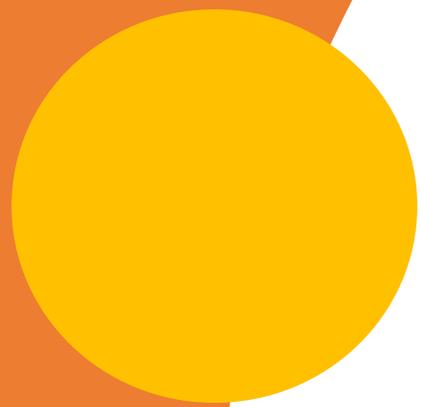


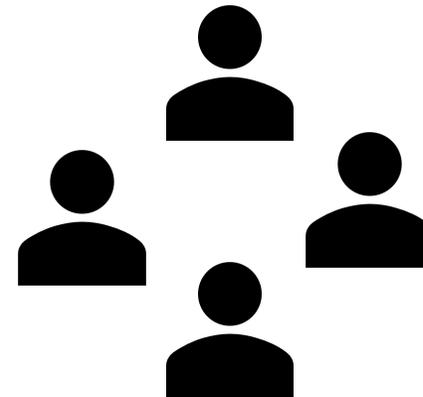
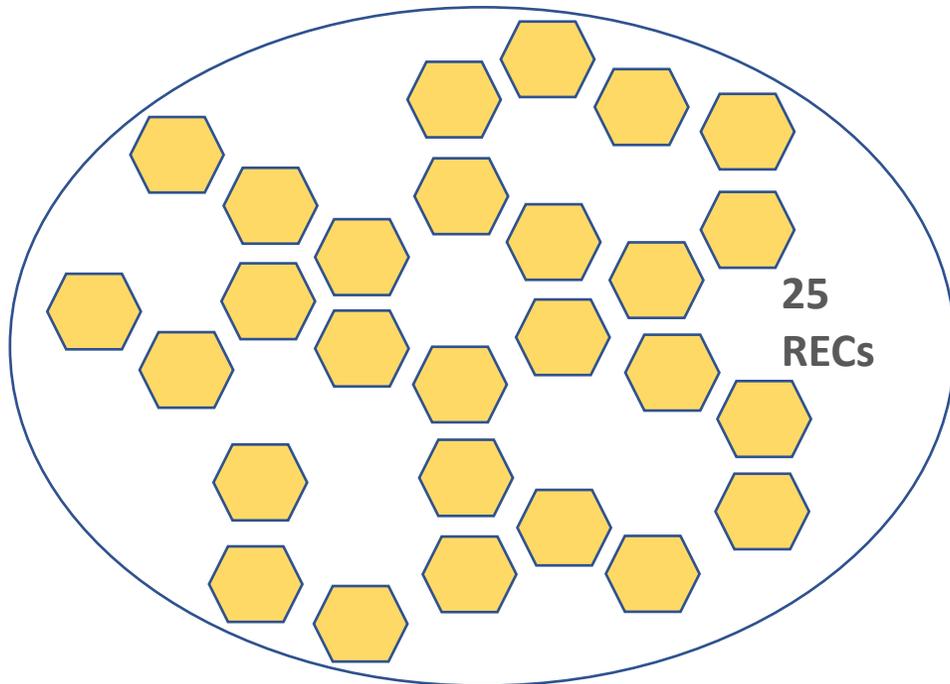
REAMs

Making An Application
Training



Overview

Where we started & where we are



REAMs is not...

.... for all research

“Because of the particular risks associated with certain types of research, ethics approval is required for research involving human subjects, their data, the use of human biological material, research on genetically modified organisms, and research conducted on animals” (Good Research Practice section 4.1)

... a replacement for expert human review

Depending on an applicant's School and the parameters of the study applications can be directed to the appropriate REC

Depending on the characteristics of a particular project applications can be checked for completeness

Applications and attachments should be at a higher standard when submitted, but cannot be read for accuracy, comprehensiveness, appropriateness, quality, relevance

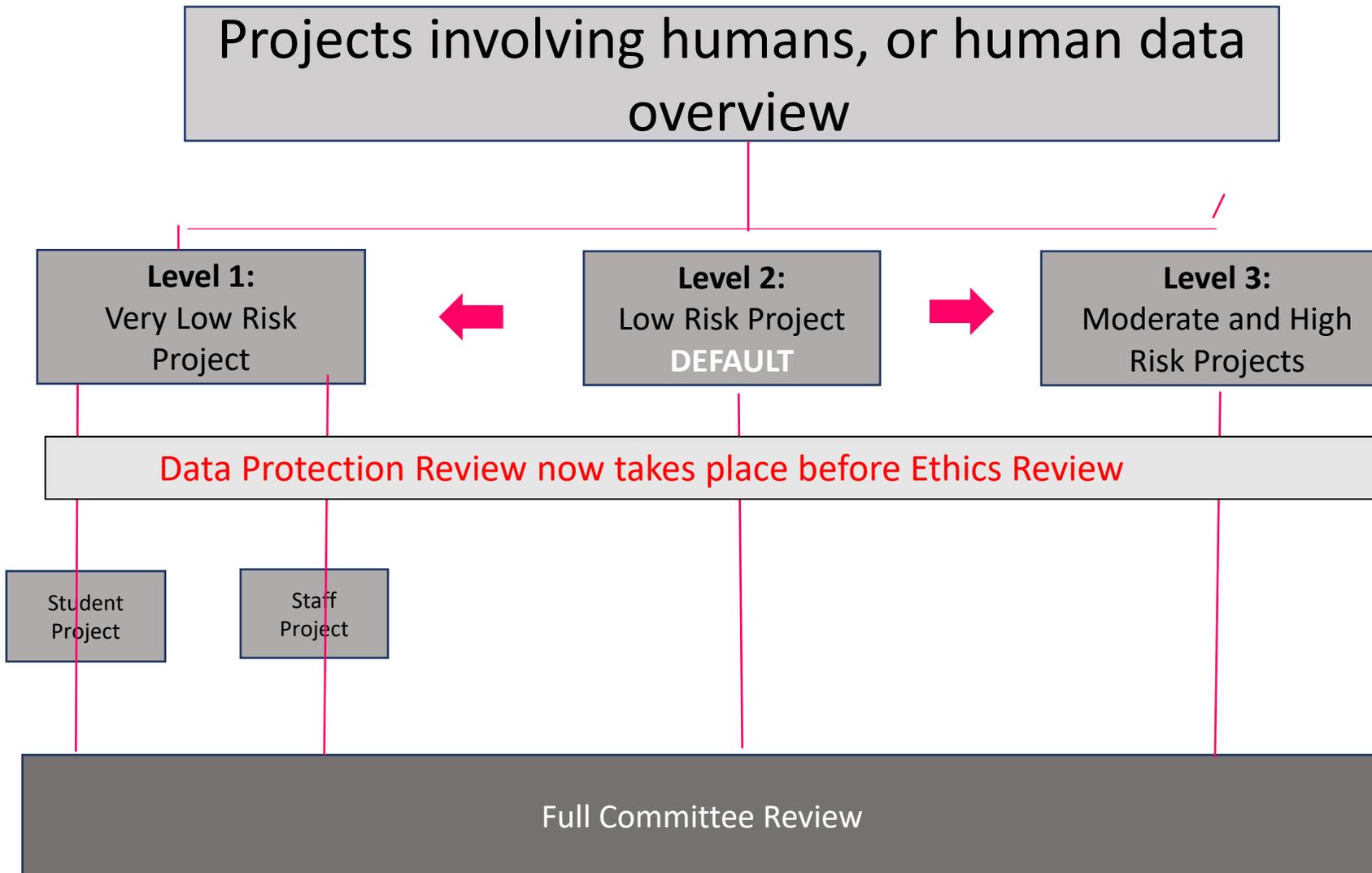
.... a static fixed system

As the context within which ethical review is embedded is dynamic and constantly changing there will be opportunities to adapt to these changes and to incorporate use-inspired improvements

There is a distinction between system bugs, immediate change needs, and cyclical updates

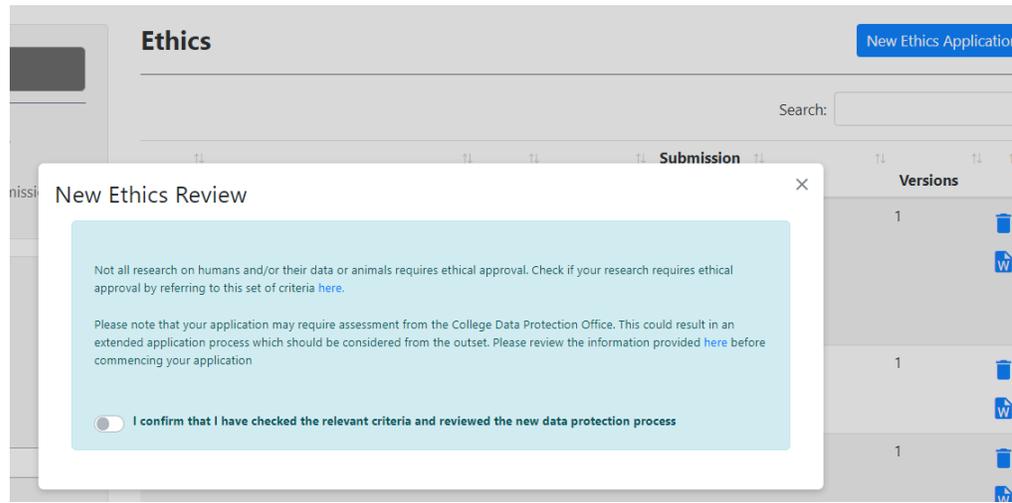


Getting Started



No longer option for supervisor or staff declare nor expedite applications within REAMs
Power with REC to decide how to treat applications depending on their risk level and whether or not they have ethics approval from an external REC

Level 0 No longer Exists



Links out to research website to a checklist of research not requiring ethical approval

Level 1 Conditions

Are you processing any personal data for your research project? *

- No
- Yes

Note this question only applies to research data see question below for other project information that has personal information

Are you processing any pseudonymised (coded) data for your research project? *

- No
- Yes

Note this question only applies to research data see question below for other project information that has personal information

Are you processing any personal data for participant recruitment?

- No
- Yes

i.e. contact details, consent forms

Participants
cannot be
identified

+

Participants
are not at
risk

+

Low risk
Methods

Which of the following best describes the general characteristics of the target population? *

- Adults currently not at risk of vulnerability
- Adults at risk of vulnerability
- Participants who require support to give consent
- Children (<18 years)
- Participants with a dependent relationship with the researcher
- Students of Trinity
- Staff of Trinity

Does the project use any of the following methods exclusively? *

- Quality assurance studies
- Anonymous Surveys
- Unrecorded and anonymous observation of individuals in public areas
- Audits of standard practices or tests
- Information, documents or data which are in the public domain
- A data source not publicly available but which you have permission to use
- No

EITHER

Could the research have detrimental legal, economic or social consequences for either the participant or their establishments? *

- Yes
- No

OR

Intentions of the study: does the project? *

- Involve deception
- Intend to uncover additional illegal activity
- Explore a topic that is potentially intrusive or is research that is harmful or may endanger participants
- Have a military role
- Have a dual purpose that could be mis-directed to do harm
- None of the above

OR

Will payment be made to research participants? *

- YES - standard gratuity with or without expenses
- YES - a higher value gratuity with or without expenses
- No

OR

Which of the following best describes the general characteristics of the target population? *

- Adults currently not at risk of vulnerability
- Adults at risk of vulnerability
- Participants who require support to give consent
- Children (<18 years)
- Participants with a dependent relationship with the researcher
- Students of Trinity
- Staff of Trinity

OR

2.2.9 Does the project require a Consent Declaration under the Health Research Regulations (2021)? * ⓘ

- Yes
- No

Please note that this is a specific declaration for Health Research and is NOT a consent form

Level 3 Criteria

Does the project include an intervention? *

- No
- Yes

OR

Logging On

Ethics.tcd.ie



Vidatum Academic

TCD Staff & Students:
TCD Email +
TCD password

Office 365

OR

Non-TCD Users:
Co-Supervisors
Co-Investigators
Lay Reviewers
Legal Reviewers
Etc.

Username

Password

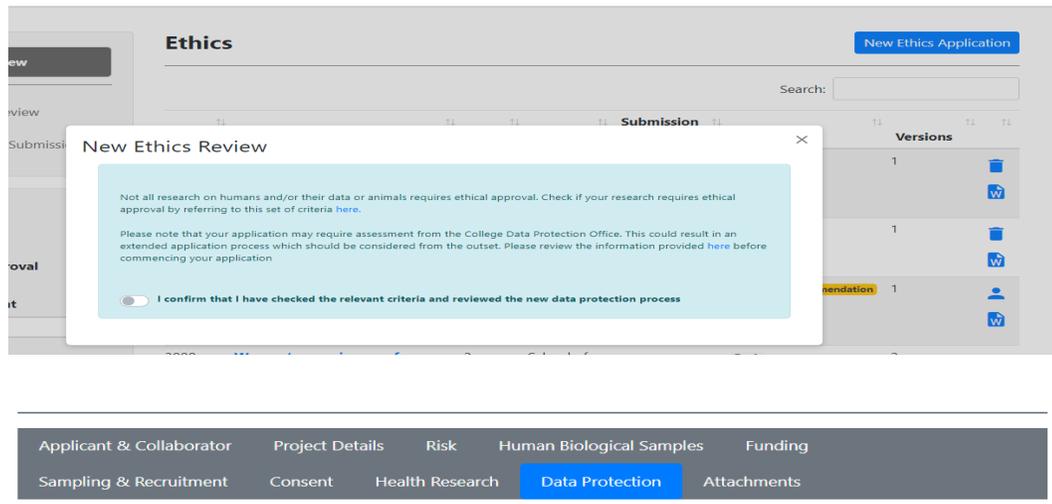
Remember Me

Login

[Forgot password?](#)

TCD4.0.170.0

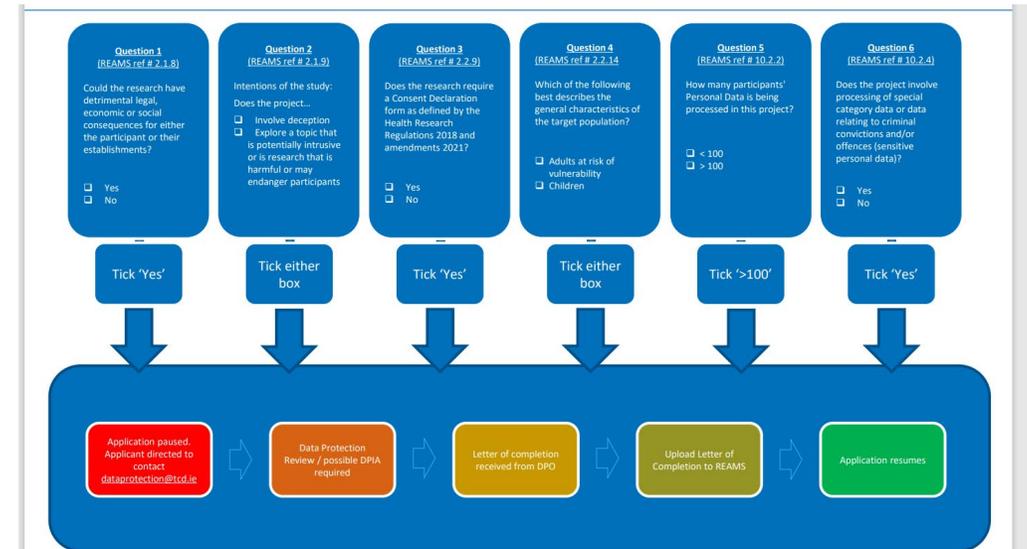
New Data Protection Process



Your application is now paused. There are data protection implications for your research which will require **review** from the Trinity College Data Protection Office before you can continue with this application. Please contact the Research Data Protection Officer at dataprotection@tcd.ie and include 'REAMS APPLICATION QUERY' in your email subject line.

Please note you will be required to upload an attachment 'DPO Review-Letter of Completion' to your application in order to proceed with your application in REAMS.

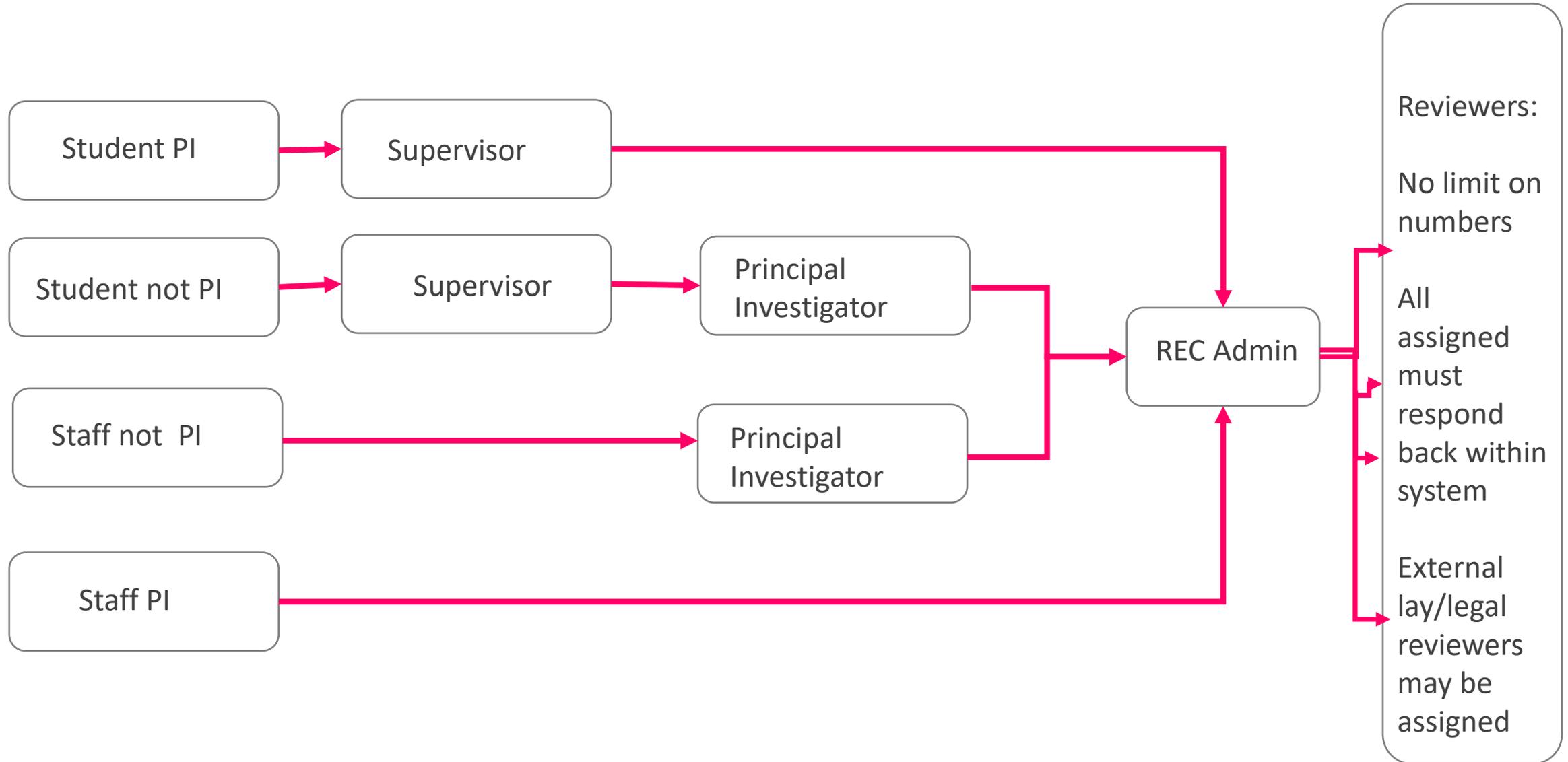
- 11.1 Application Attachments
- The following attachments are required before submission
- Informed Consent Form
 - Trinity students access permissions
 - Recruitment Documentation
 - Garda Vetting Clearance
 - Participant Information Leaflet (PIL)
 - DPO review-letter of completion
 - Data Protection Training certificate (For User: Jennifer Banks)



Summary:

- pop-up window in REAMs to prewarn and direct to information on new process
- 6 questions in REAMs may trigger a DP review
- further pop-up if application requires a review
- a 'DPO-letter of completion' attachment call request
- directs applicant to dpo for review
- when complete, dpo provide a letter of completion to upload to REAMs

Who Signs off before Reviewers?



The Homepage

Tasks

latum Academic TCD4.0.2.0 Home Profile Submissions Reporting Administration Welcome Corri



Corrinna Moore
Personnel No: [REDACTED]
Address:
Office of the Dean of Research

Username

Submit

Notifications and Tasks

Notifications **224**

Tasks **1**

Search:

Ref #	PI	Title	Approval Step / Role	Notification	Date	link
2911	[REDACTED]	Involving key stakeholders to advance Oncology Physiotherapy Services in Oman	Ethics Rec Admin	Hello, The following ethics application has been submitted and requires your review Please note the	21/11/2023 11:50	

Notifications

Notifications and Tasks

Notifications **224**

Tasks **1**

Search:

Subject

Ethics Application "Test V2" has been approved **New**

Actions



The Submissions Tab

 **Ethics Review**

 Awaiting Review

 Administer Submissions

Ethics

[New Ethics Application](#)

Search:

REF#	Title	Risk	REC	Submission Date	Status	Versions	
2966	Students' Perception of the Use of Virtual Reality for Anatomy	3	Faculty of Health		Draft	1	 
3014	Tafamadis utilisation	2	School of Medicine		Draft	1	 
2796	Factors influencing the early development of interest in a clinical academic career	2	School of Medicine	23/11/2023	Awaiting Recommendation	1	 
3008	Women's experiences of effectiveness of frenotomy (a procedure to correct tongue-tie) in overcoming challenges in breastfeeding infants diagnosed with ankyloglossia (tongue-tie) – a qualitative descriptive study	2	School of Nursing & Midwifery		Draft	2	  

Approved

Draft

Pending Approval

Rejected

Filter by Applicant

Filter by REC

-- Please Select --

Filter by Keyword

[Submit](#)





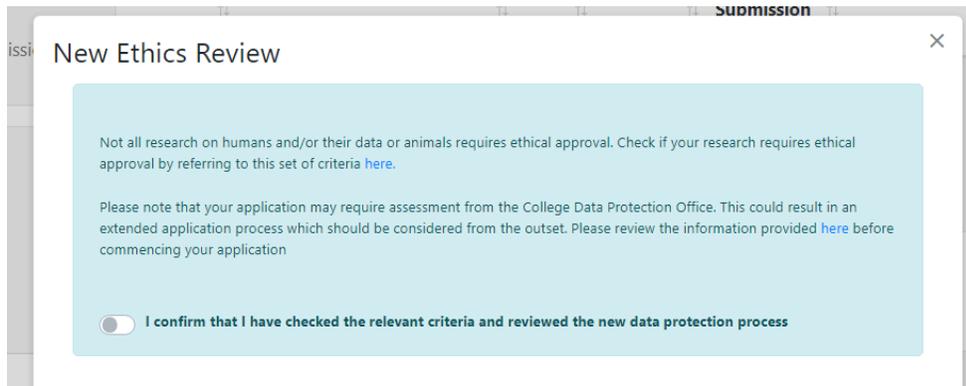
Making an Application

1. Click on New Ethics Application

Ethics

New Ethics Application

2. Check against list of research not requiring ethics & read about new data protection review process



Submission

New Ethics Review

Not all research on humans and/or their data or animals requires ethical approval. Check if your research requires ethical approval by referring to this set of criteria [here](#).

Please note that your application may require assessment from the College Data Protection Office. This could result in an extended application process which should be considered from the outset. Please review the information provided [here](#) before commencing your application

I confirm that I have checked the relevant criteria and reviewed the new data protection process

3. Add project title & choose application type: new or amendment

Project Title *

Application Type *

-- Please Select --

Submit

NB An amendment will be prepopulated with the contents from the original application

Functionality

TEST Risk 2

Applicant & Collaborator Project Details Risk Attachments

Errors Save Exit

1.1 Applicant Details

1.1.1 Applicant Name * Corrinna Moore	1.1.2 Are you applying as a member of staff or a student? * -- Please Select --
1.1.3 Staff / Student Number * [Redacted]	1.1.4 Email Address * Moorec22@tcd.ie
1.1.5 School / Department * -- Please Select --	1.1.6 Role on the Project * -- Please Select --
1.1.7 Primary Employer (if not Trinity) * [Empty]	1.1.8 Other affiliations (if applicable) * [Empty]
1.1.9 Course (for student applicant only) * -- Please Select --	1.1.10 Part time / full time * -- Please Select --
1.1.11 I have read and understood Trinity's policy on good research practice * <input type="radio"/> Yes <input type="radio"/> No	1.1.12 I have completed a TCD Research Integrity Training Module * <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> NA
1.1.13 I have completed a Data Protection Training module within the last 24 months * <input type="radio"/> Yes <input type="radio"/> No	

Applicant Details

This section is required for all projects.

Search: Role on Project
Search: Data Protection
Search: Research Integrity

Refer to the following documents:
Trinity Policy on Good Research Practice
Research Integrity Training (PhDs)
EPIGEUM Research Integrity Training (staff)
Data Protection Training Module

1.2 Trinity Collaborators

No data available in this section

Trinity Collaborators

team. Only Trinity Collaborators (staff or students) can access and edit this application online.

Search: Trinity Collaborators

Add Trinity Collaborators

profile Submissions Reporting Administration Welcor

2

1

3

4

Responsiveness

6

5

TEST Risk 2

- Applicant & Collaborator
- Project Details
- Risk
- Attachments

Errors Save Exit

2.1 Main Project Details

2.1.1 Title of Project *

TEST

2.1.2 Data Collection Start Date *

2.1.3 Data Collection End Date *

2.1.4 Project end date *

Calendar input fields for dates.

Main Project Details
This section is required for all projects. Read the Guidance Document closely while completing this section.

- Profile
- Submissions
- Reporting
- Administration

Welcome

Humans (or their data)

2.1.8 Could the research have detrimental legal, economic or social consequences for either the participant or their establishments *

- Yes
- No

2.1.9 Intentions of the study: does the project *

- Involve deception
- Intend to uncover additional illegal activity
- Explore a topic that is potentially intrusive or is research that is harmful or may endanger participants
- Have a military role
- Have a dual purpose that could be mis-directed to do harm
- None of the above

2.1.10 State research aim(s) and objective(s), research question or hypothesis (Word limit :100 words) *

Text area for research aim(s) and objective(s).

2.1.11 Lay Summary: including background / rationale / justification, research approach, study design. Exclude detail of measurement instruments and intervention and analysis if applicable (Word limit: 250 words) *

Text area for Lay Summary.

involve 1) humans or their data or 2) animals, if you unable to answer yes to either of these categories, your project may not require ethics approval. If you are a student discuss this with your supervisor. Note if this question is not answered it will be picked up by the system and submission of the application will not be facilitated.

- Search: Start Dates
- Search: Writing Phase
- Search: Deception Research
- Search: Potentially Intrusive or Harmful
- Search: Dual Purpose
- Search: Aims and Objective (s) and Summary



Possible Sections

Human Participants & their Data

2.2 Details on Human Participants and their Data

2.2.1 Is your study a phased study? * ⓘ

- No
 Yes

2.2.3 Does the project use data from? * ⓘ

- Primary sources only
 Secondary sources only
 Both primary data and secondary sources

2.2.4 Will you obtain consent from participants for their participation and for the use of their data. In the case of children – consent from a parent / legal guardian. In the case of adults who lack capacity - consent from a proxy. * ⓘ

- No
 Yes

2.2.8 Is the Project Health Research? * ⓘ

- No
 Yes

2.2.10 Are you processing any personal data for your research project? * ⓘ

- No
 Yes

Note this question only applies to research data see question below for other project information that has personal information

2.2.11 Are you processing any pseudonymised (coded) data for your research project? * ⓘ

Details on Human Participants & their Data

There are two types of phased research:

- One involves independent phases ie where one method is independent of the other-one. An application can be submitted if all the methods etc are ready to upload for review.
- The other involves distinct but interdependent phases (eg. phase 1 results in the development of a questionnaire to be used in phase 2). These studies require separate ethics approval for each phase i.e. separate submissions which can then be referenced or linked by the title of the study.

(Link to guidance 'Search: phased research')

Sampling & Recruitment

Applicant & Collaborator Project Details Risk **Sampling & Recruitment** Attachments

Errors Save Exit

Profile Submissions Reporting Administration Welcome Corri

7.1.1 Outline the sampling method *

7.1.2 Describe the time commitment of the participant *

7.1.3 Will the research require/use a gatekeeper *

Yes
 No

7.1.8 Give a detailed step by step description of how participants will be recruited and append the recruitment material (Word limit: 100 words). *

Sampling & Recruitment
This section is required because you will be collecting data from primary sources.

Search: Sampling method
Search: Time commitment
Search: Gatekeeper
Search: Recruitment

Previous Save Next

Health Research

TFST **Risk 2**

Profile Submissions Reporting Administration Welcome

Applicant & Collaborator Project Details Risk Sampling & Recruitment **Health Research** Attachments

[← Errors](#) [Save](#) [Exit](#)

9.1 Health Research

9.1.1 Please indicate which of the following apply to your Health Research project * [?](#)

-- Please Select --

9.1.2 Is the PI a medical professional covered by the State Claims Agency (SCA) Clinical Indemnity Scheme (CIS) for research conducted within a designated state authority (HSE hospital or Service Provider) ?

Yes
 No

Only required where an intervention is part of the project protocol.

9.1.3 Will the project involve the administration of any substances or require participants to refrain from taking any substance * [?](#)

Yes
 No

9.1.5 Will there be ongoing clinical supervision of the participants by a duly insured clinical practitioner during the project * [?](#)

Yes
 No

9.1.6 Will the research participant's general practitioner be informed that they are taking part in the project * [?](#)

Yes
 No

Health Related
This section is required because your research meets the definition in the Health Research Regulations 2018. Health Research generally requires Explicit Consent unless the conditions for an exception are met.

[Search: Health Research](#)
[Search: Informed Consent](#)
[Search: Explicit Consent](#)
[Search: PI and Insurance](#)
[Search: Consent Declaration](#)

Health Research Regulations 2018

Consent

TEST **Risk 2**

Applicant & Collaborator Project Details Risk Sampling & Recruitment **Consent** Health Research

Attachments

← Errors Save Exit

8.1 Consent

8.1.1 How will consent be obtained and by whom * ⓘ

Consent
This section is required because you will obtain

Profile Submissions Reporting Administration Welcome C

Yes
 No

8.1.4 Do you require assent from participants e.g. because of their vulnerability * ⓘ

Yes
 No

8.1.7 Are you required to have garda vetting * ⓘ

Yes
 No

8.1.8 What is the time interval between giving information and securing consent ? * ⓘ

Less Than 7 Days
 7 or More Days

8.1.10 Describe how you will inform participants about the use of their personal data * ⓘ

8.1.11 Describe how participants can withdraw their consent and/or their data * ⓘ

Consent and/or assent are recorded, documented, stored and destroyed.

[Search: Informed Consent](#)
[Search: Risk of Vulnerability](#)
[Search: Garda Vetting](#)
[Search: Time Interval](#)
[Search: Personal Data](#)

Previous Save Next

Biological Samples

TEST **Risk 3**

Applicant & Collaborator Project Details Risk **Human Biological Samples** Sampling & Recruitment
Consent Health Research Data Protection Attachments

← Errors Save Exit

5.1 Human Biological Samples

5.1.1 Will the samples in any form be stored for any period after the project completion * ⓘ

- Yes
- No

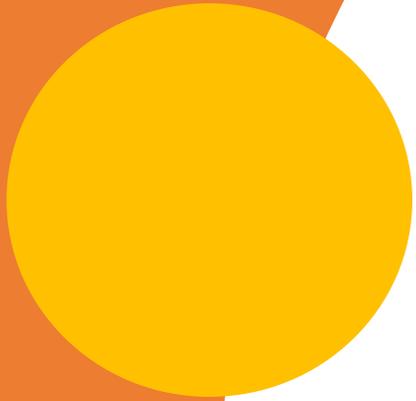
5.1.5 Does the PROJECT involve the use of genetic data? * ⓘ

- Yes
- No

Biological Samples
Search: Biological
Samples.

Previous

Save Next



DPO: Data Protection

Data Protection: Tab Opens

PRISM project Risk 2

Applicant & Collaborator Project Details Risk Funding Sampling & Recruitment Consent

Health Research **Data Protection** Attachments

Errors Save Exit

Your application is now paused. There are data protection implications for your research which will require **review** from the Trinity College Data Protection Office before you can continue with this application. Please contact the Research Data Protection Officer at dataprotection@tcd.ie and include 'REAMS APPLICATION QUERY' in your email subject line.

Please note you will be required to upload an attachment 'DPO Review-Letter of Completion' to your application' in order to proceed with your application in REAMS.

Profile Submissions Reporting Administration Welcome

10.1 Opening Questions

10.1.1 Have all Trinity researchers (staff and students) in this project completed the College Data Protection GDPR training module? *

Yes

Review guidance before answering

10.1.2 Are all Trinity Staff and Trinity Students working on the project familiar with the Trinity College Personal Data Breach Procedural Guidelines? *

Yes

Application cannot proceed unless the answer to the question is 'Yes'

Opening Questions
This section is required because your Research Data contains information that could directly or indirectly identify a participant. Trinity staff and students who will process personal data must complete data protection (GDPR) training.

Trinity Breach Procedural Guidelines

Search: Data Protection Opening Questions
Refer to GDPR training module and Research Integrity Training

10.3 Processing Risk

No data available in this section.

Processing Risk

Search: Data Protection Processing Risk

Add Processing Risk

10.4 Closing Section

10.4.1 Include any additional information in respect of the study which may be relevant *

Closing Section
Provide details that you believe to be relevant but which have not been asked in this section

Previous Save Next

10.2 Data Protection Information

Profile Submissions Reporting Administration Welcome

10.2.1 How many participants' Personal Data are being processed in this project? *

≥100

10.2.2 List all types of Personal Data (including any special category or sensitive personal data) that you will process during the lifecycle of the project? *

Name and email address is required to contact participants and share initial study information. Participants will be asked for explicit consent. They will be asked to print, [icon]

10.2.3 Does the project involve processing of special category data or data relating to criminal convictions and/or offences (sensitive personal data)? *

No

Yes

10.2.4 Is the Personal Data shared outside the research team with any other units within Trinity College? *

No

Yes

10.2.5 Is this data shared with any third party outside of Trinity? *

Yes

No

10.2.6 Provide names of these organisations and detail what Personal Data will be shared with them and why.

Please note that Trinity is not the data controller or processor of the personal data in this study (there was no option to select a different role from the drop-down list above). Trinity is an affiliation of all applicants, but the study is sponsored by Our Lady's Hospice [icon]

10.2.7 Describe what IT due diligence you intend to carry out or have carried out on these organisations.

We have confirmed with the head of IT services at OLH&CS the security measures in place within the research department at the ADPM.

Information
Trinity as an organisation may be the data controller or data processor dependent on staff and student's role in the project. Detail how information is shared within Trinity, with external third parties and with parties outside the EEA/EU as applicable.

Search: Data Protection Information

Verification

Applicant & Collaborator Project Details Risk Funding Sampling & Recruitment Consent

Health Research Data Protection Attachments

Errors Save Exit

11.1 Application Attachments

The following attachments are required before submission

- Consent Form
- Recruitment Documentation
- Participant Information Leaflet (PIL)
- DPO review-letter of completion

File name Browse

profile Submissions Reporting Administration ⚙️ Welcome

11.1.3 Document type

-- Please Select --

11.1.4 Select Item

-- Please Select --

Only use this field if the attachment requested has a specific item (site, person, method) within brackets

Upload

Application/Submission Attachments

To upload an attachment follow these steps:

1. File name: select the file to upload ensuring the REAMs reference number is in the file name
2. File name description: the name you want to give the file
3. Document type: choose from
4. Please select which item this attachment applies to: choose from the drop down menu the specific person, site or item (will be within brackets).
5. Click Upload: clears the attachment request

To delete an attachment, click on Delete (bin icon) in the Actions column. Please note that attachments can be sorted by date of upload by clicking on the 'loaded on' column.



Pre-Approval



PI / Supervisor

- All student applications require a Supervisor to be added as a TCD Collaborator
- If the applicant is not the PI a PI must be added as a TCD Collaborator
- PI and / or Supervisor can collaborate with applicant & can edit application before submission
- PI and / or Supervisor must approve an application before it passes to the REC

Supervisor Sign Off

REF#	Title	Risk	REC	Submission Date	Status	Versions		
2907	An Exploration of the Experiences of Intensive Care Nurses in the Assessment of Pressure Areas in Patients with Dark Skin Tones [REDACTED]	2	School of Nursing & Midwifery	22/11/2023	With Primary Supervisor	2		

Read & Proceed

Applicant & Collaborator | Project Details | Risk | Human Biological Samples | Funding
Sampling & Recruitment | Consent | Health Research | Data Protection | Attachments

Proceed Exit

Your Approval and Comments

I have reviewed the documents and confirm they comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations. I undertake to ensure that the research study will be conducted in line with the approval received both from the Research Ethics Committee and the Data Protection Office. I will seek further approval if changes are proposed to the research after this submission. I will report any adverse events or serious complaints, return all required reports and process research project data in accordance with Trinity College policies and regulations and relevant legislation.

Update Status To:

- Send to REC for ethical review
- Send back to applicant to make revisions

Add Comment

Text entered here is visible to the applicant-the names of reviewers "MUST NOT" be included in this field

Cancel Save

PI Sign Off

REF#	Title	Risk	REC	Submission Date	Status	Versions	
2937	Understanding NK cell immune function and its potential application in cancer research [REDACTED]	3	Faculty of STEM	22/11/2023	With Principal	1	 

Read & Proceed

Applicant & Collaborator | Project Details | Risk | Human Biological Samples | Funding

Sampling & Recruitment | Consent | Health Research | Data Protection | Attachments

[Proceed](#) [Exit](#)

Your Approval and Comments

I hereby declare that the details provided in this application accurately reflect the research proposal. I confirm the documents have been prepared to comply with Good Research Practice, Data Protection Legislation, including the Health Research Regulations (where appropriate), and Trinity College policies and regulations. I undertake to carry out the research as described and will seek further approval if substantive changes to the research are proposed after this submission. I will report any adverse events or serious complaints, return all required reports and process research project data in compliance with Trinity College policies and regulations and relevant legislation.

- Update Status To:
- Send to REC for ethical review
 - Send back to applicant to make revisions

Add Comment

Text entered here is visible to the applicant-the names of reviewers "MUST NOT" be included in this field

[Cancel](#) [Save](#)



Approval



REC: 3 stages to Approval

Status 1- Awaiting Recommendation: Application Lands in REC:
-REC action is to assign out to reviewers

Status 2-Awaiting Reviewer Feedback: Application out with reviewers:
-Reviewer action is to complete their review of application within system

Status 3-Awaiting Approval: REC give feedback to applicant
-REC actions is to approve, reject or ask for revisions

3 STAGE APPROVAL PROCESS

REF#	Title	Risk	REC	Submission Date	Status	Versions
3013	Beekeepers survey about plant protection products [REDACTED]	1	School of Natural Sciences	22/11/2023	Awaiting Recommendation	1

Application Lands in REC:
-action assign out to reviewers

REF#	Title	Risk	REC	Submission Date	Status	Versions
2796	Factors influencing the early development of interest in a clinical academic career [REDACTED]	2	School of Medicine	23/11/2023	Awaiting Reviewer Feedback	1

Application out with reviewers:
-action reviewers must complete

REF#	Title	Risk	REC	Submission Date	Status	Versions
2833	Provision of a Qualitative Study on Urban Speeding [REDACTED]	2	School of Psychology	20/11/2023	Awaiting Approval	3

Feedback given to applicant
-approve, reject, make revisions

Screengrab of
View:
How Applicant
sees Feedback

3008	Women's experiences of effectiveness of frenotomy in overcoming challenges in breastfeeding infants diagnosed with ankyloglossia	2	School of Nursing & Midwifery	Draft	2	  
------	--	---	-------------------------------	-------	---	---

Click person (head and shoulders) icon

Comments Upload Attachments

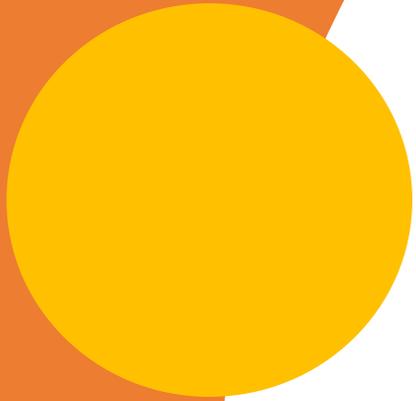
Add Comments / Files

Comments

The names of the 'uploaders' will be visible to the applicant-reviewers MUST NOT upload their feedback directly here but rather email it to the REC to upload

Submit

Feedback visible in add comment box
There may be some attachments to view



Confirming Revisions

Making Revisions

- If revisions are required:
 - Application is RESET TO DRAFT
 - Applicant can make revisions in form
- Revisions are identifiable by a red icon next to the field which shows that it has been changed

2.1.11 Lay Summary: including background / rationale / justification, research approach, study design. Exclude detail of measurement instruments and intervention and analysis if applicable (Word limit: 250 words) * ⚠

- Applicant may add a cover letter confirming and summarising that changes have been made-upload in attachments as 'Other Documentation'

A stylized sun graphic on the left side of the slide. It features a solid yellow circle at the bottom left, with several yellow dashed lines of varying lengths curving upwards and to the right, suggesting rays of light. The background is a solid orange color.

Support Pages:

www.tcd.ie/research/support/ethics-approval.php