

LEON – Loughborough Ethics ONline

LEON User Guide

This User Guide provides detailed information for users. There is also a [Quick Start Guide](#).

LOG-IN

To log-in to LEON go to:

<https://leon.lboro.ac.uk>

You will be asked to enter your usual University username and password.

If the single sign-on takes you to the incorrect user account, you can 'sign out'. Once the system has closed you can reopen LEON and it should show the University log-in page. You can sign in using the relevant log-in details.

WORK AREA

When you log-in to LEON you will be taken to your WORK AREA.

In the 'General' tiles you will see how many notifications you have received, signature requests you have been sent if you are a staff member, projects which have been transferred to you and projects that have been shared with you.

The 'Projects' section is a list of your projects and projects that have been shared with you, for instance, if you are a co-investigator on a study.

On the left-hand side are the 'Actions' which are available in this area. These will change depending on which part of the system you are viewing.

LEON - Loughborough Ethics ONLINE Home Contacts Help **Beta Test Mode**

Work Area

Home Notifications 6

Actions

Create Folder Delete Folder Create Project

Delete Project Duplicate Project Transfer

Work Area

General

Notifications 6 Signatures 0 Transfers 0 Shared 0

Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified
New Project	112	Dr Ann Reviewer	26/07/2019 11:57	30/07/2019 15:41
new sharing project	111	Dr Ann Reviewer	26/07/2019 11:08	30/07/2019 15:45
Sharing 222	110	Dr Ann Reviewer	26/07/2019 09:52	26/07/2019 09:57
testing again	109	Dr Ann Reviewer	25/07/2019 14:40	25/07/2019 14:48
reviewers project	108	Dr Ann Reviewer	25/07/2019 13:45	25/07/2019 14:02

Showing 1 to 5 of 5 entries

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ACTIONS

On the left-hand side of the screen you will see a variety of 'Actions' that can be performed. These will change depending on which part of the system you are viewing. If the 'Actions' section is not visible, use the drop-down list  on the top left.

 Home	To return to the Work Area.	 Project	To view the project overview including any amendments or resubmissions.	 Previous Next	To progress through the form.
 Create Project	To Create a New Project.	 Share Roles	To share your project and give permissions and roles to other investigators.	 Collaborators	To see who the form has been shared with and their permissions.
 Create Folder Delete Folder	To create folders in your Work Area to file projects. Empty folders can be deleted if no longer required.	 Completeness Check	To check which parts of the form still need to be completed.	 Navigate	To return to the project home page so that you can see the sections of the form.
 Delete Project	To delete unsubmitted projects.	 Automatic Submission	To switch off automatic submission. Once signatures are obtained you will need to submit the project.	 Documents	To view documents attached and print or save them as a pdf.
 Duplicate Project	To duplicate a previous submission if you want to repeat a project or undertake a similar study.	 Print	To print the project.	 Signatures	To view signature requests and whether signatures have been received.
 Transfer	To transfer the 'ownership' of a project if you are leaving an active study or the institution.	 Refresh	To refresh the form if you have changed your responses.	 Save	To save the form.
 Unlock	To unlock submissions so that they can be edited.				

PROJECTS

From the Work Area select 'Create Project' on the left-hand side to start a submission. Enter a title for the project and select 'Create'. This will take you to the Ethics Review Form.

The heading will show the project title.

The 'Project Tree' displays the current status of the project.

The tabs allow you to view information regarding your project.

The screenshot displays the LEON - Loughborough Ethics Online interface. The top navigation bar includes 'Home', 'Contacts', 'Help', and 'Beta Test Mode'. The user is identified as 'J.A. Green (J.A.Green@lboro.ac.uk)'. The main content area shows a project titled 'This is the Project Title' with ID '0139'. A 'Project Tree' table shows the project status as 'Not Submitted' with a 'Review Reference' of 'N/A' and a 'Date Modified' of '18/10/2019 10:42'. Below the table are tabs for 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', and 'History'. The 'Ethics Approvals Form' section is visible, with a 'START HERE' button and links for 'Applicant', 'Responsible Investigator', 'Additional Investigators', 'Project Details', 'Funding and Insurance', and 'Application Signatures'. The footer includes copyright information for Infonetica Ltd 2019 and links to Terms and Conditions, Data Controller Privacy Policy, and Data Processor Privacy Policy.

The Ethics Review Form shows the sections of the form that initially need to be completed. This view will change depending on your initial selections and your responses to the questions.

To start your application, click on the 'Start Here' link in blue.

ETHICS REVIEW FORM

The first section of the form requires the selection of the options that apply to the project. This will determine the information that is requested within the form.

Use the 'information button' to obtain guidance on the options to select:



You should indicate whether this is a new submission or a revised submission in response to feedback from the Sub-Committee.

Once you have selected the options you should select 'next' from the Actions on the left-hand side of the screen to progress through the form.

The screenshot shows the 'Ethics Approvals Form' in 'Beta Test Mode'. The interface includes a top navigation bar with 'LEON - Loughborough Ethics ONLINE', 'Home', 'Contacts', 'Help', and 'Beta Test Mode'. The user is identified as 'Dr. Jacqueline Green (J.A.Green@lboro.ac.uk)'. The form title is 'Ethics Approvals Form' with a version number '0139' and 'Version: Beta'. On the left, there is an 'Actions' menu with options: Previous, Next, Navigate, Print, Documents, Signatures, Save, Share, Roles, Collaborators, and Completeness Check. The main form area contains the following sections:

- Select those that apply** (with an information icon):
 - Select those that apply:
 - Study involving Human Participants
 - Study involving Animals or Animal Cells/Tissues
 - Study involving Security Sensitive Material
 - New Generic Protocol Proposal (select one)
 - Study with Existing External Ethical Approval (select one)
- Select one:** (with an information icon):
 - New Study involving Human Participants
 - Study covered by existing Generic Protocol
 - Secondary data analysis of pre-existing data only
 - Module Approval (Staff Only)
- Please indicate whether this is a NEW submission or a RESPONSE to feedback from the Sub-Committee?**
 - This is a NEW submission.
 - This is a RESPONSE to feedback from the Sub-Committee.
- Please select 'next' on the left hand side to continue.**

The following sections will only appear if they are required for the project you are submitting.

INVESTIGATOR DETAILS

APPLICANT DETAILS

Some of the applicant information will be prepopulated from your account. You should add your details as necessary and confirm the School that will be responsible for approving your submission.

Staff will be asked to indicate whether they are the responsible investigator.

RESPONSIBLE INVESTIGATOR

For student projects the responsible investigator will be the project supervisor. The responsible investigator must be a member of staff.

ADDITIONAL OR EXTERNAL INVESTIGATORS

Provide details of any additional Loughborough University or external investigators. Use the 'Add Another' button to include multiple investigators.

Add Another

SHARING YOUR PROJECT

You can share your submission with other investigators using the 'Share' tile. Different levels of permission can be granted depending on whether investigators require access to write parts of the submission or only to view the details. They can leave comments which you will see in the speech bubble in each section. For further information refer to the Guidance Note on Sharing your project. Students must share the form with their supervisor.



PROJECT DETAILS

Please enter details of your project as requested in this section. This section will vary depending on the type of submission. Most studies will require the submission of a short project summary. This should be written in everyday language and should be a brief description of the project of no more than 100 words.

Project start and end dates are also required for most submissions (except New Generic Protocol proposals). These should be the dates that relate to the activity being submitted for approval. The end date provided will be the date the ethics approval expires.

NHS or EXTERNAL REVIEW

Please provide details of any external reviews that are required or have already been obtained.

Studies that involve NHS patients recruited through the NHS, staff, data, premises or equipment may require additional NHS approval. NHS patients within the NCSEM may fall under NHS ethics requirements. If you have been advised that your project does not require approval via the Health Research Authority, or is classed as audit/service evaluation, please attach written confirmation.

If your project is approved by the Health Research Authority, please attach details.

SECTION A: CHECKLIST

For studies involving human participants. Please ensure that you read the questions in Section A and answer them as accurately as possible. These questions will determine the type of ethical review that is required and whether additional information needs to be submitted. Students should check with their supervisors that these answers are correct.

If none of the questions apply to your project, you MUST select 'None of the Above'.

If the project is covered by an existing generic protocol the next page following Section A will request the generic protocol number. If you do not see this page, please check that you have selected the correct options on the first section of the project.

SECTION B: CHECKLIST

For studies involving human participants. Please ensure that you read the questions in Section B and answer them as accurately as possible. These questions will determine the type of ethical review that is required and whether additional information needs to be submitted.

If you tick any of these questions you will be asked to provide further information.

If none of the questions apply to your project, you MUST select 'None of the Above'.

SECTION C: PROJECT PROPOSAL

If you have selected 'yes' to questions in Section A you will need to supply further details of your project and the proposal will be considered by the Ethics Review Sub-Committee (unless it is covered by an existing Generic Protocol).

To view the sections that require completion you can select 'navigate' on the left-hand side to show you the form. Sections written in blue need to be completed. These will vary depending on which questions you selected in section A.

The screenshot displays the LEON - Loughborough Ethics ONLINE interface in Beta Test Mode. The user is Dr. Jacqueline Green (J.A.Green@lboro.ac.uk). The page title is "This is the Project Title" with ID 0139. The interface includes a navigation menu on the left with options like Home, Notifications (3), Actions, Project, Share, Roles, Completeness Check, Automatic Submission, Refresh, and Print. The main content area shows a "Project Tree" table with columns for Form Status, Review Reference, and Date Modified. Below this is a navigation bar with tabs for Navigation, Documents, Signatures, Collaborators, Submissions, and History. The "Ethics Approvals Form" section is visible, listing various sections and questions that need to be completed, such as "START HERE", "Investigators", "Project Details", "External Ethical Review", "Section A: Checklist", "Section B: Checklist", "Section C: Project Proposal" (with sub-sections C1-C6), "Section E: Data Storage and Security", "Section F: Funding and Insurance", "Supporting Documents", and "Declarations".

Form Status	Review Reference	Date Modified
Not Submitted	N/A	18/10/2019 14:06

Ethics Approvals Form

Section	Questions
START HERE	START HERE
Investigators	Applicant Responsible Investigator Additional Investigators
Project Details	Project Details
External Ethical Review	NHS Ethical Review External Ethical Review
Section A: Checklist	SECTION A
Section B: Checklist	SECTION B
Section C: Project Proposal	C1: Proposal Details C2: Study Description C3: Researcher Safety C4: Participant Details C5: Vulnerable Participants C6: Bodily Samples
Section E: Data Storage and Security	Data Storage and Security
Section F: Funding and Insurance	Funding and Insurance
Supporting Documents	Supporting Documents
Declarations	Application Signatures

If sections appear which do not seem to relate to your project, e.g. the bodily samples section if you are not collecting samples, please check that your responses to Section A are correct.

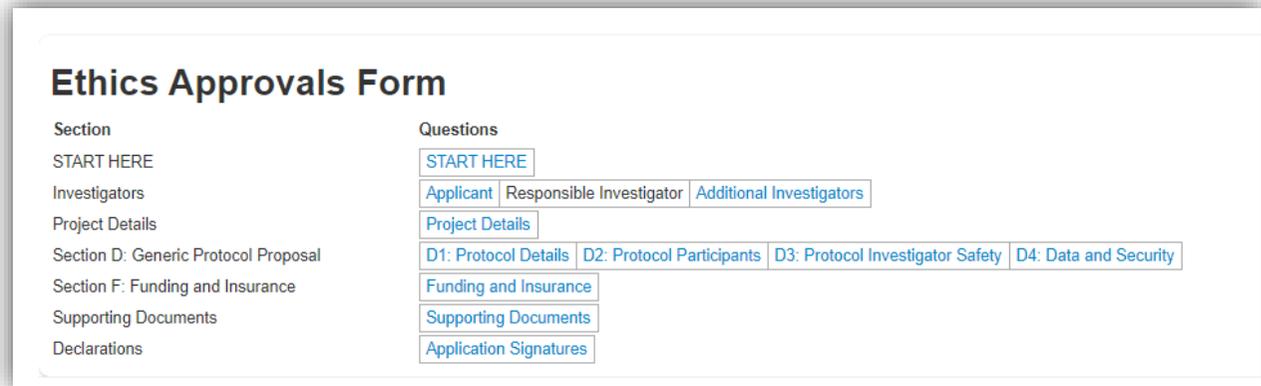
SECTION D: GENERIC PROTOCOL PROPOSAL

Section D will only be available if you have selected 'New Generic Protocol Proposal' in the 'Start Here' section.

The establishment of Generic Protocols is intended to allow **named investigators** to use the same set of procedures/techniques involving human participants as part of a number of different research projects, without needing to submit a full proposal to the Sub-

Committee on each occasion. Generic Protocols are for procedures/techniques involving human participants that are **used on a regular basis**, and which form all or part of subsequent research projects or taught modules. This option should **not** be selected for one-off research projects.

The four sections should be completed including a detailed description of the methodology. The proposal will be considered by the Ethics Review Sub-Committee.



The screenshot shows the 'Ethics Approvals Form' navigation menu. It is divided into two columns: 'Section' and 'Questions'. The 'Section' column lists: START HERE, Investigators, Project Details, Section D: Generic Protocol Proposal, Section F: Funding and Insurance, Supporting Documents, and Declarations. The 'Questions' column lists: START HERE, Applicant, Responsible Investigator, Additional Investigators, Project Details, D1: Protocol Details, D2: Protocol Participants, D3: Protocol Investigator Safety, D4: Data and Security, Funding and Insurance, Supporting Documents, and Application Signatures. The 'START HERE' link in the Questions column is highlighted with a blue border.

Section	Questions
START HERE	START HERE
Investigators	Applicant Responsible Investigator Additional Investigators
Project Details	Project Details
Section D: Generic Protocol Proposal	D1: Protocol Details D2: Protocol Participants D3: Protocol Investigator Safety D4: Data and Security
Section F: Funding and Insurance	Funding and Insurance
Supporting Documents	Supporting Documents
Declarations	Application Signatures

SECTION E: DATA STORAGE AND SECURITY

If you have selected 'yes' to questions in Section A you will need to supply further details of your data storage. Please refer to our Guidance Notes on [Data Collection and Storage](#) and [Compliance with Data Protection Requirements](#).

SECTION F: FUNDING AND INSURANCE

If your project is externally funded, please provide details of the funder.

Please complete the section on insurance. If your project is not classed as normal activity or your study is overseas you should contact insurance.support@lboro.ac.uk. Please send them a copy of the project description and the Insurance Questionnaire and request confirmation of insurance. If possible, this should be attached to your submission by uploading a copy of the email confirmation. Confirmation of insurance must be received before the project commences.

SECTION G: SECURITY SENSITIVE MATERIAL

If you have indicated that your project will involve accessing [Security Sensitive Material](#), you will be asked to complete Section G of the form.

This Section will ask for additional information regarding your project.

Projects which involve access to Security Sensitive Material require approval by the Chief Operating Officer in the Declarations Section.

G1: Security Sensitive Material

Are all of the following statements true?

1. The conduct and outcomes of my research/activity adhere without question to the ethical principles outlined in Section Two of the Ethical Policy Framework.
2. My project/activity and its outcomes are clearly legal.
3. I am comfortable with the activities and their consequences.
4. I believe that the activities and outcomes will be acceptable to my personal and professional associates and in the wider public domain.

Yes
 No

Please specify the nature of the security-sensitive material and the purpose for which you will be accessing it.

Please specify the time period during which you will need to access the security-sensitive material

SECTION H: RESEARCH INVOLVING ANIMALS, ANIMAL TISSUES OR CELLS

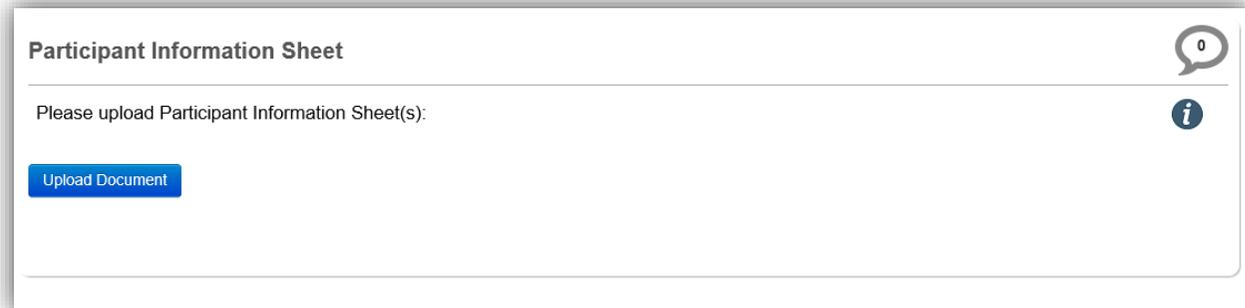
If you have indicated that your project will involve [Animals, Animal Tissues or Cells](#), you will be asked to complete Section H of the form.

This section will involve a series of questions to determine whether the project has the required additional approvals.

SUPPORTING DOCUMENTS

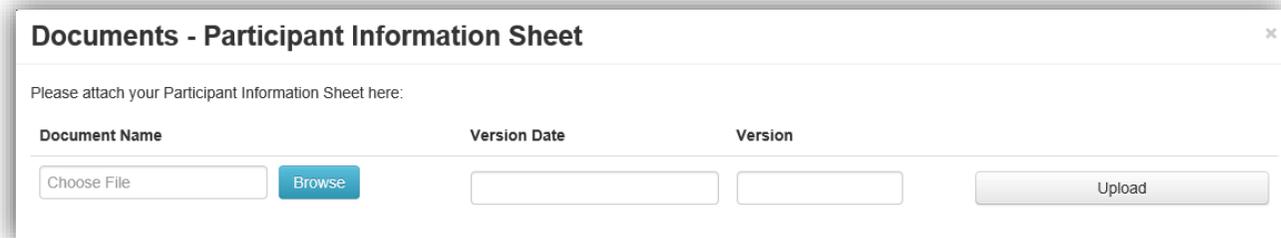
You must attach copies of Participant Information Sheets, Informed Consent Forms and Risk Assessment for your project. Templates for supporting documents are available under the Help tab at the top of the screen.

Please select Upload Document:



The screenshot shows a web interface titled "Participant Information Sheet". At the top right, there is a speech bubble icon with the number "0" and an information icon "i". Below the title, the text reads "Please upload Participant Information Sheet(s):". A blue button labeled "Upload Document" is positioned below the text.

Then Browse to select the correct document. Once you have selected the correct document please select 'Upload'.



The screenshot shows a web interface titled "Documents - Participant Information Sheet" with a close button "x" in the top right corner. Below the title, the text reads "Please attach your Participant Information Sheet here:". There are three columns: "Document Name", "Version Date", and "Version". Under "Document Name", there is a "Choose File" button and a blue "Browse" button. Under "Version Date" and "Version", there are empty input fields. To the right of these fields is a grey "Upload" button.

Any other study documents should also be attached under 'Other Documents'.

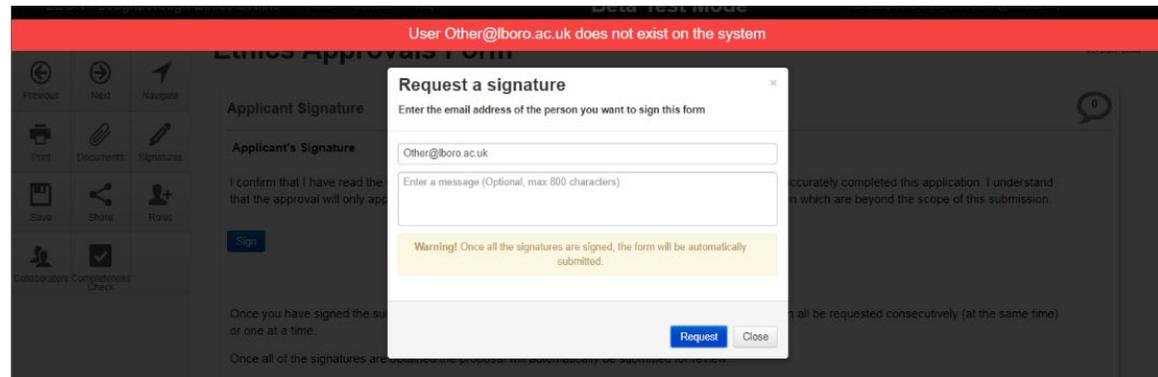
PLEASE DO NOT ATTACH SENSITIVE PERSONAL DOCUMENTS SUCH AS DBS CHECKS OR OCCUPATIONAL HEALTH RECORDS.

DECLARATIONS

The applicant should sign the project by selecting 'sign' and then adding username and password. The time and date of the signature will be recorded.

Applicants should then request any additional signatures that are required. These will be listed below the applicant's signature, **scroll down** to view all the required signatures. For each signature required, select 'request' and then add the relevant email address.

The contact must have an active account in LEON to sign submissions. If you receive the message on the right you should ask the signatory to access LEON, this will activate their account. You will then be able to request their signature.



The screenshot shows a web interface for 'LEON Approvals Form'. A red error banner at the top states 'User Other@lboro.ac.uk does not exist on the system'. A modal dialog box titled 'Request a signature' is open, containing the following elements:

- Header: 'Request a signature'
- Text: 'Enter the email address of the person you want to sign this form'
- Input field: Contains 'Other@lboro.ac.uk'
- Text: 'Enter a message (Optional, max 800 characters)'
- Warning box: 'Warning! Once all the signatures are signed, the form will be automatically submitted.'
- Buttons: 'Request' and 'Close'

The background interface shows a sidebar with icons for 'Previous', 'Next', 'Navigate', 'Print', 'Documents', 'Signatures', 'Save', 'Share', 'Rate', and 'Collaboration'. The main content area includes a 'Sign' button and text indicating that the user has signed the submission.

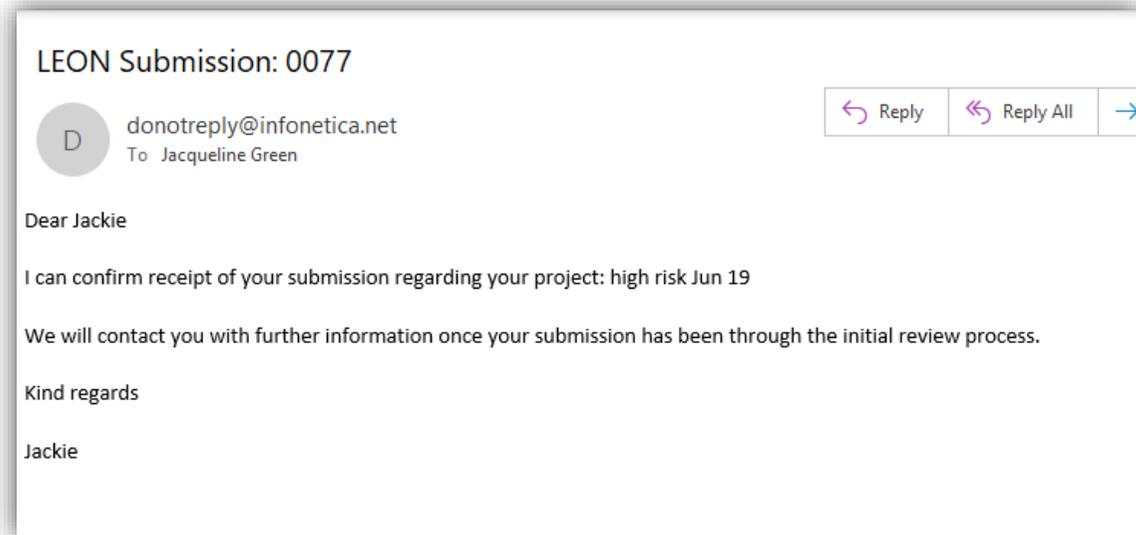
It is recommended that signatures are requested by the 1st of the month if approval is required that month (unless the relevant School issues further instructions).

If the submission is urgent, please check that the signatories are available before requesting signatures.

SUBMISSION

Once the signatures are obtained the form will automatically be submitted (unless auto-submission is switched off – in this case the form would need to be submitted by selecting ‘submit’ on the left-hand side once all signatures are obtained).

Applicants will receive an email from the system confirming receipt of the submission. This will either confirm approval or will explain the next steps that will be taken to review the project. This email will be headed ‘LEON’ and will be from the @infonetica.net email address.



SUPPORT

Please refer to the Guidance Notes and Frequently Asked Questions for further information in the first instance.

Students requiring guidance on the contents of the form should contact their project supervisor.

If you require further guidance please contact LEON@lboro.ac.uk.