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 REC's

25 REC's

25 REC's
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

**Are you processing any personal data for your research project?**
- **No**
- **Yes**

**Are you processing any pseudonymised (coded) data for your research project?**
- **No**
- **Yes**

**Are you processing any personal data for participant recruitment?**
- **No**
- **Yes**

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**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

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

- Yes
- No

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

Will payment be made to research participants? *

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

Written or the following text 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

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.

Does the project include an intervention? *

- □ No
- □ Yes
Logging On

Ethics.tcd.ie

TCD Staff & Students:
TCD Email +
TCD password

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

Vidatum Academic

Office 365

Login

Forgot password?
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?

- Student PI
- Student not PI
- Staff not PI
- Staff PI

Reviewers:
- No limit on numbers
- All assigned must respond back within system
- External lay/legal reviewers may be assigned
The Submissions Tab
Making an Application
1. Click on New Ethics Application

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

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

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

### 2.2.11 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.

**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.

[Link to guidance 'Search phased research']
Sampling & Recruitment

7.1.1 Outline the sampling method

7.1.2 Describe the time commitment of the participant

7.1.3 Will the research require 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.
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 apply 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 qualified 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
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?

8.1.7 Are you required to have garda vetting?

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

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.
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
Verification
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

• PI and / or Supervisor must approve an application before it passes to the REC
<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>
</tr>
</thead>
<tbody>
<tr>
<td>2907</td>
<td>An Exploration of the Experiences of Intensive Care Nurses in the Assessment of Pressure Areas in Patients with Dark Skin Tones</td>
<td>2</td>
<td>School of Nursing &amp; Midwifery</td>
<td>22/11/2023</td>
<td>With Primary Supervisor</td>
<td>2</td>
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</tbody>
</table>

**Supervisor Sign Off**

**Read & Proceed**

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**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.
### Table: Understanding NK cell immune function and its potential application in cancer research

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<th>Versions</th>
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</thead>
<tbody>
<tr>
<td>2937</td>
<td>Understanding NK cell immune function and its potential application in cancer research</td>
<td>3</td>
<td>Faculty of STEM</td>
<td>22/11/2023</td>
<td>With Principal</td>
<td>1</td>
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</tbody>
</table>

**Read & Proceed**
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

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<th>Versions</th>
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</thead>
<tbody>
<tr>
<td>3013</td>
<td>Beekeepers survey about plant protection products</td>
<td>1</td>
<td>School of Natural Sciences</td>
<td>22/11/2023</td>
<td>Awaiting Recommendation</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Application Lands in REC:** action assign out to reviewers

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<th>Submission Date</th>
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<th>Versions</th>
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<tbody>
<tr>
<td>2796</td>
<td>Factors influencing the early development of interest in a clinical academic career</td>
<td>2</td>
<td>School of Medicine</td>
<td>23/11/2023</td>
<td>Awaiting Reviewer Feedback</td>
<td>1</td>
</tr>
</tbody>
</table>

- **Application out with reviewers:** action reviewers must complete

<table>
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<th>Submission Date</th>
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<th>Versions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2833</td>
<td>Provision of a Qualitative Study on Urban Speeding</td>
<td>2</td>
<td>School of Psychology</td>
<td>20/11/2023</td>
<td>Awaiting Approval</td>
<td>3</td>
</tr>
</tbody>
</table>

- **Feedback given to applicant:** approve, reject, make revisions
Click person (head and shoulders) icon

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

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