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

25 RECs
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
Projects involving humans, or human data overview

Level 1:
Very Low Risk Project

Level 2:
Low Risk Project
DEFAULT

Level 3:
Moderate and High Risk Projects

Data Protection Review now takes place before Ethics Review

Full Committee Review

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

Participants cannot be identified

Participants are not at risk

Low risk Methods
<table>
<thead>
<tr>
<th>Level 3 Criteria ctd</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1.5 Does the project involve * ◦</td>
</tr>
<tr>
<td>Animals</td>
</tr>
<tr>
<td>2.1.6 Does this Animal Project involve * ◦</td>
</tr>
<tr>
<td>Moderate risk wildlife and ecology projects</td>
</tr>
<tr>
<td>2.1.13 Does the project involve * ◦</td>
</tr>
<tr>
<td>Human biological samples of any size or type that could have impact on future treatment (e.g. human DNA sequencing)</td>
</tr>
<tr>
<td>2.1.13 Does the project involve * ◦</td>
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<tr>
<td>Human biological samples taken in an invasive manner</td>
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<tr>
<td>OR</td>
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<tr>
<td>2.1.13 Does the project involve * ◦</td>
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<td>Human biological samples from patients</td>
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<tr>
<td>OR</td>
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<tr>
<td>8.1.2 Do your participants require support to give consent * ◦</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
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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?

Reviewers:
- No limit on numbers
- All assigned must respond back within system
- External lay/legal reviewers may be assigned

- Student PI
- Student not PI
- Staff not PI
- Staff PI
- Supervisor
- Principal Investigator
- REC Admin
The Submissions Tab

<table>
<thead>
<tr>
<th>REF#</th>
<th>Title</th>
<th>Risk</th>
<th>REC</th>
<th>Submission Date</th>
<th>Status</th>
<th>Versions</th>
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<td></td>
<td>Draft</td>
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<td>Tafamadis utilisation</td>
<td>2</td>
<td></td>
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<td>Draft</td>
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<td>Factors influencing the early development of interest in a clinical</td>
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<td>23/11/2023</td>
<td>Awaiting Recommendation</td>
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<td>3008</td>
<td>Women's experiences of effectiveness of frenotomy (a procedure to</td>
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<td></td>
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<td>Draft</td>
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<td>correct tongue-tie) in overcoming challenges in breastfeeding</td>
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<td>infants diagnosed with ankyloglossia (tongue-tie) – a qualitative</td>
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<td></td>
<td>MARIA LOZANO TORJAY</td>
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Making an Application
Functionality
Possible Sections
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? *
- No
- Yes

Details on Human Participants & their Data

There are two types of phased research:

- One involves independent phases i.e 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 (e.g. 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.
Sampling & Recruitment
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 applicable 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

9.1.4 Will there be ongoing clinical supervision of the participants by a duly licensed clinical practitioner during the project ?

- Yes
- No

9.1.5 Will the research participants' general practitioner be informed that they are taking part in the project ?

- Yes
- No
8.1 Consent

8.1.1 How will consent be obtained and by whom *

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

8.1.5 Are you required to have gende vetting *

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

8.1.9 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 *
Biological Samples

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
DPO: Data Protection
Data Protection: Tab Opens
11.1 Application Attachments

The following attachments are required before submission:
- Consent Form
- Recruitment Documentation
- Participant Information Leaflet (PIL)
- DPO review letter of completion

To upload an attachment, follow these steps:
1. File name: Select the file to upload, ensuring the RA/PC reference number is in the file name.
2. File name description: The name you want to give the file.
3. Document type: Choose from:
   - 11.1.1.1 Document type
   - 11.1.1.2 Select Item

4. Please select which item the attachment applies to: choose from the drop-down menu the specific person, site, or item (will be within brackets).
5. Click 'Upload' and share the attachment.

To delete an attachment, click on 'Delete' (the icon) in the Actions column. Please note that attachments can be sorted by date of upload by clicking on the date column header.
Pre-Approval
• 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  2  School of Nursing & Midwifery  22/11/2023  With Primary Supervisor  2

Read & Proceed

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.

[Options: Cancel, Save]
Understanding NK cell immune function and its potential application in cancer research

Conor de Barra
Assigning Reviewers
• 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
Consolidate Reviews

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

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
• 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
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
• 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’
• 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