REAMs

Making An Application

Training


Overview

Where we started & where we are

2012:
Requests for Support to Dean of Research

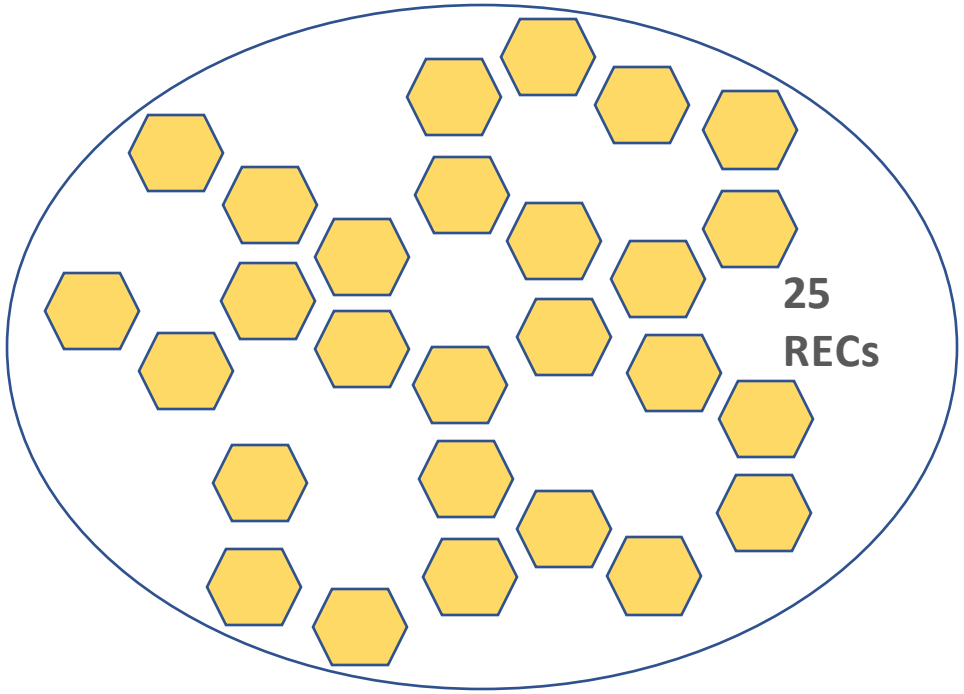
Jan 2021:
Business Plan Approved

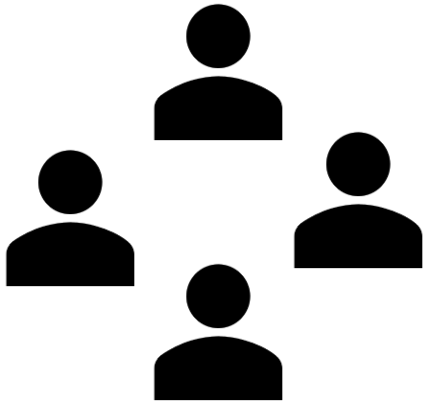
Oct 2021:
Contract Awarded

Nov 2022:
Go Live for Staff and PhD students

Nov 2023:
REAMs V2 Live

2017
2018
2019
2020
Technical Specification
Outline Design
Tender process
Detailed Design
Development
User Testing
Redevelopment
Training
Review
Assess
Brief Version 2
Training
Review





REAMs is not…

…. for all research

"Because of the particular risks associated with certain types of research, ethics approval is required for research involvinghuman 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

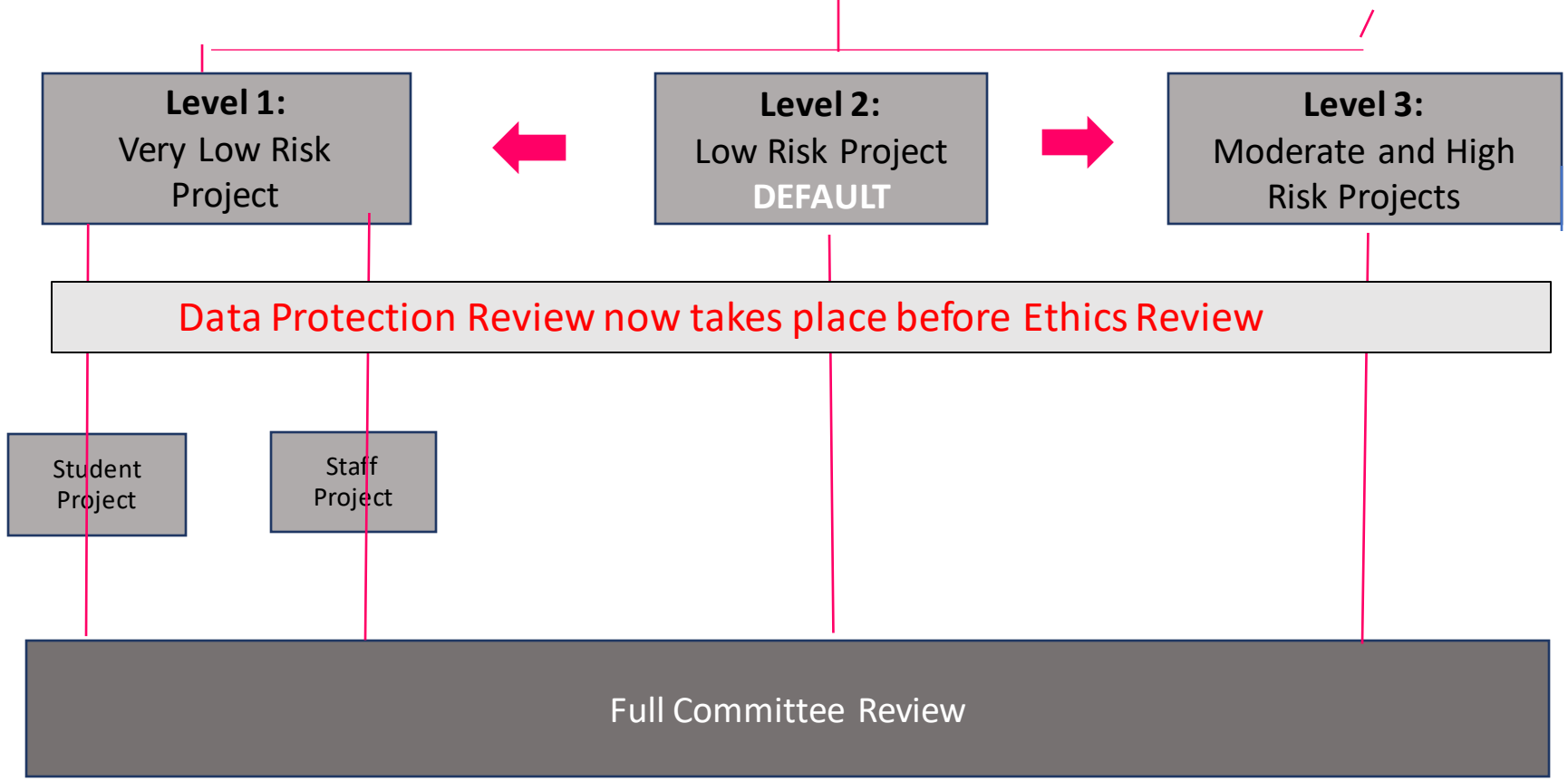
….a static fixed system

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

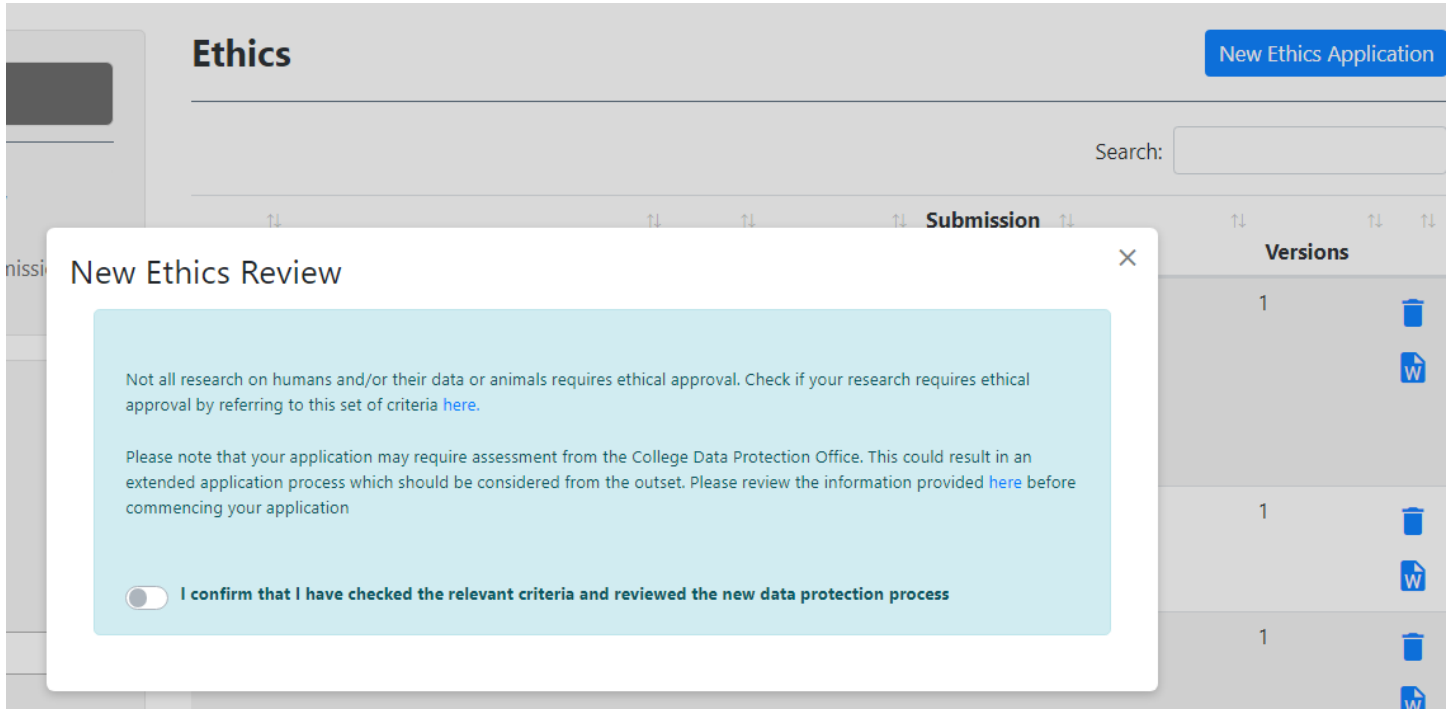

Getting Started

Projects involving humans, or human data overview



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

EITHER

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

+

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

- [x] 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
- [x] Students of Trinity
- [x] Staff of Trinity

Participants are not at risk

+

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

Low risk Methods

Level 3 Criteria

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 *

- [x] Involve deception
- [x] Intend to uncover additional illegal activity
- [x] Explore a topic that is potentially intrusive or is research that is harmful or may endanger participants
- [x] Have a military role
- [x] 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
- [x] Adults at risk of vulnerability
- [x] Participants who require support to give consent
- [x] Children (<18 years)
- [x] 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

OR

Does the project include an intervention? *

- ( ) No
- (•) Yes

Level 3 Criteria ctd

2.1.5 Does the project involve *

Animals

2.1.6 Does this Animal Project involve *

Moderate risk wildlife and ecology projects

OR

2.1.13 Does the project involve *

Human biological samples of any size or type that could have impact on future treatment (e.g. human DNA sequencing)

OR

2.1.13 Does the project involve *

Human biological samples taken in an invasive manner

OR

2.1.13 Does the project involve *

Human biological samples from patients

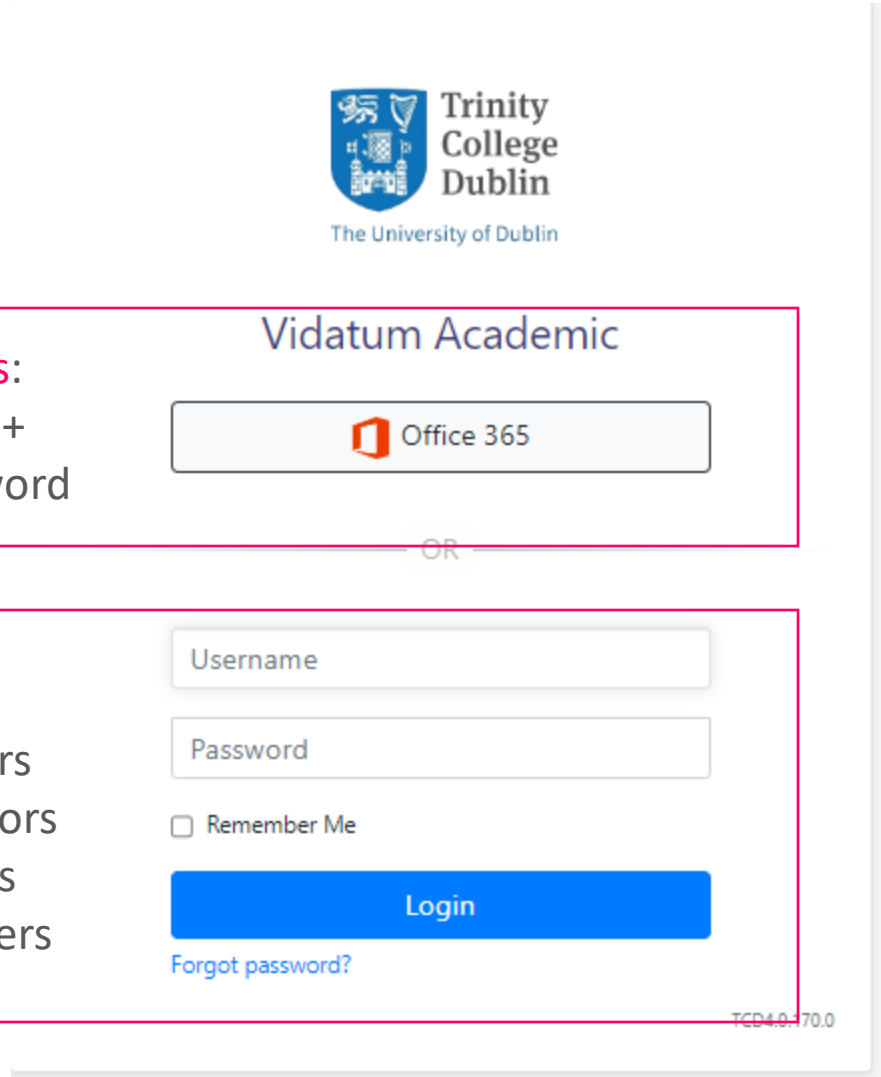
OR

8.1.2 Do your participants require support to give consent *

- (●) Yes
- ( ) No

Logging On

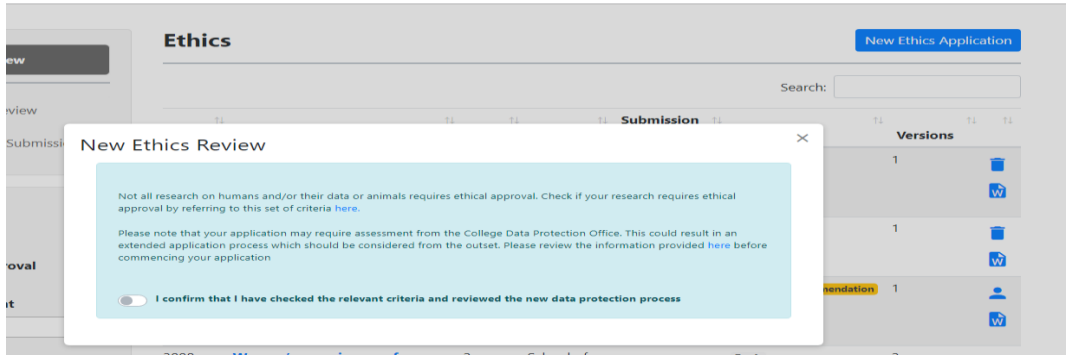
Ethics.tcd.ie

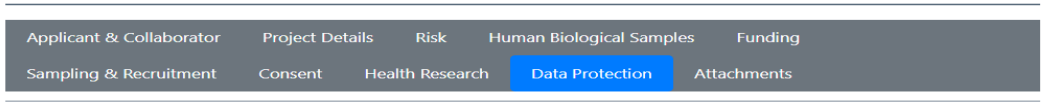


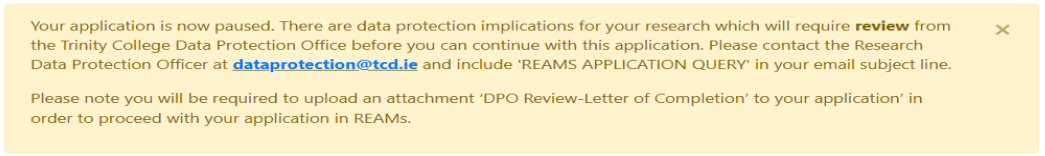
TCD Staff & Students:
TCD Email +
TCD password

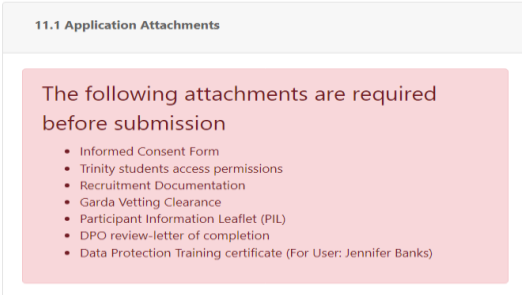
Non-TCD Users:
Co-Supervisors
Co-Investigators
Lay Reviewers
Legal Reviewers
Etc.

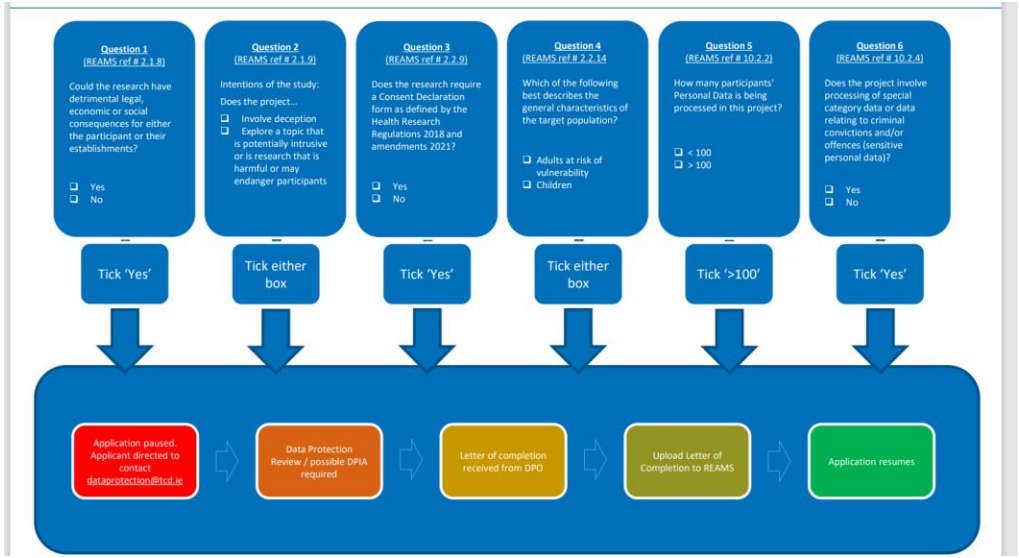
New Data Protection Process











Summary:

-pop-up window in REAMs to prewarn and direct to information on new process

-6 questions in REAMs may trigger a DP review

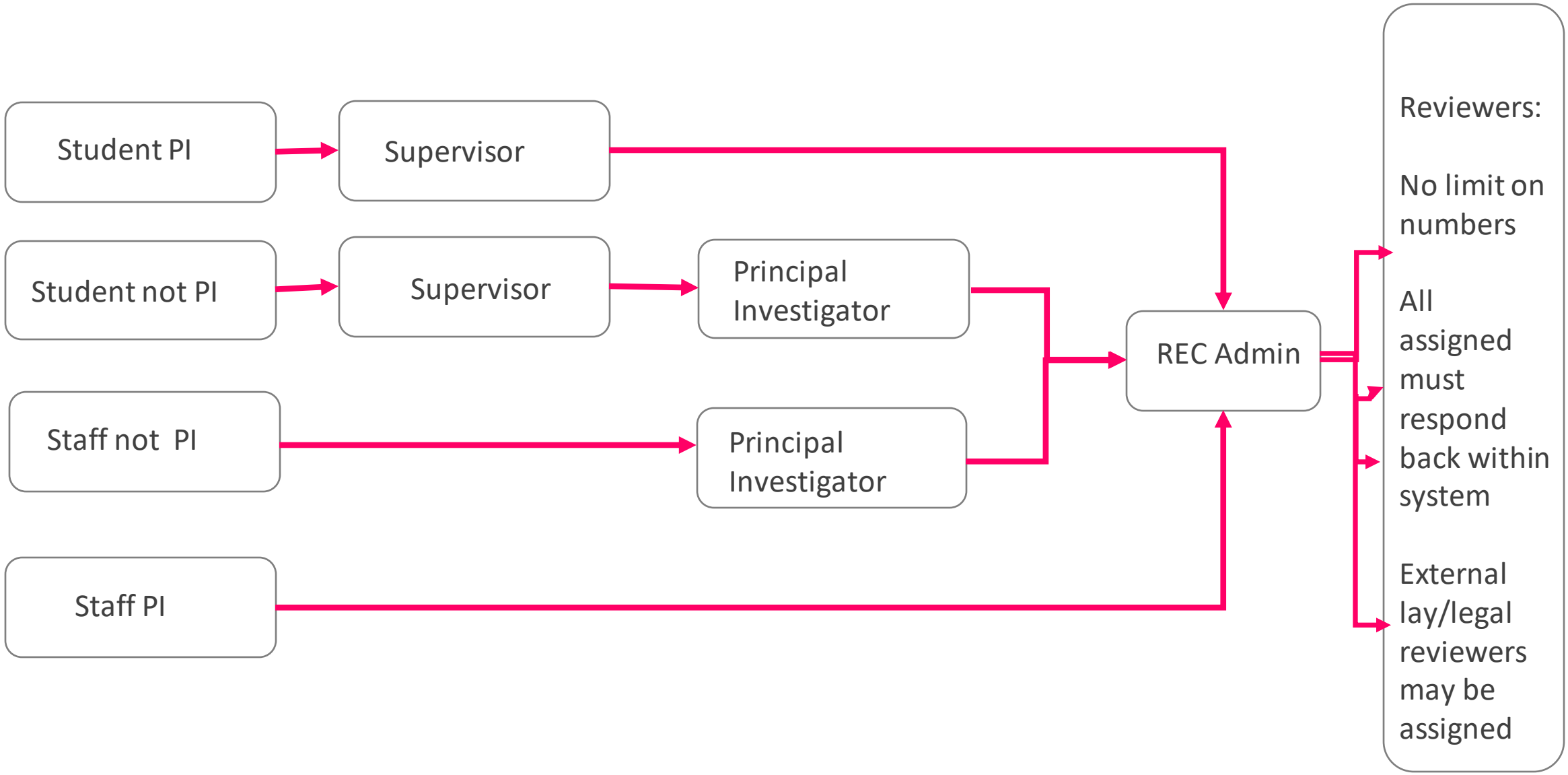
-further pop-up if application requires a review

-a 'DPO-letter of completion' attachment call request

-directs applicant to dpo for review

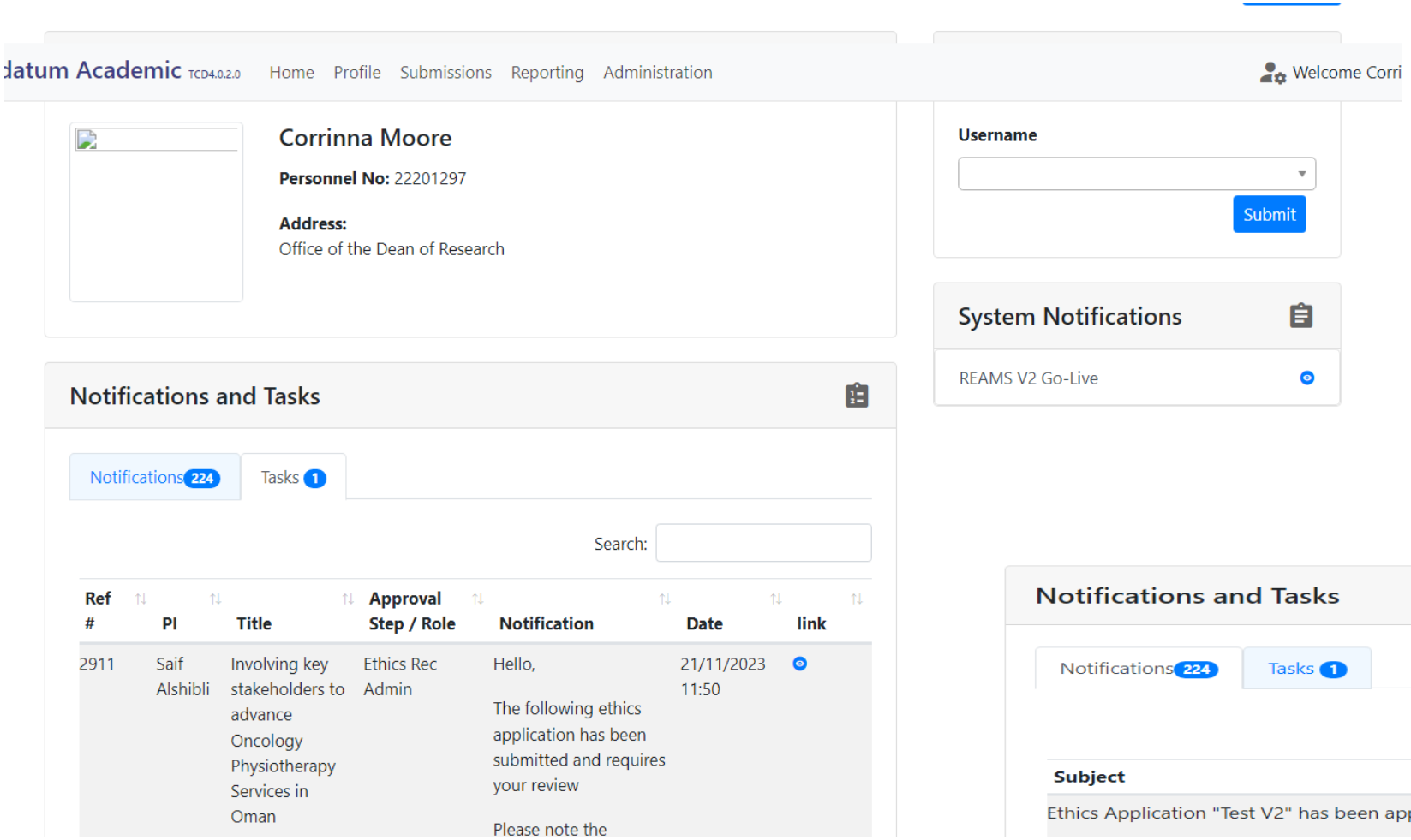
-when complete, dpo provide a letter of completion to upload to REAMs

Who Signs off before Reviewers?

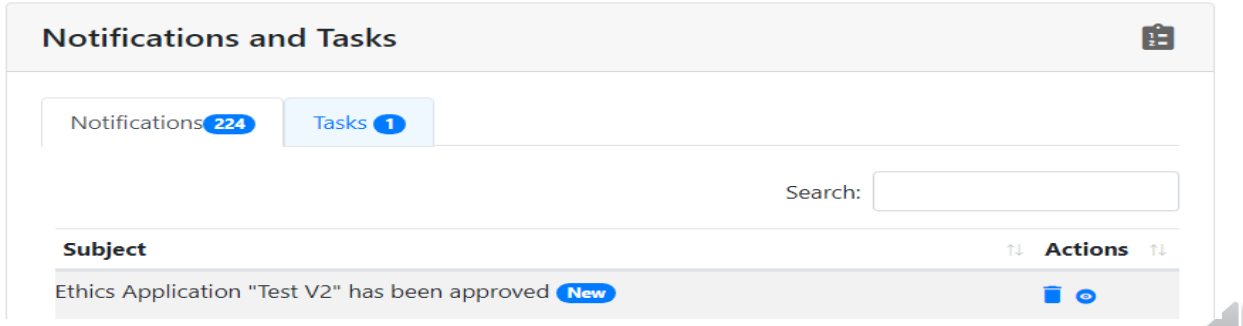


The Homepage

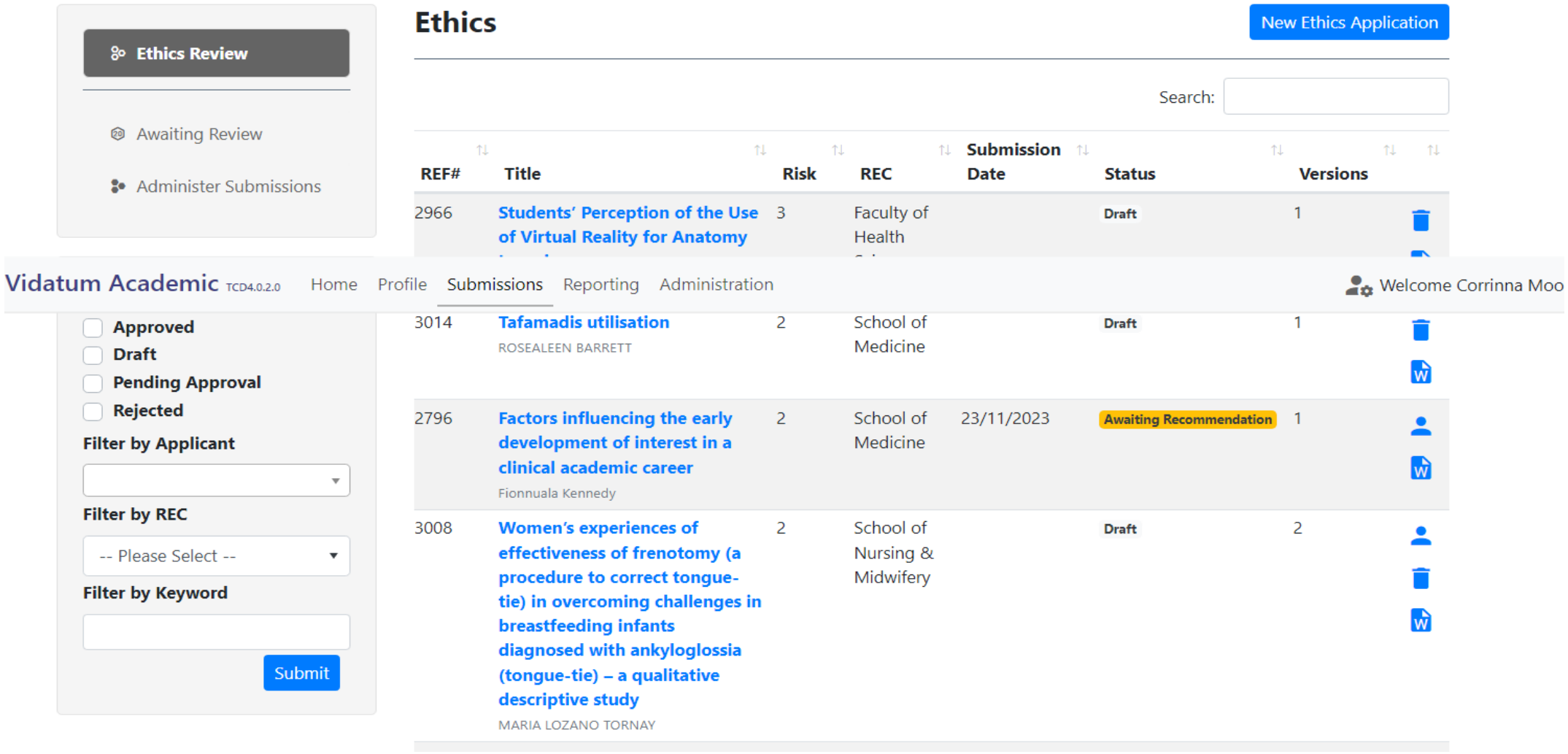
Tasks

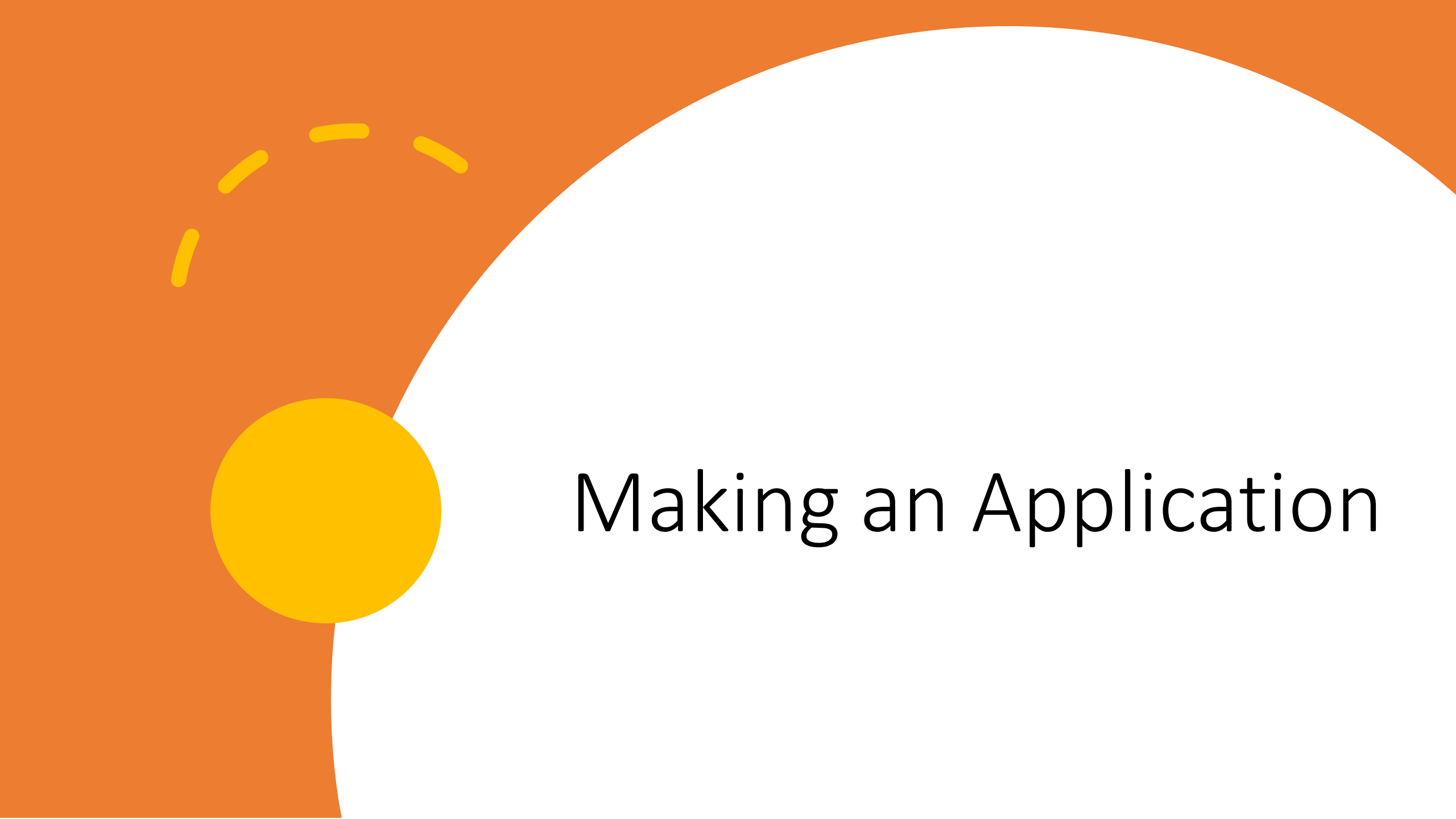


Notifications

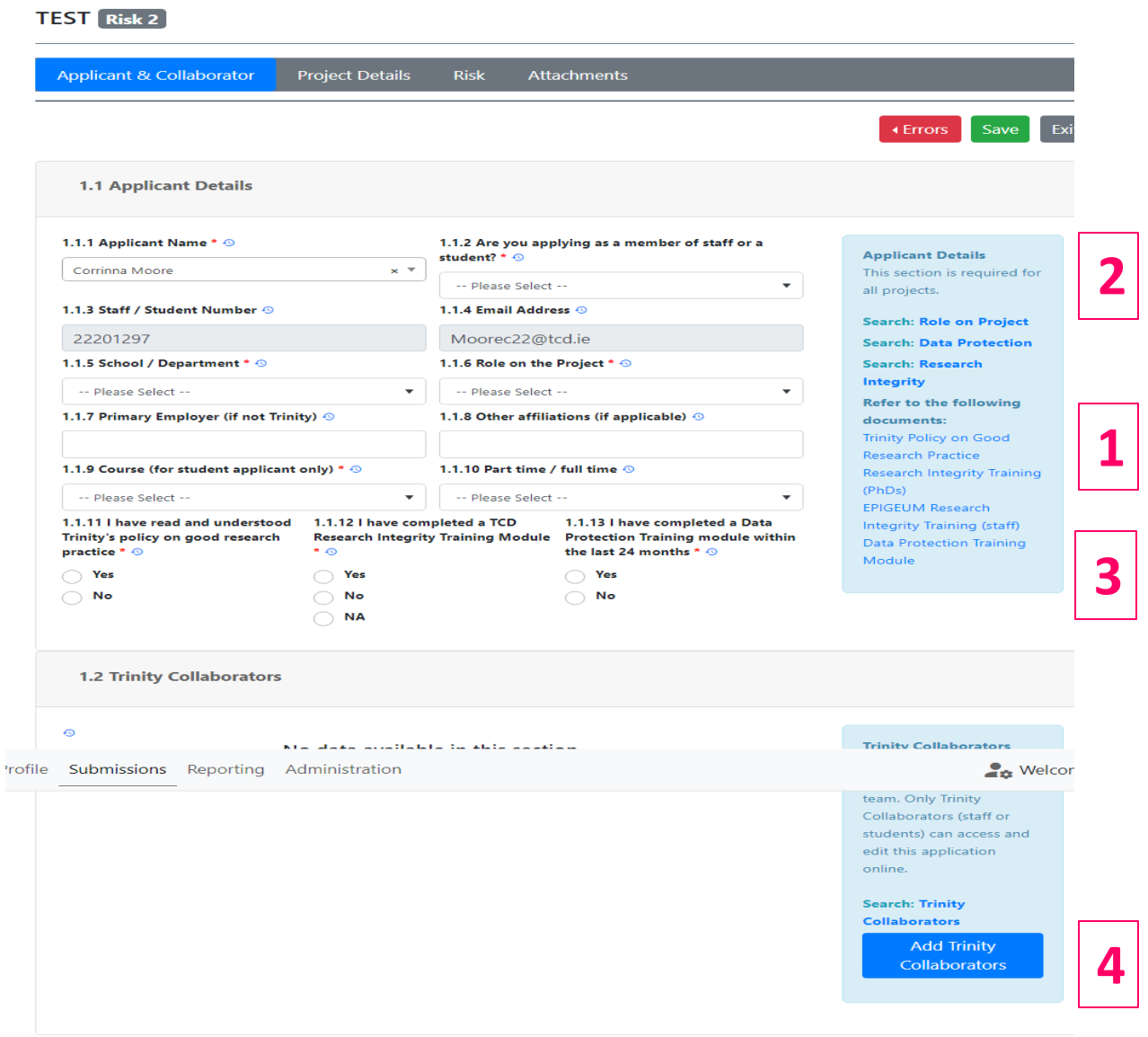


The Submissions Tab




Making an Application

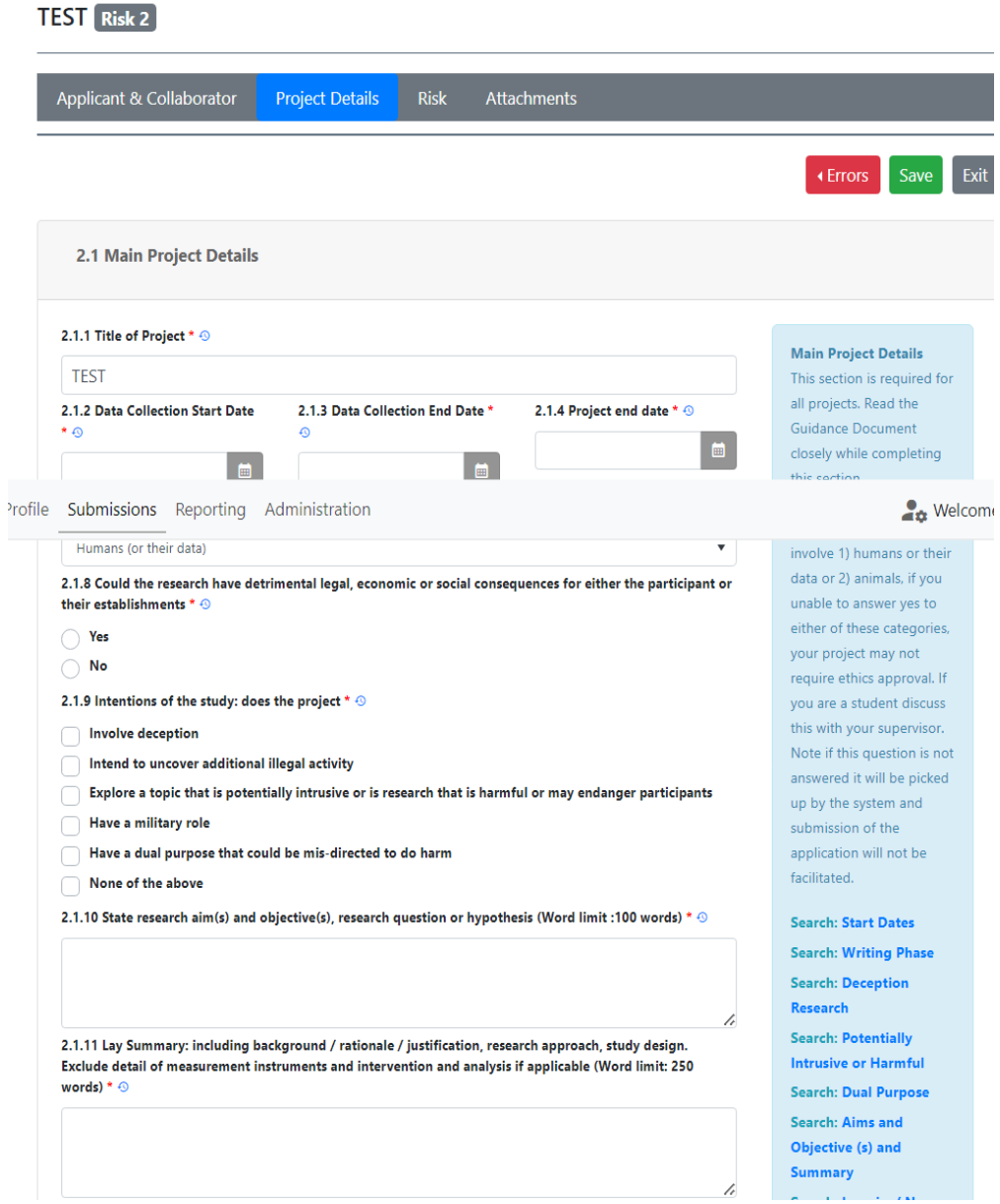
Functionality



Responsiveness

6

5



Possible Sections

Human Particpants & 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? *

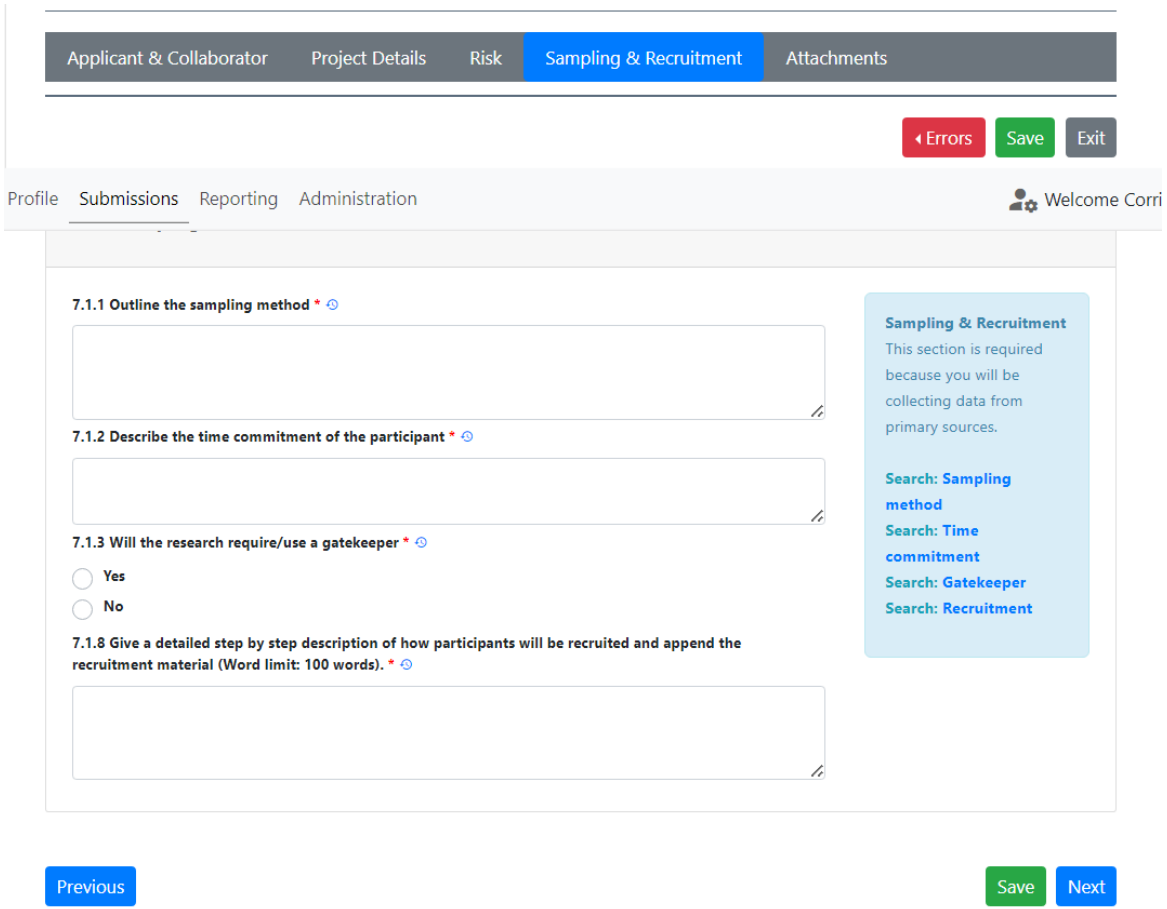
Details on Human Participants & their Data

There are two types of phased research:

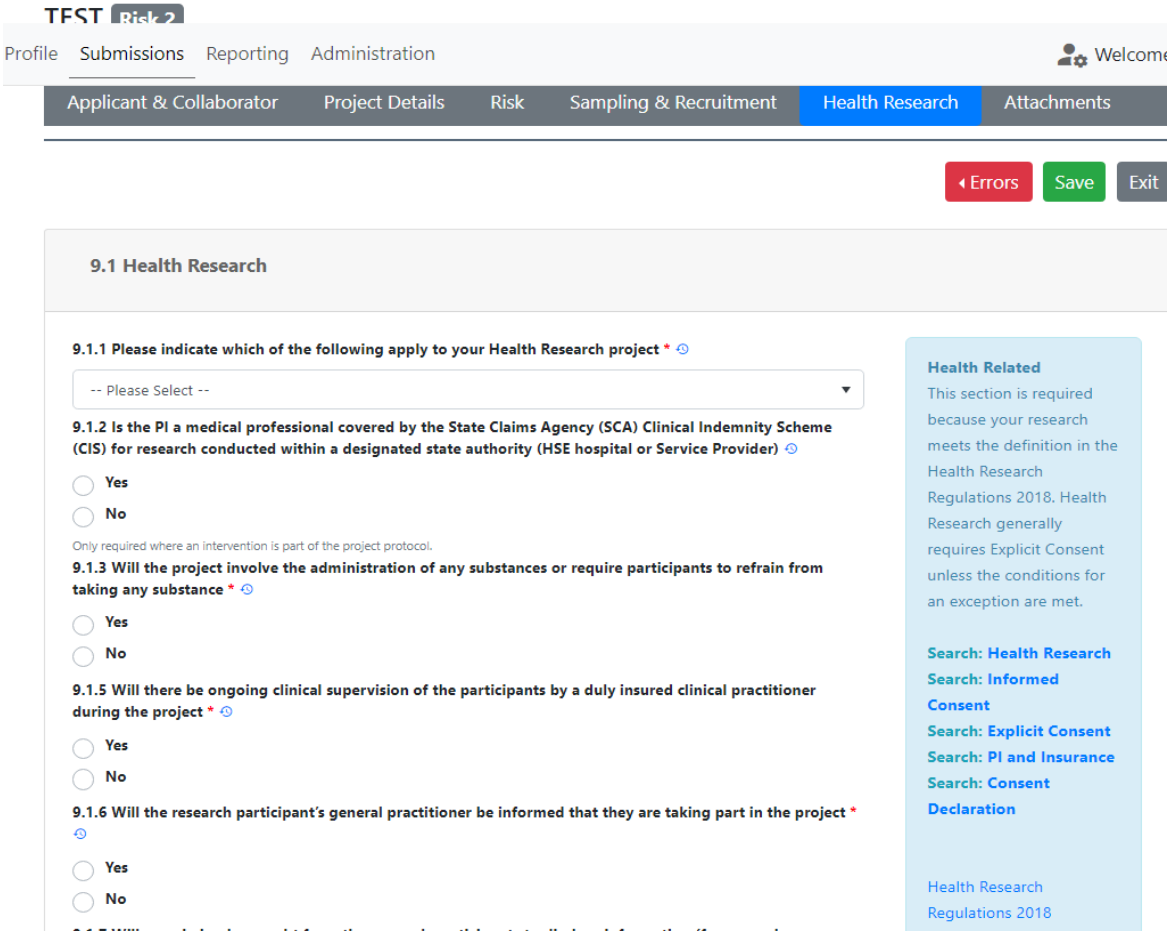
- One involves independent phases ie where one method is independent of the other-one. An application can be submitted if all the methods etc are ready to upload for review.
- The other involves distinct but interdependant phases (eg. phase 1 results in the development of a questionnaire to be used in 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')

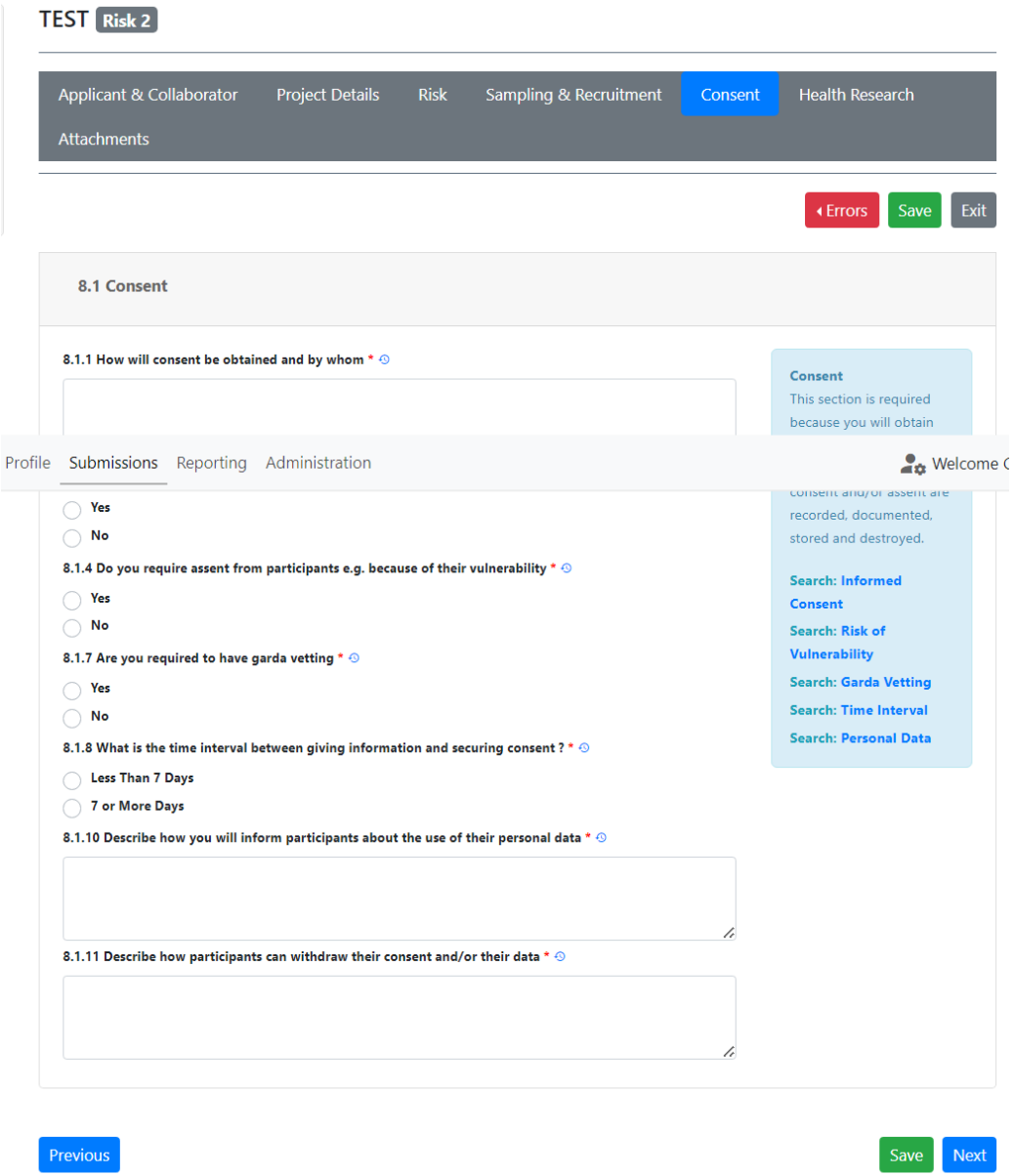
Sampling & Recruitment



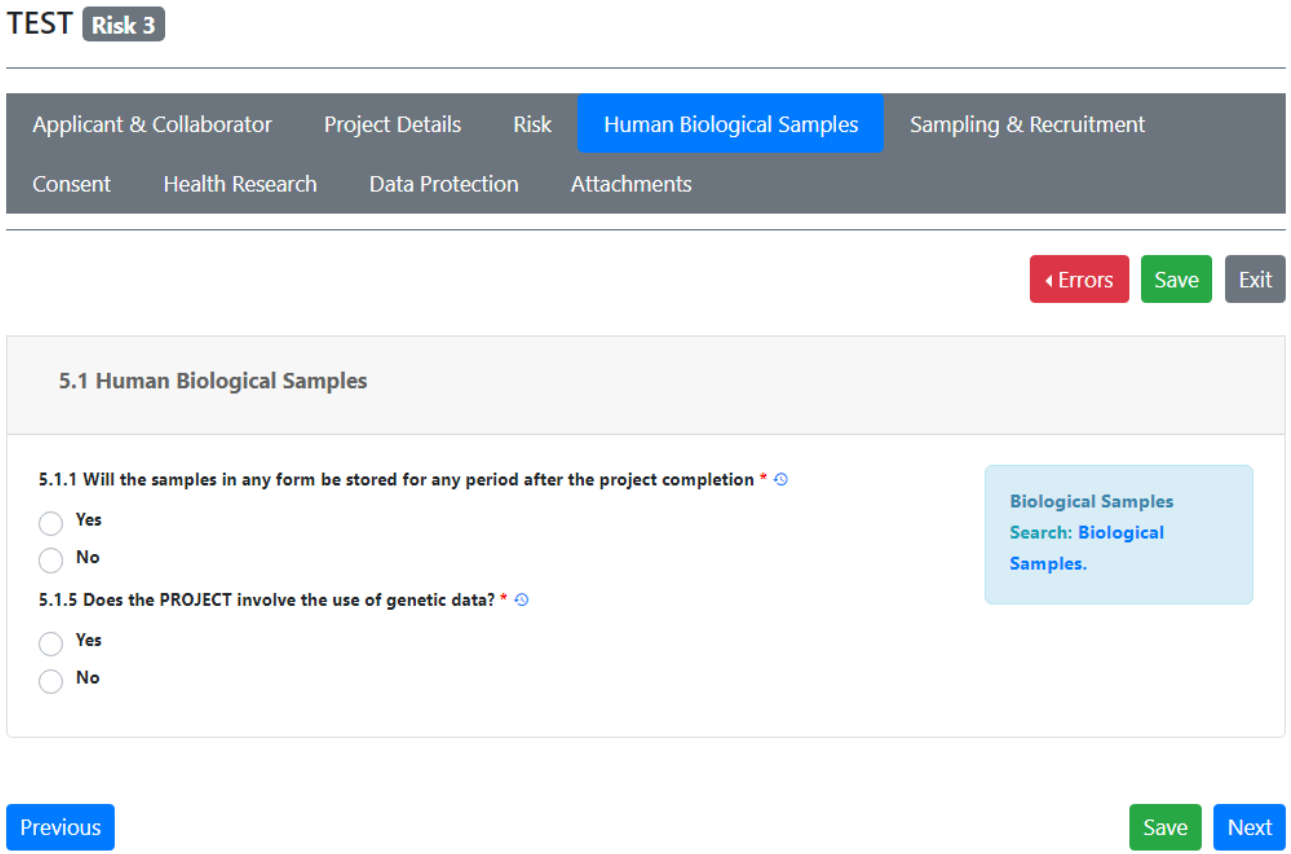
Health Research



Consent

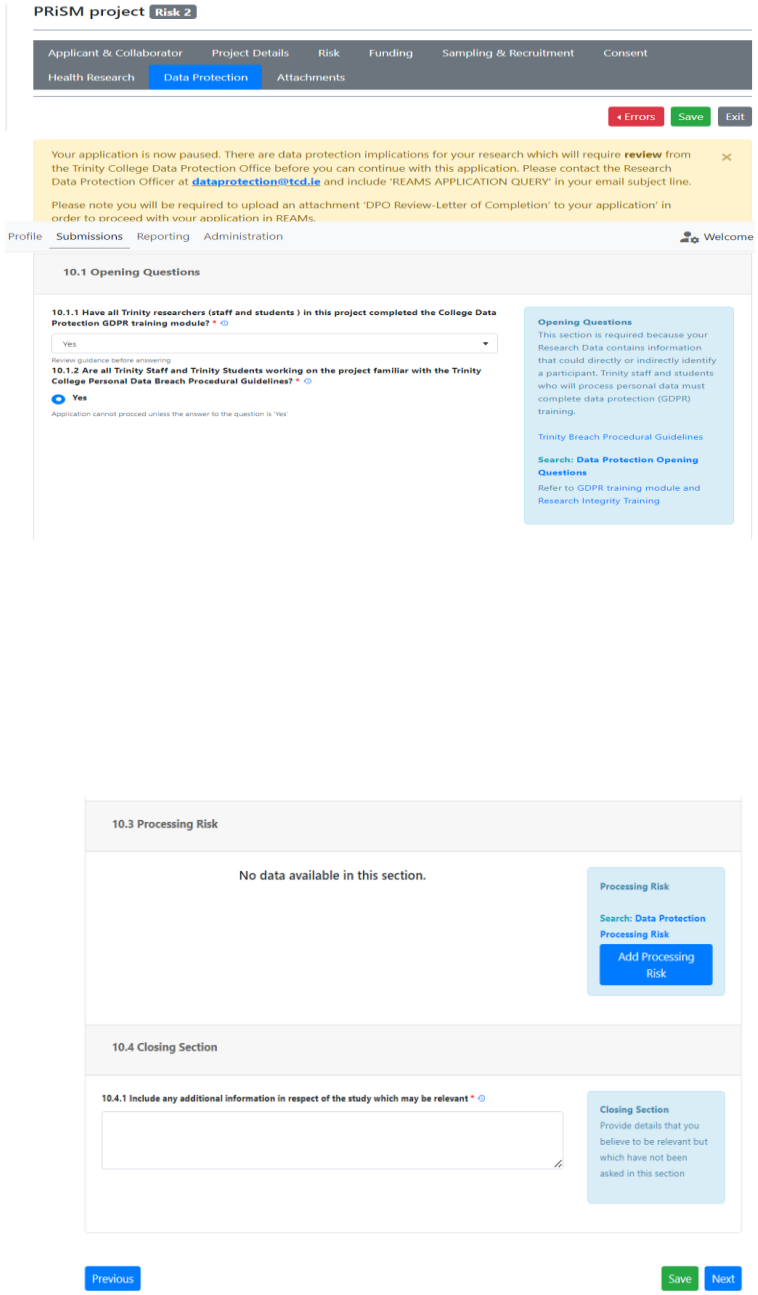

TEST Risk 2
Applicant & Collaborator
Project Details
Risk
Sampling & Recruitment
Consent
Health Research
Attachments
Errors
Save
Exit
8.1 Consent
8.1.1 How will consent be obtained and by whom *
Consent
This section is required because you will obtain
Profile
Submissions
Reporting
Administration
Welcome
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
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 *
Previous
Save
Next

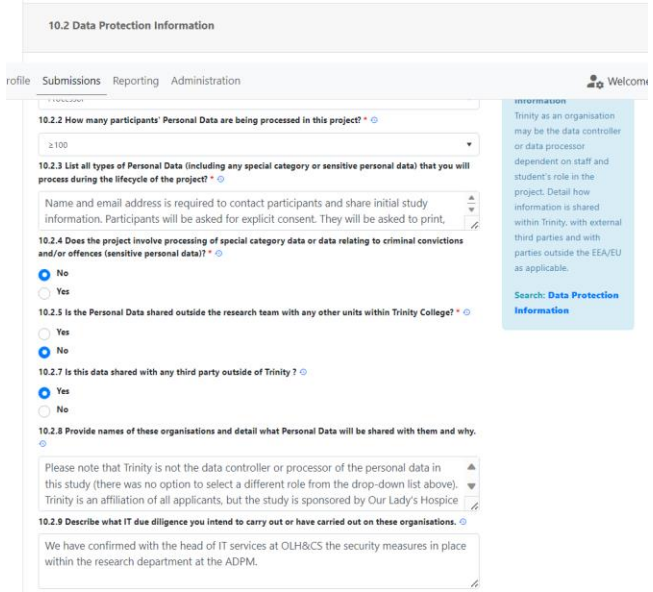
Biological Samples



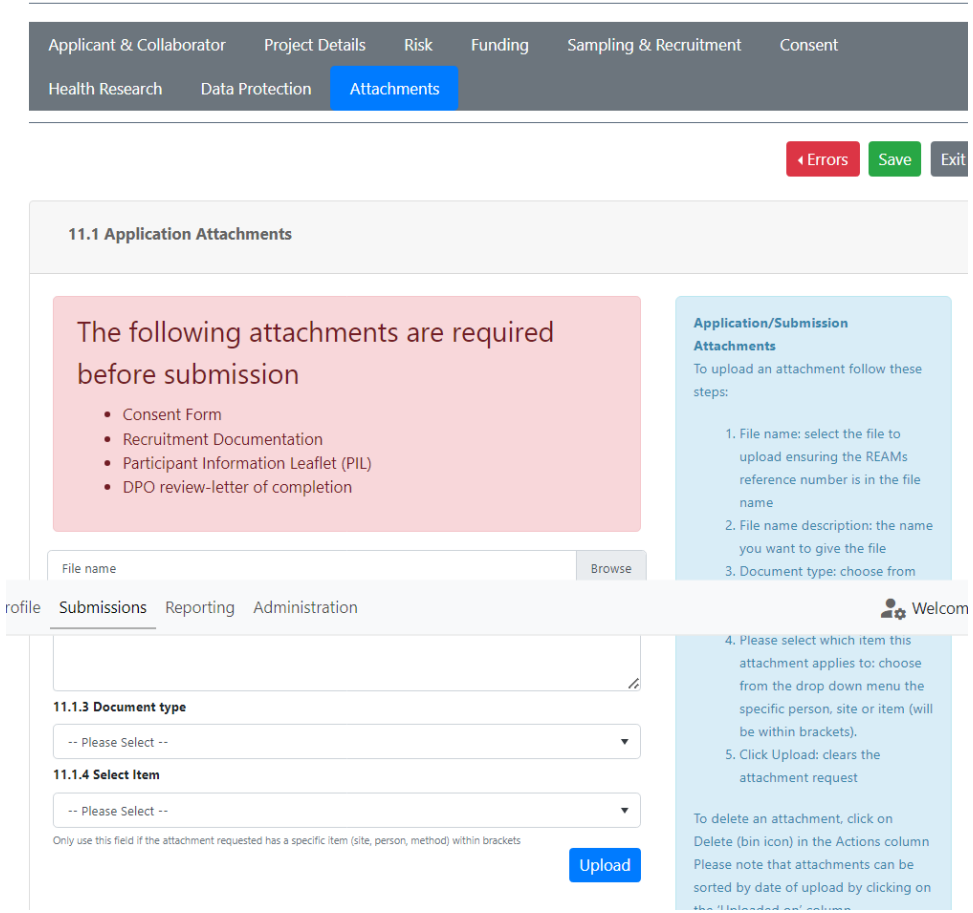
DPO: Data Protection

Data Protection: Tab Opens





Verification



Pre-Approval

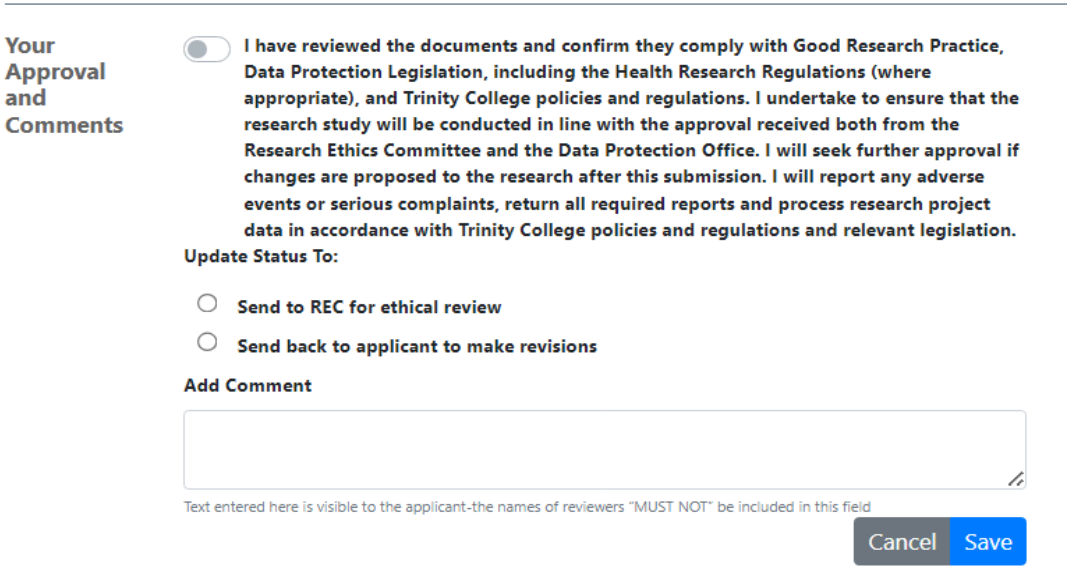
PI / Supervisor

- 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 ie. in draft form
- PI and / or Supervisor must approve an application before it passes to the REC

Supervisor Sign Off

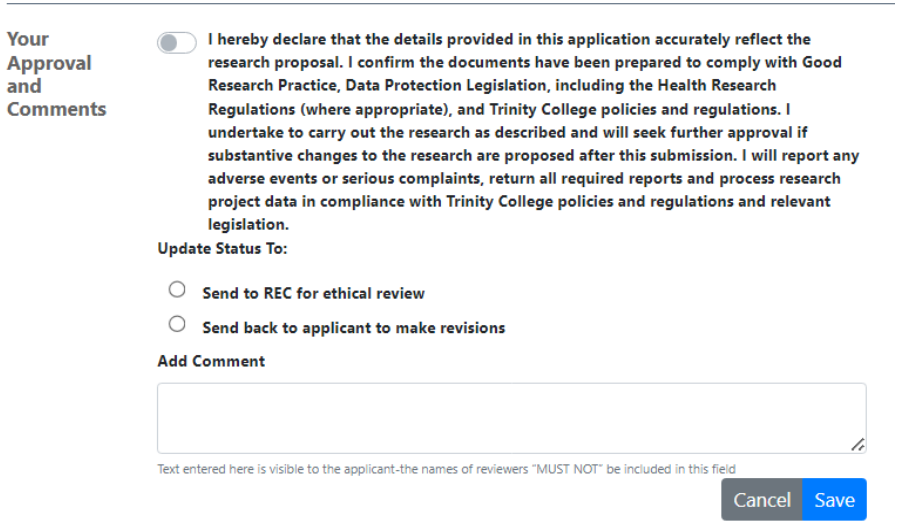
REF#	Title	Risk	REC	Submission Date	Status	Versions
2907	An Exploration of the Experiences of Intensive Care Nurses in the Assessment of Pressure Areas in Patients with Dark Skin Tones HERMINIGILDO LO	2	School of Nursing & Midwifery	22/11/2023	With Primary Supervisor	2

Read & Proceed



PI Sign Off

Read & Proceed



Assigning Reviewers

REC Admin Role

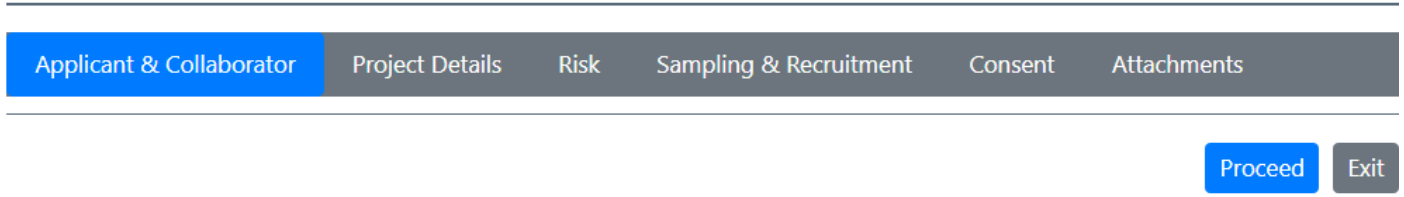
- REC Admin (REAMs role) incorporates REC Secretary & REC Chair (TCD roles)

- REC Admin can:
  - Redirect to a different REC
  - Assign Reviewers
  - Synthesize Reviews
  - Deliver final decision to applicant

- Manual checks
  - Check that REC is accurate
  - Do not assign applicant / PI / supervisor as Reviewer
  - Assign to legal or lay review according to local practice
  - Chair Review

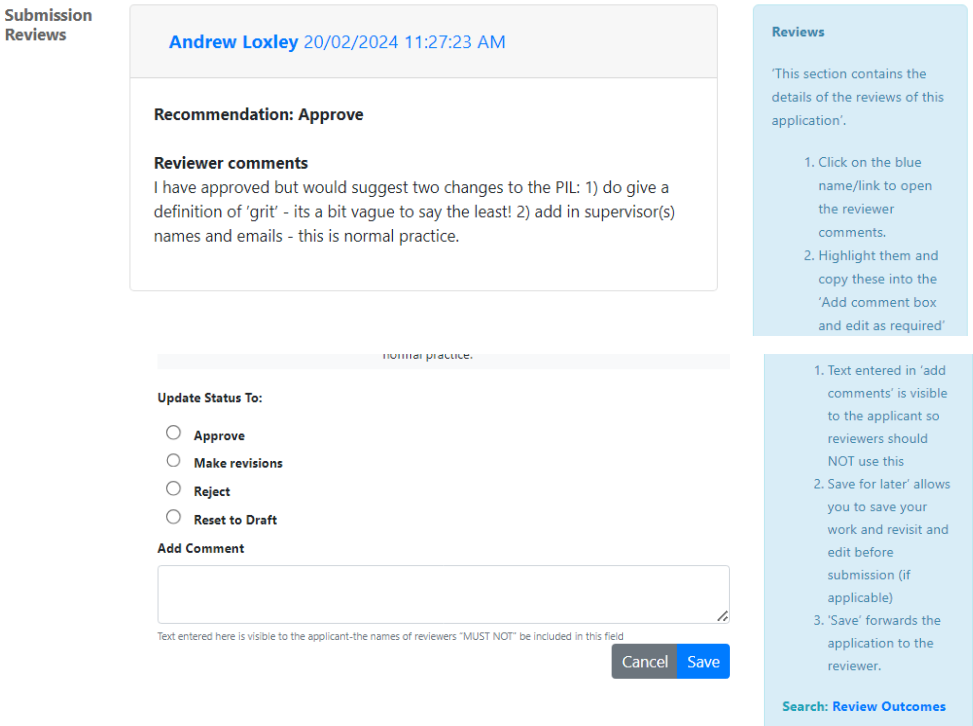
Confirming the Outcome

Read & Proceed



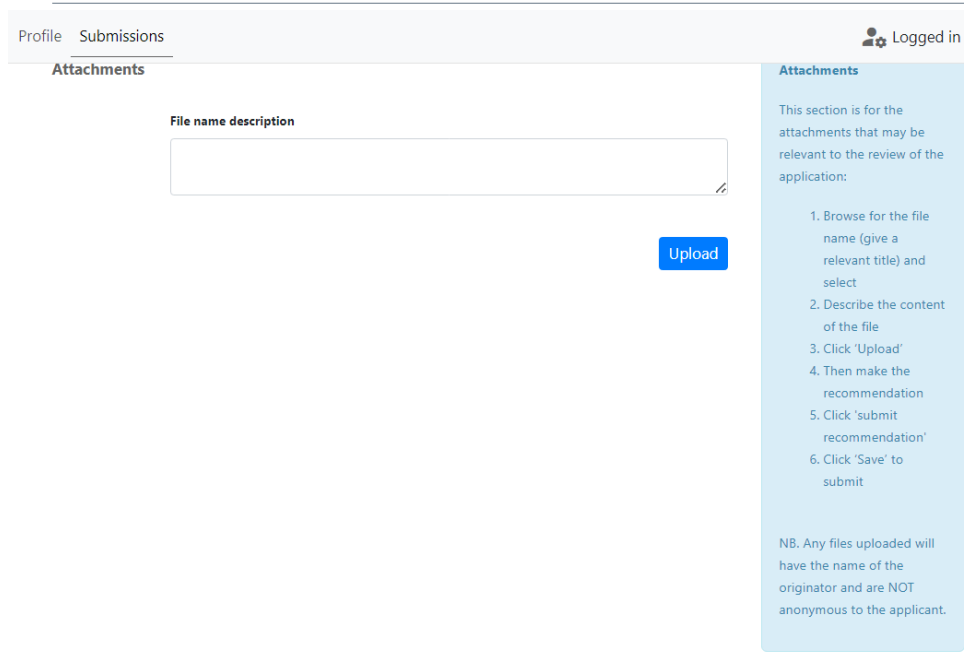
Consolidate Reviews

1.



2&3

4.



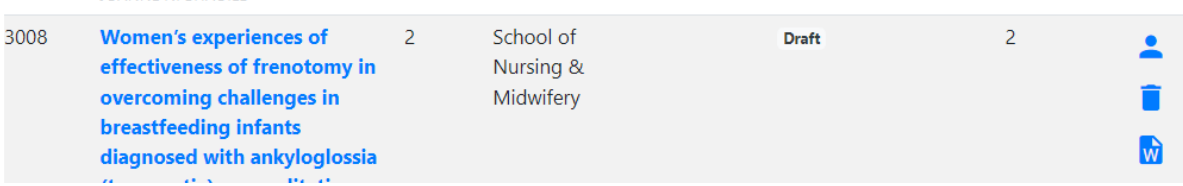
Please note:
-clicking 'make revisions' automatically resets the application to draft so that the applicant can make the revisions
-clicking 'reset to draft' at this stage should be rarely used as it is a short circuit to
eg. enable the applicant to replace a document before the approval process is complete
enable the REC to bypass the reviewer feedback stage if the reviewer was not available/ completed offline

1. Click on blue reviewer
2. Copy and paste into 'add comment' box
3. Update status: click on decision
4. Where applicable upload extra documents

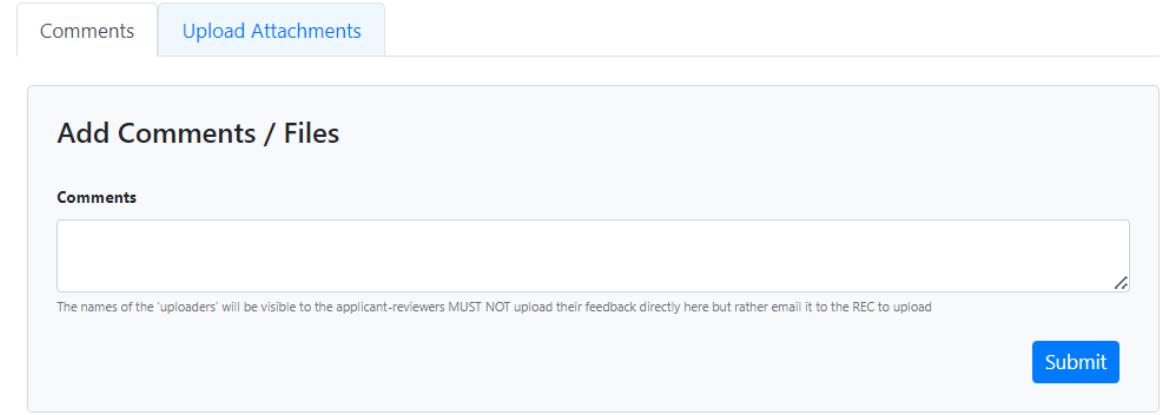
Reconciliation of Reviews

- REC Admin (Chair / Secretary) can see reviews:
  - Recommended outcome
  - Suggested revisions
- Reviewer returns are date stamped and a tick shows its complete:
  - therefore the REC Admin can move the application along.
  - Reviews are requested to be back within 2 weeks
  - All reviews need to be back for REC Admin to reconcile
- REC Admin resolves differences, synthesizes comments, consolidates into a response
- One-stop feedback to the applicant

Screengrab of View: How Applicant sees Feedback



Click person (head and shoulders) icon



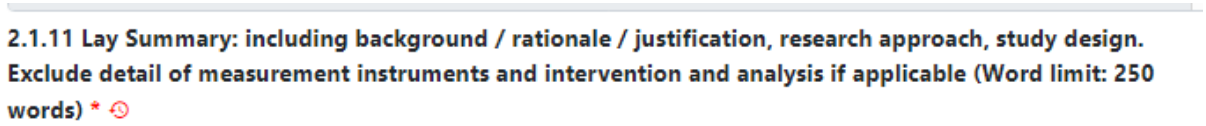
Feedback visible in add comment box
There may be some attachments to view

NB. The person icon should only ever be used in 2 instances:
-for the applicant to see the feedback from you the REC admin (on behalf of the reviewers)
-for the REC Admin to have a quick summary/ audit trail of where the application is in the approval process
-the reviewers should never need to use it

Confirming Revisions

Making Revisions

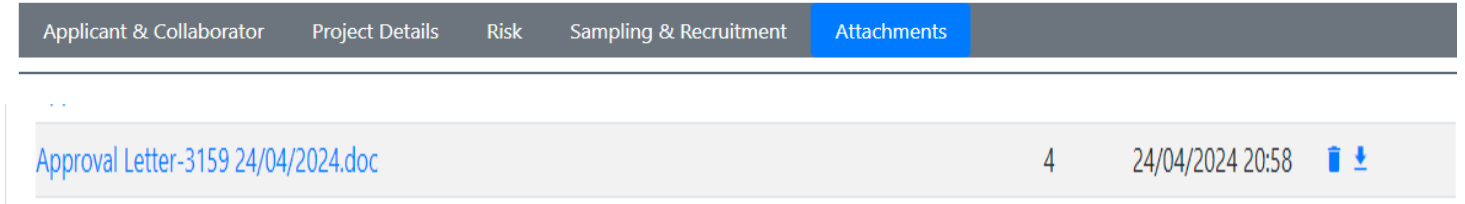
- If revisions are required:
  - Application is set to 'make revisions' and is automatically reset to draft
  - Applicant can make revisions in form
- Revisions are identifiable by a red icon next to the field which shows that it has been changed



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

Approval Letter

- On approval of an application, an automatically generated approval letter lands in the attachment section of the application.
- This letter can be downloaded onto TCD headed notepaper



- Within the letter there is a reminder to the applicant of their responsibilities regarding:
  - GDPR compliance
  - reporting of adverse events with links to the process/form
  - annual and/or end of project reports with links to the form

NB. Should the REC wish to use their own approval letter they can:
-delete the approval letter using the bin icon (to the right-hand side of its listing in the attachment section of the application)
-upload their own approval letter by clicking the person icon and uploading the file which will land in the attachment section

Support Pages:

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