# REAMs

Making An Application

Training



## 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 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



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

Ethics		New Ethics Ap	plication
	Search:		
	sion 1	↑↓	tt tt
<sup>nissi</sup> New Ethics Review	×	Versions	
		1	Î
Not all research on humans and/or their data or animals requires ethical approval. Check if your research requires eth approval by referring to this set of criteria here.	hical		<b>1</b>
Please note that your application may require assessment from the College Data Protection Office. This could result i	in an		
commencing your application		1	
I confirm that I have checked the relevant criteria and reviewed the new data protection process		1	
		I	Î

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

#### EITHER

Are you processing any personal data for your research project? \* ①
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? \* ①
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?

#### O No



i.e. contact details, consent forms

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

#### Participants cannot be identified

# Level 1 Conditions

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

O No

#### Low risk Methods

#### EITHER



# Level 3 Criteria

Does the project include an intervention? \*



#### 2.1.5 Does the project involve \* 🕙

Animals

#### 2.1.6 Does this Animal Project involve \* 🕙

Moderate risk wildlife and ecology projects



#### 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)



#### 2.1.13 Does the project involve \* 🕙

		•
OR		
.13 Does the project involve * 📀		

OR

## Level 3 Criteria ctd

8.1.2 Do your participants require support to give consent \* 🕙

v

v

Ŧ



No

# Logging On

#### Ethics.tcd.ie



Trinity

#### **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 <u>dataprotection@tcd.ie</u> 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

		Corrine Personne Address: Office of t	1 <b>a Moore</b> I No: 22201297 he Dean of Resea	arch				Username		▼ Submit	
								System No	tifications	Ê	
Notific	ations a	and Tasks					Ê	REAMS V2 Go-L	ive	0	
Notifica	ations 224	Tasks 1		Search:							Notificatior
Ref 1	l îl PI	n. Title	Approval Step / Role	Notification	n Date	link	î↓	No	tifications ar	nd Tasks	
n	C 11	Involving key	Ethics Rec	Hello,	21/11/2023 11:50	٥		N	otifications 224	Tasks 1	

Ê

ti Actions ti

# The Submissions Tab

% Ethics Review	Ethic	S				Ne	w Ethics Application	
						Search:		
<ul> <li>Awaiting Review</li> </ul>	↑. REF#	↓ ↑ Title	ມ ∩ມ Risk	t. REC	L Submission ↑↓ Date	1↓ Status	t î↓ î↓ Versions	
<ul> <li>Administer Submissions</li> </ul>	2966	Students' Perception of the Use of Virtual Reality for Anatomy	3	Faculty of Health		Draft	1	
Vidatum Academic TCD4.0.2.0 Home P	rofile Subr	nissions Reporting Administratio	on				argent Welcome	Corrinna Mo
<ul><li>Approved</li><li>Draft</li><li>Pending Approval</li></ul>	3014	Tafamadis utilisation ROSEALEEN BARRETT	2	School of Medicine		Draft	1 💼	
Rejected Filter by Applicant	2796	Factors influencing the early development of interest in a clinical academic career	2	School of Medicine	23/11/2023	Awaiting Recommendation	1 🚨 🔂	
Filter by REC Please Select ▼ Filter by Keyword Submit	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	

# Making an Application

#### TEST Risk 2



### Functionality

### Responsiveness

	Applicant & Collaborator	Project Details	Risk Att	achments		
_						
	2.1 Main Project Details					
	2.1.1 Title of Project * 0					
					M	lain Project Detail
	TEST				Th	his section is require
	2.1.2 Data Collection Start Date	2.1.3 Data Collect	tion End Date *	2.1.4 Project end date * 🕚	G	uidance Document
		•	_		iii cle	osely while comple
					th	is section
ofilo	Submissions Reporting	Administration				
onie	Submissions Reporting	anniseration				
Ionie	Humans (or their data)				▼ in	volve 1) humans of
one	Humans (or their data) 2.1.8 Could the research have det	rimental legal, econon	nic or social conse	quences for either the participa	▼ in ht or da	volve 1) humans of ata or 2) animals, if
Ione	Humans (or their data) 2.1.8 Could the research have det their establishments * ()	rimental legal, econor	nic or social conse	quences for either the participa	▼ in at or da	volve 1) humans or ata or 2) animals, if nable to answer yes
	Humans (or their data) 2.1.8 Could the research have det their establishments * 0 Yes	rimental legal, econon	nic or social conse	quences for either the participa	in it or ur ei	volve 1) humans of ata or 2) animals, if nable to answer yes ther of these categ
	Humans (or their data) 2.1.8 Could the research have det their establishments * 0 Yes No	rimental legal, econor	nic or social conse	quences for either the participa	▼ in nt or da ur ei yc	volve 1) humans o ata or 2) animals, if hable to answer ye ther of these categ our project may no quire ethics approv
	Humans (or their data) 2.1.8 Could the research have det their establishments * Yes No 2.1.9 Intentions of the study: doe	rimental legal, econor	nic or social conse	quences for either the participa	<ul> <li>in</li> <li>in</li> <li>it or</li> <li>ur</li> <li>ei</li> <li>yc</li> <li>re</li> <li>yc</li> </ul>	volve 1) humans or ata or 2) animals, if nable to answer yes ther of these categ our project may no quire ethics appro- pu are a student dis
	Humans (or their data) 2.1.8 Could the research have det their establishments * Yes No 2.1.9 Intentions of the study: doe	rimental legal, econon	nic or social conse	quences for either the participa	▼ in tt or da ur ei yc re yc th	volve 1) humans or ata or 2) animals, if hable to answer yes ther of these categ our project may no quire ethics appro- ou are a student dii is with your superv
	Humans (or their data) 2.1.8 Could the research have det their establishments * ③ Yes No 2.1.9 Intentions of the study: doe Involve deception Intend to uncover additional	rimental legal, econom s the project * ۞	nic or social conse	quences for either the participa	▼ in it or ei yc re yc th N	volve 1) humans or ata or 2) animals, if nable to answer yes ther of these categ our project may not quire ethics approv ou are a student dis is with your superv ote if this question
	Humans (or their data)       2.1.8 Could the research have det their establishments * ③       Yes       No       2.1.9 Intentions of the study: doe       Involve deception       Intend to uncover additional       Explore a tonic that is not on	rimental legal, econon s the project * illegal activity	nic or social conse	quences for either the participar	v in it or or it or or or or or or or or or or	volve 1) humans or ata or 2) animals, if aable to answer yes ther of these categ pur project may not quire ethics approv ou are a student dis is with your superv ote if this question aswered it will be p
	Humans (or their data)       2.1.8 Could the research have det their establishments * ③       Yes       No       2.1.9 Intentions of the study: doe       Involve deception       Intend to uncover additional       Explore a topic that is potent	rimental legal, econon s the project * ③ illegal activity ially intrusive or is res	nic or social conse earch that is harm	quences for either the participar ful or may endanger participant	▼ in it or it or vyc vyc vyc th Ni s up	volve 1) humans or ata or 2) animals, if hable to answer yes ther of these categ pur project may not quire ethics approv bu are a student dis is with your superv ote if this question how read it will be p o by the system an
	Humans (or their data)         2.1.8 Could the research have det         their establishments * ③         Yes         No         2.1.9 Intentions of the study: doe         Involve deception         Intend to uncover additional         Explore a topic that is potent         Have a military role	rimental legal, econom s the project * ③ illegal activity ially intrusive or is res	nic or social conse earch that is harm	quences for either the participar ful or may endanger participant	<ul> <li>in in in it or</li> <li>in it or</li> <li>in</li></ul>	volve 1) humans or ata or 2) animals, if nable to answer yes ther of these categ pur project may not quire ethics approv ou are a student dis is with your superv ote if this question iswered it will be p o by the system and ubmission of the
	Humans (or their data) 2.1.8 Could the research have det their establishments * ③ Yes No 2.1.9 Intentions of the study: doe Involve deception Intend to uncover additional Explore a topic that is potent Have a military role Have a dual purpose that cou	rimental legal, econom s the project * ۞ illegal activity ially intrusive or is resulted be mis-directed to o	nic or social conse earch that is harm do harm	quences for either the participar ful or may endanger participant	▼ in it or dia ur ei yyc re yyc th Ni ar s uu su su	volve 1) humans or ata or 2) animals, if hable to answer yes ther of these categ pur project may not quire ethics approv bu are a student dis is with your superv ote if this question howered it will be p to by the system and hom sistion of the oplication will not b
	Humans (or their data)         2.1.8 Could the research have det         their establishments * ③         Yes         No         2.1.9 Intentions of the study: doe         Involve deception         Intend to uncover additional         Explore a topic that is potent         Have a military role         Have a dual purpose that com         None of the above	rimental legal, econom s the project * () illegal activity tially intrusive or is resulted to a	nic or social conse earch that is harm do harm	quences for either the participar	▼ in ttor da ur ei yc yc yc th N· ar s ur su af fa	volve 1) humans or ata or 2) animals, if hable to answer yes ther of these categ our project may not quire ethics approv ou are a student dis is with your superv ote if this question uswered it will be p to by the system and ubmission of the oplication will not b cilitated.
	Humans (or their data)     L1.8 Could the research have det their establishments * ③  Yes  No  L1.9 Intentions of the study: doe Involve deception Intend to uncover additional Explore a topic that is potent Have a military role Have a dual purpose that cor None of the above  L1.10 State research aim(s) and co	rimental legal, econom s the project * () illegal activity tially intrusive or is result uld be mis-directed to a bijective(s), research q	aic or social conse earch that is harm do harm uestion or hypoth	quences for either the participan ful or may endanger participant esis (Word limit :100 words) * @	▼ in ttor dia ur yc yc yc th N· s up su ap fa	volve 1) humans or ata or 2) animals, if hable to answer yes ther of these categ our project may not quire ethics approv ou are a student dis is with your superv ote if this question howered it will be p to by the system and homission of the opplication will not b cilitated.
	Humans (or their data)  2.1.8 Could the research have det their establishments * ③  Yes  No  2.1.9 Intentions of the study: doe Involve deception Intend to uncover additional Explore a topic that is potent Have a military role Have a dual purpose that cor None of the above 2.1.10 State research aim(s) and co	rimental legal, econom s the project * () illegal activity tially intrusive or is result uld be mis-directed to () bijective(s), research q	nic or social conse earch that is harm do harm uestion or hypoth	quences for either the participan ful or may endanger participant esis (Word limit :100 words) * @	▼ in ttor dia ur yc re yc th N· s ur su ar fa Ste Ste	volve 1) humans o ata or 2) animals, if hable to answer ye ther of these categ our project may no quire ethics appro- ou are a student di- is with your super- ote if this question swered it will be p o by the system an abmission of the oplication will not to cilitated. earch: Start Dates earch: Writing Phi-

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) \* 🕙

Save Exit

🎝 Welcom

g Phase tion Research Search: Potentially Intrusive or Harmful Search: Dual Purpose Search: Aims and Objective (s) and

Summary 

1.

5

6

# **Possible Sections**

### Human Particpants & their Data

2.2 Deta	ils on	Human	Partic	ipants	and	their	Dat	i
----------	--------	-------	--------	--------	-----	-------	-----	---

#### 2.2.1 Is your study a phased study \* 👀

O 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. \* ①

O No

O Yes

2.2.8 Is the Project Health Research? \* 🕙

O No

O Yes

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

O No

O 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? \* ③ 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

e Submissions Reporting	Administration				🛵 Welcon
7110-45	at a d * O				
7.1.2 Describe the time comm	itment of the participant	* 😔		1.	Sampling & Recruitment This section is required because you will be collecting data from primary sources.
7.1.3 Will the research require	/use a gatekeeper * 📀			li	Search: Sampling method Search: Time commitment Search: Gatekeeper
No 7.1.8 Give a detailed step by s	tep description of how pa mit: 100 words). * 👀	articipants v	vill be recruited and append	the	Search: Recruitment

Previou



### Health Research



### Consent



## Biological Samples

TEST	Risk 3
------	--------

Applicant &	Collaborator	Project Details	Risk	Human Biological Samples	Sampling & Recruitment
Consent	Health Resear	ch Data Protec	tion /	Attachments	
					Errors     Save
5.1 Hum	an Biological S	amples			
5.1.1 Will the	samples in any fo	rm be stored for any pe	riod after t	he project completion * 🕙	Piele sizel Complex
Yes					Search: Biological
No No					Samples.
5.1.5 Does th	e PROJECT involve	the use of genetic data	i? * 🕙		
Yes					

Previous



# **DPO:** Data Protection

#### PRiSM project Risk 2



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

#### Search: Data Protection Opening Questions

Refer to GDPR training module an Research Integrity Training

10.2 Data Protection Information

rofile Submissions Reporting Administration

process during the lifecycle of the project? \* 💿

and/or offences (sensitive personal data)?\*

10.2.7 Is this data shared with any third party outside of Trinity ? 💿

10.2.2 How many participants' Personal Data are being processed in this project? \* O

10.2.3 List all types of Personal Data (including any special category or sensitive personal data) that you will

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,

10.2.4 Does the project involve processing of special category data or data relating to criminal convictions

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

A Welcome

or data processor

information is shared

1

within Trinity, with externa

Search: Data Protection

Information

### Data Protection: Tab Opens

	No data available in this section.	Processing Risk
		Search: Data Protection Processing Risk Add Processing Risk
0.4 Closing Section		
4.1 Include any additiona	) information in respect of the study which may be relevant " $\odot$	Closing Section Provide details that you believe to be relevant but



≥100

O No Yes

Yes O No

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

10.2.9 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.



## Verification

Applicant & Collaborator Project Details Risk Funding Health Research Data Protection <mark>Attachments</mark>	Sampling &	Recruitment	Consent
11.1 Application Attachments			<pre> • Errors Save Ex </pre>
The following attachments are required before submission • Consent Form • Recruitment Documentation • Participant Information Leaflet (PIL) • DPO review-letter of completion		Application Attachmen To upload a steps: 1. File: uplo refer nam 2. File:	/Submission ts n attachment follow these name: select the file to ad ensuring the REAMs rence number is in the file e name description: the name want to nive the file
File name	Browse	3. Doc	ument type: choose from
11.1.3 Document type Please Select		4. Plea atta from spec be w 5. Click	were were the select which item this chment applies to: choose to the drop down menu the fife person, site or item (will vithin brackets).
1.1.1.4 Select Item     Please Select Only use this field if the attachment requested has a specific item (site, person, method) within brackets	▼ Upload	attad To delete an Delete (bin Please note sorted by da	chment request a attachment, click on iccon) in the Actions column that attachments can be ate of upload by clicking on



## 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

↑↓ PEE#	n. Title	l î↓ Pick	î↓ REC	Submission 1	t↓ Status	î↓ Versions		î↓
IXEI #	The	NISK	REC	Date	Status	VEISIONS		
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	•	Ŵ

#### Read & Proceed

Applicant & Collaborator	Project Det	ails Risk	Human Biological Samples	Funding
Sampling & Recruitment	Consent	Health Resear	ch Data Protection A	ttachments



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

O 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



- 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

# 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





#### Consolidate Reviews



#### 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



#### Click person (head and shoulders) icon

Comments	Upload Attachments	
Add Co	nments / 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	
		Culum

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

Screengrab of

View:

How Applicant

sees Feedback

# **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

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) \*  $\odot$ 

• 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

Applicant & Collaborator	Project Details	Risk	Sampling & Recruitment	Attachments			
Approval Letter-3159 24/04/2024.doc					4	24/04/2024 20:58	i ±

- 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