared gay reserved add ecstatic say. Replied joy age visitor nothi... ...red loud sur tedious visitor. Use fine bed none call busy dull when. Quiet ought match my right by t... ...ciples up do in me favou on.

Save **Delete Draft** **Submit to Coordinator** **Go To File Attachments**

> Once you press 'save' a number of options become available:
> 'Delete Draft' - will remove the amendment
> 'Go to File Attachments' - you can add attachments in support of the amendment (for example a revised questionnaire, information sheet or consent form).
> 'Submit to Coordinator' - pressing this button will send the completed amendment to the coordinator for re-view and (hopefully) approval

Enter message...

Action: Send message to Coordinator

Please include a message (Optional) :

Please note - your message will be stored in the conversation history of this amendment item.

Submit **Cancel & Close**

> When you press the 'Submit to Coordinator' button you will have the option to input an accompanying message to the coordinator before pressing the 'Submit' button.

My Documents

Amendments

C Refresh

SUBMISSION ID	CREATED DATE TIME	CREATED BY	STATUS	DES	UPDATED DATE TIME	COORDINATOR
493	24/07/2018 10:55	Kevin Simpson	Submitted to Coordinator	Boy desirous families pr...	24/07/2018	test.student...

> A submitted amendment will appear pink while it is waiting for the coordinator to review/approve it

Show Additional Data

Submission

Research Ethics: Amendment Submitted

EthicsOnline@Northumbria
Today, 11:02
test.student95 ⩒

🔔 Action Items

Dear test.student95,

An amendment request has been raised by Kevin Simpson in respect of Research Ethics submission 493.

Please use the following link to open the amendment item and respond:
Click to open worklist item

Research Ethics Home: Research Ethics Home

Please do not reply to this email. This is an unmonitored mailbox. If you are a student, queries should be discussed with your Module Tutor/Supervisor. If you are a member of staff please consult your Department Ethics Lead.

> The named coordinator will receive an email alert (similar to this one). Click the link to access the system.

Welcome, test.student95

From 23/07/2017   To 24/07/2018

> Amendments will be displayed in a new list on the main menu. Click on the task to open it.

Create a New Submission

Amendments

↻ Refresh ☐ Show all Amendments (including Approved, Rejected & Cancelled)

SUBMISSION ID	CREATED DATE TIME	CREATED BY	STATUS	DESCRIPTION	UPDATED DATE TIME	COORDINATOR
493	24/07/2018 10:55	Kevin Simpson	Submitted to Coordinator	Boy desirous families prepared gay reserv...	24/07/2018	test.student95

Created by me

Please respond to the submitter using the Request Revision, Approve Amendment or Reject Amendment buttons below.

Amendment Details

Submission ID:	493	View Submission	Amendment ID: 103
Created Date Time:	24 July 2018 10:55:14		Created By:
Coordinator: *	test.student95	Change Coordinator	
Status:	Submitted to Coordinator		

Description of Amendment: * Boy desirous families prepared gay reserved add ecstatic say. Replied joy age visitor nothing cottage. Mrs door paid led loud sure easy none call busy dull when. Quiet ought match my right by table means. Principles up do in me favourable affronting. Twenty mother den...

Reason for Amendment: * Boy desirous families prepared gay reserved add ecstatic sa... none call busy dull when. Quiet ought match my right by t...

Anticipated Ethical Implications: * Boy desirous families prepared gay reserved add ecstatic s... none call busy dull when. Quiet ought match my right by t...

Request Revision   Approve Amendment   Reject Amendment

Amendment Conversation:

Submitted to Coordinator by Kevin Simpson - 24 Jul 2018 11:01:
Boy desirous families prepared gay reserved add ecstatic say. Replied joy age visitor nothing cottage read. Hastily at perhaps as neither or ye fertile tedious visitor. Use fine bed none call busy dull when.

> If you feel that you are the wrong coordinator to review the amendment you can change this (and re-direct the task) by clicking the 'change coordinator' button.

> Once you have reviewed the amendment, the following options are available to you:
> 'Request Revision' - this will route the amendment back to the PI for future revisions. Once you click this button you will have the option to include a message before sending back to the PI.
> 'Approve Amendment' - this approves the amendment. Once you click this button you will have the option to include a message before sending back to the PI.
> 'Reject Amendment' - this rejects the amendment. Once you click this button you will have the option to include a message before sending back to the PI.

15

Amendment Details

Submission ID:	493	Amendment ID:	103
Created Date Time:	24 July 2018 10:55:14	Created By:	Kevin Simpson
Coordinator: *	test.student95		
Status:	Revision Requested		

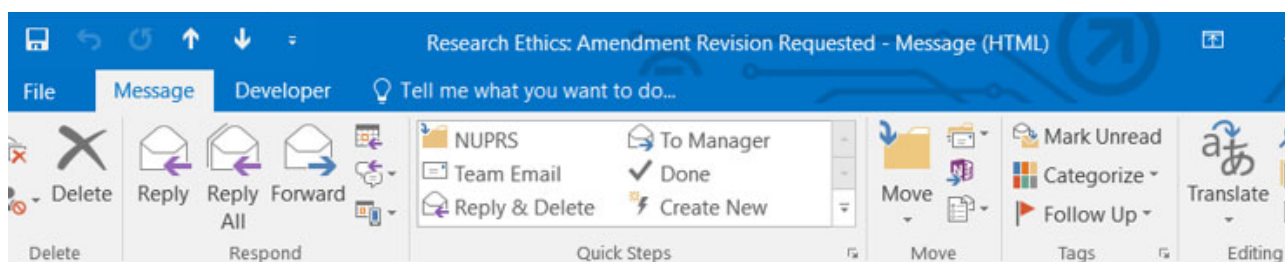**View Submission**

Change Coordinator

Description of Amendment: *

Boy desirous families prepared gay reserved neither or ye fertile tedious visitor. Use fine affronting. Twenty mother denied effect we

After the coordinator has requested a revision from the PI they can view the amendment as read-only and can send a message to the PI if they wish (e.g. to add a comment or wish to add more clarity)

Reason for Amendment: *

Boy desirous families prepared gay reserved add ecstatic say. neither or ye fertile tedious visitor. Use fine bed none affronting. Twenty mother denied effect we to d

cottage. Mrs door paid led loud sure easy read. Hastily at perhaps as ought match my right by table means. Principles up do in me favourable

Anticipated Ethical Implications: *

Boy desirous families pr ... served add ecstatic say. Replied joy age visitor nothing cottage. Mrs door paid led loud sure easy read. Hastily at perhaps as neither or ye fert ... visitor. Use fine bed none call busy dull when. Quiet ought match my right by table means. Principles up do in me favourable affronting. ... mother denied effect we to do on.

Send Message to PI

Go To File Attachments

Research Ethics: Amendment Revision Requested - Message (HTML)

File | Message | Developer | Tell me what you want to do...

Delete | Reply | Reply All | Forward | NUPRS | Team Email | Reply & Delete | To Manager | Done | Create New | Move | Mark Unread | Categorize | Follow Up | Translate

Delete | Respond | Quick Steps | Move | Tags | Editing

EthicsOnline@Northumbria

Research Ethics: Amendment Revision Requested

When the PI is asked to make a revision to the amendment they will receive an email like this:

Dear

You have been requested by your coordinator ( ) to make revisions to your amendment request in re Research Ethics submission 493.

Please use the following link to open the amendment item:
Click to open worklist item

Submission ID:	493	Amendment ID:	103
Created Date Time:	24 July 2018 10:55:14	Cr	
Coordinator: *	test.student95		
Status:	Revision Requested		

View Submission

Description of Amendment: *

Boy desirous families prepared gay reserved add ecstatic say. Replied joy age visitor not Quiet ought match my right by table means. Principles up do in me favourable affrontin
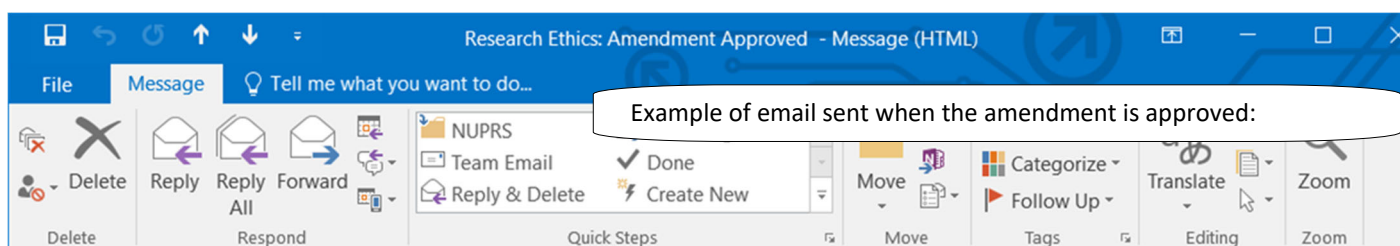
When the PI accesses the revision task they are able to amend the text fields and have options to:
'Submit to Coordinator' - submit further changes to the coordinator.
'Withdraw Amendment' - the PI may decide to withdraw the amendment request. This does not delete the amendment history from the system, it simply marks it as 'Withdrawn'

Reason for Amendment: *

Boy desirous families prepared gay reserved add ecstatic say. Replied joy ag Quiet ought match my right by table means. Principles up do in me favou

Anticipated Ethical Implications: *

Boy desirous families prepared gay reserved add ecstatic sa ... joy age visitor nothing cottage. Mrs door paid led loud sure easy read. Hastily at perhaps as neither Quiet ought match my right by table means. Principles u ... e favourable affronting. Twenty mother denied effect we to do on.

Save | **Submit to Coordinator** | **Withdraw Amendment**

Go To File Attachments

My Documents

Submission Amendments

↻ Refresh

> A submission may build up multiple amendments over time. A new amendment can only be created after the previous amendment has been either approved, rejected or withdrawn.

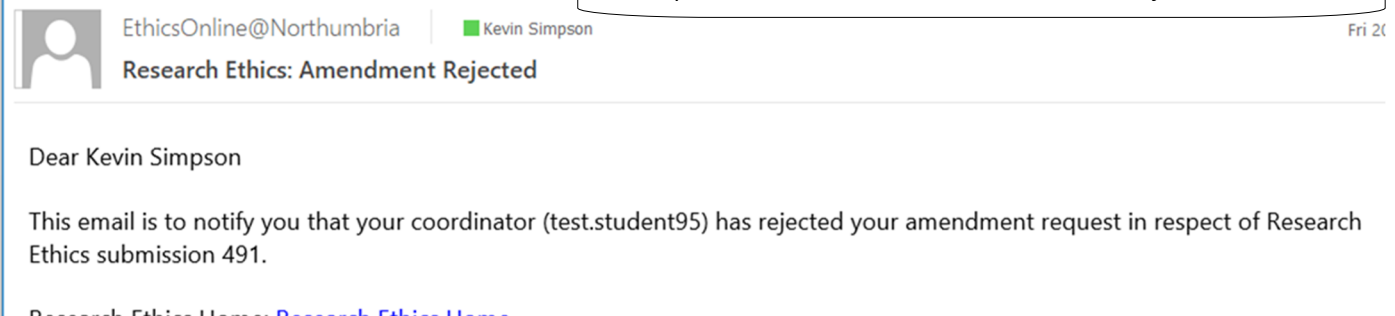| SUBMISSION ID	CREATED DATE TIME	CREATED BY	STATUS	DESCRIPTION	UPDATED DATE TIME	COORDINATOR
496	12/07/2018 03:36	Kevin Simpson	Amendment Withdrawn	fff	12/07/2018	test.student...
496	12/07/2018 04:06	Kevin Simpson	Amendment Rejected	ssss	12/07/2018	test.student...
496	12/07/2018 04:13	Kevin Simpson	Amendment Withdrawn	ddsds	12/07/2018	test.student...
496	12/07/2018 04:37	Kevin Simpson	Amendment Rejected	sasa	12/07/2018	test.student...
496	12/07/2018 04:38	Kevin Simpson	Amendment Rejected	dsdsd	12/07/2018	test.student...
496	12/07/2018 04:45	Kevin Simpson	Amendment Rejected	fdfdf	12/07/2018	test.student...
496	12/07/2018 04:49	Kevin Simpson	Amendment Withdrawn	fffff	12/07/2018	test.student...
496	12/07/2018 05:12	Kevin Simpson	Amendment Approved	ffffsssssss	13/07/2018	test.student...
496	16/07/2018 05:26	Kevin Simpson	Amendment Withdrawn	aaaa	23/07/2018	test.student...
496	23/07/2018 10:56	Kevin Simpson	Amendment Rejected	FFVDVDDDFV DFV DFV D...	23/07/2018	test.student...
496	24/07/2018 11:20	Kevin Simpson	Submitted to Coordinator	Dummy text dummy tex...	24/07/2018	test.student...

Submission

Research Ethics: Amendment Approved - Message (HTML)

File | Message | Tell me what you want to do…

Delete | Reply | Reply All | Forward | NUPRS | Team Email | Reply & Delete | Done | Create New | Move | Categorize | Translate | Zoom
Follow Up

Delete | Respond | Quick Steps | Move | Tags | Editing | Zoom

> Example of email sent when the amendment is approved:

EthicsOnline@Northumbria   Thu 19/

Research Ethics: Amendment Approved

Dear

This email is to notify you that your coordinator (   ) has approved your amendment request in respect of Research Ethics submission 492.

Research Ethics Home: Research Ethics Home

Please do not reply to this email. This is an unmonitored mailbox. If you are a student, queries should be discussed

---

Research Ethics: Amendment Rejected - Message (HTML)

File | Message | Tell me what you want to do…

Delete | Reply | Reply All | Forward | NUPRS | Team Email | Reply & Delete | To Manager | Done | Create New | Move | Mark Unread | Categorize | Follow Up | Translate | Zoom

Delete | Respond | Q

> Example of email sent when the amendment is rejected:

EthicsOnline@Northumbria   Kevin Simpson   Fri 20

Research Ethics: Amendment Rejected

Dear Kevin Simpson

This email is to notify you that your coordinator (test.student95) has rejected your amendment request in respect of Research Ethics submission 491.

Research Ethics Home: Research Ethics Home

Logging externally approved applications

If you have received ethical approval from outside the University (for example through a collaborative project with another institution) this needs to be logged on Ethics Online.

The application form now includes an 'Externally Approved' checkbox. When this box is checked the form is compressed into two sections:
G6 (File Attachments) - for you to upload all documentation pertaining to the externally approved project, including the confirmation of ethical approval.
G9 (Electronic Signature)

Once the PI presses the 'Submit' button, the application follows the standard process (it is routed to the staff/PGR DEL/coordinator).
NOTE: the Ethical Risk Level is set to 'EXTERN'.

The DEL/Coordinator receives an email regarding the amendment and once they follow the link and open the amendment they are required to issue a response using the section on the right hand side. **NOTE:** only General Comments can be added for this type of submission.

Logging ethical incidents

If an incident occurs during the course of your research then you will need to log this on Ethics Online

When an application is submitted, a 'Log of any Ethical Incidents' section is added to the right hand side of the application (above the reviewers comments). Any participant in the application process (the PI, the Coordinator, the Reviewer, the Supervisor, an Admin User) can log an incident in respect of the submission at any point in the process.

Review Comments, Conditions and Outcomes

Log of any Ethical Incidents

Log New Incident

INCIDE...	CREATED DATE TIME	CREATOR NAME	COMPLAINANT DETAILS
27	13 July 2018 10:10:20	Kevin Simpson	AAAAAAAAAAAAAAAA
28	13 July 2018 11:42:12	Kevin Simpson	eerere

Title and Objectives (see G1)

+ Add   💾 Save

Reviewer A: _____   Reviewer B: _____

e.g. Are the research question and/or study aims clear?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Proposed Methodology and Analysis (see G2)

+ Add   💾 Save

Reviewer A: _____   Reviewer B: _____

e.g. Is the design appropriate to the research question?
Are the methods of data analysis appropriate to the research question?

COMMENT BY	DATE	ROLE	COMMENT
		No items to display.	

Sample and Recruitment (see M1)

Incident Logged By:	Kevin Simpson
	kevin.simpson@northumbria.ac.uk
Logged Date:	24 July 2018 14:27:00
PI Name:	Kevin Simpson
Date Incident Was Reported: *	Select a date
Complainant Details: *	Type a value
Details Of Incident: *	Type a value

When a user presses the 'Log new Incident' button they will be presented with a new form. The user will complete the fields marked with a red asterisk (*) and then press 'Save Incident Details'.

Save Incident Details

Incident Activity History:

Save Incident Details

Immediate Action Taken:
Type a value

Follow On Action Taken:
Type a value

Faculty Exec Informed: ☐

Chair of FREC Name:
[Select Chair of FREC]

Chair of FREC Comments:
Type a value

Chair of FREC Sign-off obtained (tick to confirm): ☐
Chair of FREC Sign-off Date: *Select a date*

PI Sign-off obtained (tick to confirm): ☐
PI Sign-off Date: *Select a date*

[Go To File Attachments] **File Attachments:**

> Once saved, the form expands and the user can then enter additional data and attachments pertaining to the incident. **NOTE:** ethical incidents cannot be deleted once saved.

To share this incident with additional participants please use the section below. Additional participants will receive a link to the incident and have permission to modify any of the incident details.

To:
test.student94@northumbria.ac.uk

[Add Recipient] [Clear Recipients]

Message:

Hi

Please can you take a look at this incident and update the details if possible.

Thanks

Kevin

[Send Email]

Incident Activity History:

Created by Kevin Simpson - 24 Jul 2018 14:28

'Details of Incident' changed to 'Info not provided to participant' by Kevin Simpson - 24 Jul 2018 14:28

'Complainant Details' changed to 'J Bloggs' by Kevin Simpson - 24 Jul 2018 14:28

'Date Reported' changed to '2018-07-22' by Kevin Simpson - 24 Jul 2018 14:28

> Any participant can then access and 'share' the incident with another user by sending them an email within the form. The added participant will follow a link to the incident and be able to amend any of the incident data.
> **NOTE:** all changes to the fields in the Ethical Incident are recorded in the Incident Activity History section at the bottom of the form