



# ICGP Ethics Module Manual

## “The Applicants Guide”



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# 1. Self-Registration

Applicants will self – register for the system as per below screenshots:

The screenshot shows the login page for Vidatum Academic. At the top is the ICGP logo, followed by the text "Vidatum Academic". Below this are two input fields: "Username" and "Password". There is a checkbox labeled "Logout when the browser close". A blue "Login" button is positioned below the checkbox. At the bottom left, there are two links: "Forgot password?" and "Register". A red arrow points to the "Register" link. The version number "ICGP4.0.2.0" is visible at the bottom right of the page.

The screenshot shows the registration form titled "Registration". It contains several fields with asterisks indicating they are required:

- First Name \***: Input field containing "Emma".
- Last Name \***: Input field containing "Joe".
- Email \***: Input field containing "emjoe77@gmail.com".
- ICGP Membership Number**: Input field containing "123456". Below this field is the text "Please leave blank if you do not have an ICGP Membership number".
- Password \***: Input field with masked characters ".....".
- Confirm Password \***: Input field with masked characters ".....".

A "Register" button is located at the bottom right of the form.



Once the applicant has registered, they will receive an email to activate their account on the ICGP Research Ethics system.

**\*Please note to check your 'SPAM' folder if you do not receive an activation email**

OR

Remember Me

Login

[Forgot password?](#)

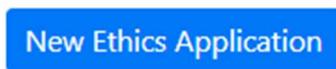


## 2. Creating an Ethics Review

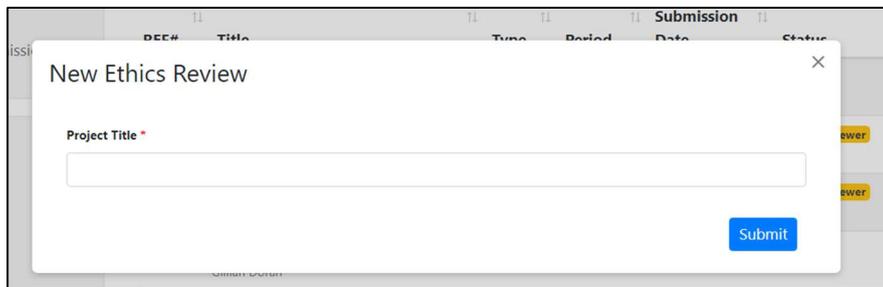
To create an Ethics Review submission, click on the blue **“New Ethics Application”** button on the top right-hand side of the page. Type in the **“Project Title”** name and click the blue **“Submit”** button.



**Stage 1:**



**Stage 2:**





### 3. Ethics Review Form

The navigation panel at the top of the page allows users to go through different sections of the ethics form. As shown by the red arrow on the screenshot.

**IMPORTANT NOTICE: Please ensure to read all instructions below on 'Saving'.**

The screenshot shows the top navigation panel of the Ethics Review Form. A red arrow points to the 'Section A' tab, which is highlighted in blue. The navigation panel includes tabs for Section A through Section L. Below the navigation panel are three buttons: 'Errors', 'Save', and 'Exit'. The main content area is titled 'General Information' and contains the following fields:

- Ethics Review Code :** 1286
- A1. Title of the Research Study \***
- A2. Is this a multi-site study? \***

A blue information box on the right side of the form provides the following text:

**General Information**  
Please complete Sections A to Section L, in order to submit your application. All mandatory and other required documentation can be uploaded in 'Section L'. For further information, FAQs, and templates for ethics applications, please see the ICGP website  
[https://www.icgp.ie/go/research/research\\_ethics](https://www.icgp.ie/go/research/research_ethics)

Below the 'General Information' section is a section titled 'Principal Investigator Details'.

When moving between sections, please make use of the **"SAVE"** button, found at the top righthand side of the page, so that progress when filling out a form is not lost. The system will warn users when trying to move between sections without saving, in this case as per below example, please ensure to choose **'NO'** or you will lose the work.

The screenshot shows a warning dialog box with a yellow border and a yellow information icon. The text inside the dialog box reads:

**Unsaved work**  
Are you sure you want to leave before saving your work?

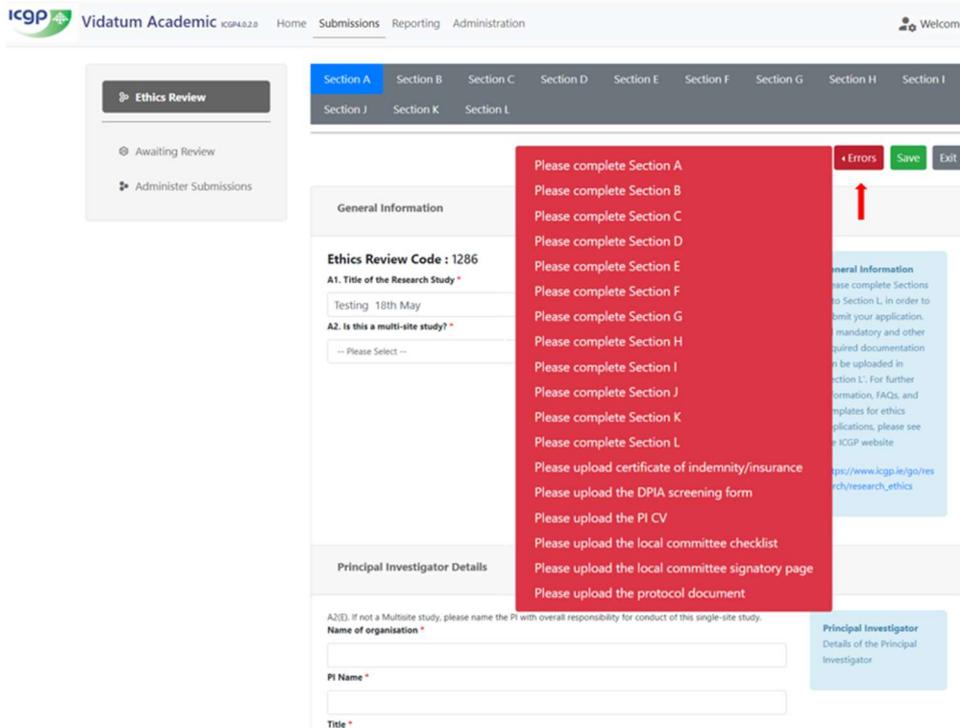
At the bottom of the dialog box are two buttons: 'YES' and 'NO'. A red arrow points to the 'NO' button, and a yellow box next to it contains the text: **Please click 'NO'**



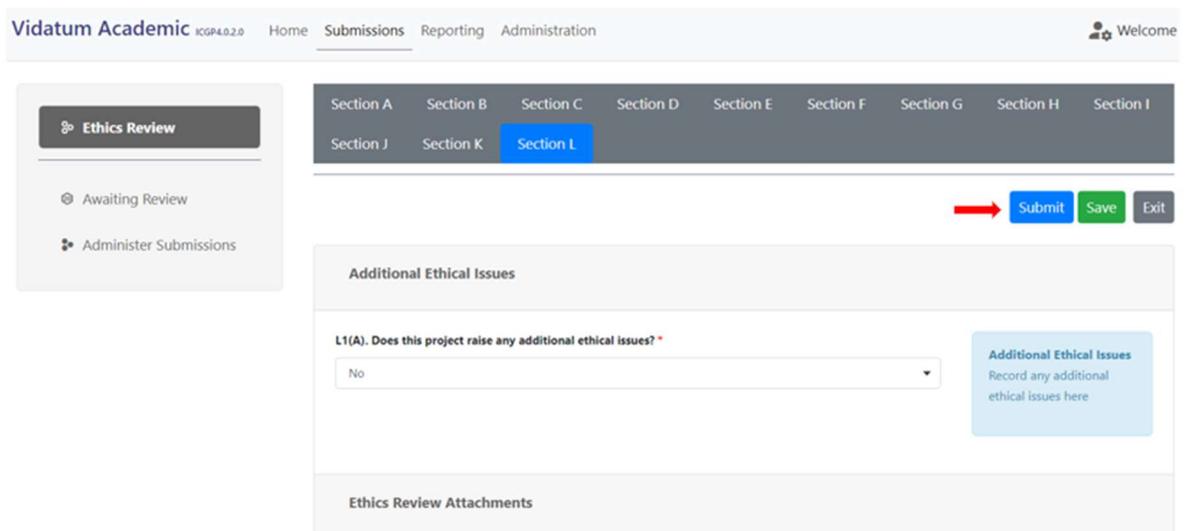
## Ethics Review Form – Submission, Workflow and Visibility

### Submission:

The red **“Errors”** button on the top righthand side of the page, will act as a guide for the user and will show any outstanding fields or documents needed to complete the submission. As shown with the red arrow on the screenshot.



When all mandatory fields and Sections have been completed, the red **“Errors”** button will turn into a blue **“Submit”** button. This has now noted that the user has completed the application and it is ready for the user to press the blue **“Submit”** button. As shown with the red arrow on the screenshot.







## Visibility of Applications

### Who can see the users Application:

- Please note the people able to view the users REC Ethics Application will be as follows:
  - REC Admin – receiving the submission
  - REC Reviewer – receiving the submission from REC Admin
  - REC Chair – receiving the submission from REC Admin
- Please note the assigned Reviewer and REC Chair to the users application will be able to see all relevant information submitted online and through documentation provided in Section L by the Applicant.
- Please note in the case of an unprecedented absence of a Reviewer already assigned to the user's application, the next steps taken are either the REC Admin, REC Chair or a reassigned REC Committee Reviewer will be required to log in as the assigned absent Reviewer which will allow access to the users submitted application.



## 4. Amendments/Clarifications/Study Completion Notification Form:

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### Responding to requests for Clarifications:

- The user will receive an email notification from Vidatum software to state you have a task to action.
- A letter requesting clarifications will be visible in 'Section L' of the user's application.
- The user will then be required to attach a clarifications document in Section L with all required information or further documentation needed.
- All further documentation can be added in Section L and choosing the option for the document called 'Other Documentation' to upload.
- Once all documentation has been uploaded the user will then re-submit their application to which the REC Administrator will receive notification for review.
- The REC Administrator will then send the further documentation to the reviewers for review.

### Uploading Amendments Request Form:

- The user will need to attach the Amendments Request form in 'Section L' with all required information or further documentation needed.
- All further documentation can be added in 'Section L' and choosing the option for the document called 'Other Documentation' to upload.
- Once all documentation has been uploaded the user will then email [research@icgp.ie](mailto:research@icgp.ie) notifying of this request.
- The REC Administrator will then send the further documentation to the reviewers for review.

### Uploading Study Completion Notification Form:

- The user will need to attach the Study Completion form in 'Section L' with all required information or further documentation needed.
- All further documentation can be added in 'Section L' and choosing the option for the document called 'Other Documentation' to upload.
- Once all documentation has been uploaded the user will then email [research@icgp.ie](mailto:research@icgp.ie) notifying of their completion.
- The REC Administrator will then update the applicant's details with same.



## 5. Ethics Approval

When a user submits their application, the user will receive an email notification on the submission (please note to check 'Spam' Inbox, if you do not receive the email). The system will automatically send the user an updated email notification on each stage of the review process. The user can click on the Project Title 'link', as shown on the below [Screenshot 1](#) with the red arrow. This will direct the user to the application that is required review or has been marked approved. As per the below on [Screenshot 2](#) with the red arrow.

### [Screenshot 1.](#)

The screenshot displays the Vidatum user interface. On the left, the 'Your Profile' section shows a placeholder for a user's name and a 'Publish Profile' button. Below it, the 'Notifications and Tasks' section has tabs for 'Notifications' (58) and 'Tasks' (13). A search bar is present above a table of notifications. The table has columns for 'Subject' and 'Actions'. The first row shows 'Your ethics application has been approved' with a red arrow pointing to the 'Actions' column. The second row shows 'An ethics application requires your review' with a red arrow pointing to the 'Actions' column. On the right, the 'Search' section allows searching for profiles, publications, and projects. Below it is the 'Login As' section with a 'Submit' button. At the bottom right, the 'System Notifications' section displays 'There are no notifications to display'.

### [Screenshot 2.](#)



**Message**

**Subject:**  
Your ethics application has been approved

**Message:**  
The following ethics application has been approved. Please note the Application Number for reference below:

- Record ID: 1484
- PI Name: User's Name
- Project Title: [20th June - Testing Comments New Application](#)
- Ethics Type: HUMAN

The application can be reviewed on the ICGP Ethics system.

**Send At:**  
21/06/2023 1:33:25 PM

The user can also view updates on their “Ethics Review” page under the Submissions Icon. This page will list all the users previously submitted Ethics Reviews and the user will be able to view them in a read-only format. As shown on the below screenshot with the red arrow.

**Ethics**

Search:

REF#	Title	Type	Period	Submission Date	Status
1286	Testing 18th May Emma Smith	Human			Draft
1063	Testing 1 Shafig Far	Human	01/03/2023	18/05/2023	Ethics Reviewer
1280	Testing email notifications Niveen Effar	Human		18/05/2023	Ethics Reviewer
1260	Gillian Test Gillian Dorian	Human			Draft
1284	Vidatum	Human			Draft

Clicking on the person profile “” button will allow the user to view which stage of approval the ethics review is on. As shown on the below screenshot with the red arrow.



**Ethics** [New Ethics Application](#)

Search:

REF#	Title	Type	Period	Submission Date	Status
1286	<a href="#">Testing 18th May</a> Emma Smith	Human			Draft
1063	<a href="#">Testing 1</a> Shafiq Far	Human	01/03/2023	18/05/2023	<b>Ethics Reviewer</b>

**Filter by Status**

Approved

Draft

Example of reviewing preview:

### Ethics Approval and Comments

**Submission Details**

**Title:** Emma sending as Applicant for testing 19th June

**PI:** Emma Smith

**Status:** REC Admin (Post Review)

Current Ethics Approval Status

Role / Approver	Date	Status
REC Admin Emma Smith	19/06/2023 2:20:30 PM	✓
Ethics Reviewer Approver Name Withheld	19/06/2023 2:21:29 PM	✓
Ethics Reviewer Approver Name Withheld	19/06/2023 2:23:23 PM	✓
REC Admin Emma Smith <b>Current Approver</b>		🕒
Ethics Chair Approver Name Withheld		?

**Current Ethics Approval Status**  
This section contains the status of each of the required approvals for this timesheet.



## 6. Applicants next steps: Actioning responses received from REC Committee

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### Decision response:

#### Next steps on receiving a 'Decision' response:

- The user will receive a notification, which they can view on their "Ethics Review" page under the Submissions Icon.
- A decision letter will be attached in Section L for the user's review.

#### Replying to a Decision response:

- The user will note that their application will be back in Draft form.
- Please review the decision response letter from the REC Committee stated in Section L, responding as required i.e., amending the user's form/documents, complete the response form and uploading all further attachments needed to Section L.
- Once a user has added all documentation and responses to Section L the user will now be required to re-submit the application.
- The application will then go through the same process and be delivered to the REC Administrator to send to the REC Committee for review.
- A REC Committee response to the decision letter will then be communicated to the user through a decision letter being attached to Section L and notified of this by the REC Administrator on an online email notification to your submission.

### Clarifications required:

#### Next steps on receiving a 'Clarifications' required:

- If clarifications are required by the user, they will be required to update their application form and any other required materials, also attaching a clarifications response form outlining the changes made.
- Once all information required is updated and all relevant documentation is attached in the Section L, the user will then submit their application.
- This will be sent to the REC Administrator who will then forward to the REC Committee for further review.

#### Replying to a Clarifications response:

- The user will note that their application will be back in Draft form.
- Please review the clarifications response letter from the REC Committee stated in Section L, responding as required i.e., amending the user's form/documents, complete the response form and uploading all further attachments needed to Section L.



- Once a user has added all documentation and responses to Section L the user will now be required to re-submit the application.
- The application will then go through the same process and be delivered to the REC Administrator to send to the REC Committee for review.
- A REC Committee response to those clarifications will then be communicated to the user through a decision letter being attached to Section L and notified of this by the REC Administrator on an online email notification to your submission.

### **Amendments requests:**

#### Next steps on submitting 'Amendments' requests:

- For any amendment requests the user will be required to upload an amendment request form to Section L of the already approved application.
- The REC Administrator will then forward the amendment request for consideration to the REC Committee.
- The user will then receive an email notification from the REC administrator with a request for further information or approval.

#### Replying to an Amendments response:

- The user will note that their application will be back in Draft form.
- Please review the amendments request response letter from the REC Committee stated in Section L, responding as required i.e., amending the user's form/documents, complete the response form and uploading all further attachments needed to Section L.
- Once a user has added all documentation and responses to Section L the user will now be required to re-submit the application.
- The application will then go through the same process and be delivered to the REC Administrator to send to the REC Committee for review.
- A REC Committee response to those amendments will then be communicated to the user through a decision letter being attached to Section L and notified of this by the REC Administrator on an online email notification to your submission.



## 7. Contact

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Questions/Queries:

\*Please email [research@icgp.ie](mailto:research@icgp.ie) with any questions or queries you may have.