REAMs Frequently Asked Questions: For The Applicant

Making an Application: FAQ	
What are the key features of the platform?	REAMs is a web-based platform that allows you to submit an application for ethical review directly to the most appropriate Research Ethics Committee. It uses a combination of yes/no questions, drop down menus and text boxes to complete an application. All sections presented must be completed. Additional sections may be presented depending on responses in the 'Project Details' section. -Blue buttons are active: e.g. New Ethics Application starts a new application -'Save' each section before moving to the 'Next' or work will be lost -A Red asterix means that an entry in the field is required Some text fields have word limits. Be sure to look for these. The ERRORs button will reveal any sections that are incomplete and indicate if attachments are still required. When all ERRORs are addressed a blue SUBMIT button appears. You cannot submit an application until all errors are resolved. New applications and amendments to current applications are selected for. The Submissions tab shows all your applications with their unique reference number and status ie where in the process they are. You can download applications in word form.
How does the platform work?	It's a responsive system that expands in response to answers you give to key questions thereby only revealing information specific to your application -questions appear/disappear (drop down) -section/tabs appear/disappear (across top) The platform: -looks at coded info, checks boxes but can't read any free text

	-checks if application is complete and forwards it to the relevant REC based on your School and the automatically determined level of risk
What are the major differences between REAMs and the current system?	There are now **3 risk levels** (level 1-3) and the appropriate level of review is automatically determined by the application. **Data Protection Approval is NOT integrated in the platform:** -any 1 of 6 trigger questions signifies that Data Protection Review is necessary -the applicant is directed to contact the DPO who will oversee a review and offer a letter of completion at the end of the DP process. -the applicant uploads this letter against an attachment call request within REAMs-then and only then can the application proceed to the REC for ethics approval
How do I know the status of my application?	Email notifications are sent out from the noreply@academic.ie to confirm when your application is submitted and when a decision has been made by the REC. A record of emails sent is available in the 'Notifications' pane on your REAMs homepage. The 'Submissions' tab shows the status of the application eg. awaiting review. The person icon on the 'Submissions' tab: -opens up an audit trail of completed steps and -give access to any comments returned from the REC
There are Errors. What does this mean?	You will have errors if you have not completed all required fields or have not uploaded all required attachments. To identify fields you have missed open a section, press save and incomplete fields will appear as outlined in red. The platform will not let you submit until the errors are all addressed. Tips: Clicking on each error doesn't take you back to where in the application so address these

	before you move on to each page/section to prevent them building up as you go.
What are the attachments and why do I have to do them?	The Attachments are like the Appendices: REAMS makes a running list of required appendices relevant to your specific application. You cannot submit an application unless all required attachments have been uploaded To upload attachments: > open the Attachments tab > browse to find the relevant file on your computer, > identify the attachment type (e.g. Recruitment Information or External Ethics) from the alphabetical drop down list under <u>document type</u> >Link to a specific method or site or name from the seconds drop down list (if required) <u>under specific item</u> > press 'UPLOAD' > Repeat for each required attachment Tips -upload each attachment as you go-ideally before you leave a section so that they don't build up - you only need those attachments that the system prompts -generic (alphabetical) menu list under document type and specific item (to named person/site) -make sure to save them with a reference to the application name/unique reference number of the application. -any extra attachments you wish to upload can be done so by selecting '<u>other documentation</u>' from the drop down menu under 'document type'
Is there any help available?	There is Help Text in a blue shaded box in every section of application that has some high level hints and links to templates, and to the accompanying Guidance Document The Guidance Document is very comprehensive but is searchable. Use the suggested search terms in the Help Text to find relevant information quickly.

	Applicant support is available on our website [here](#). There is a dedicated System Administrator available to help with all queries who can be contacted by emailing: Office.Team.Res@tcd.ie
How do I Log-in?	1. <u>TCD Academic Staff/Students</u> are automatically registered on REAMs: Go to https://www.ethics.tcd.ie Select Office 365 Enter TCD Email when prompted (not user name) Enter TCD password when prompted 2. <u>TCD Professional staff, Visiting Academics/Students, non-TCD collaborators</u> must be pre-registered manually by the REAMs administrator by emailing Office.Dean.Res@tcd.ie Go to https://www.ethics.tcd.ie Ignore Office 365 rather Click on the cursor Enter your email when prompted Click on the forgot password and follow the prompts.
Is it possible to log-in via a group email?	No -it has to be an individual email address due to how the authentication works at log-in -can still keep the general email but need to log in as self
Can I change my personal details?	You can customise your profile in REAMS, for example by adding a picture. If the auto-populated information about you is incorrect it means that your staff or student record is inaccurate. -to correct your staff record contact HR. -to correct a student record contact Academic Registry
Can I see an application form in totality?	Upfront overview of sections is not possible: -REAMs is not a mirror of old SAF -questions turn off/on sections to make it more appropriate to application -generates the form -no separate (eg. SAF) form required

	Rather answers to certain questions turns off/on 11 sections (across bar at top) eg. -human/animal -funding/risk -consent/ health -data protection
What if I have external ethical approval already eg do I still need to complete an application in REAMs?	Yes. You can indicate that you have ethical approval from another committee and will be asked to upload the approval as an attachment.
Where do I get the data protection application form?	If your application triggers a requirement for a data protection review, a pop-up will appear alerting you to this and advising you to contact the data protection office. The DPO will then oversee a review of your application (including any DPRA/DPIA) and on completion you will get a letter to upload against an attachment call request on REAMs. NB. If you have been required to complete a DPIA for another research site you can uploaded this as an attachment.
Where do I get my consent forms?	There are two different consent forms you may be asked to develop: -informed consent -explicit consent for health research Links to templates for each can be found in the blue shaded help text and in the Guidance Document
Is there a particular PIL to use?	There are 3 possible templates for the PIL. - PIL for a Health related project where personal data is being processed - PIL for any other project where personal data is being processed - PIL for research where personal data is NOT being processed
What do I choose-I am staff and a student?	This depends on your role in the research. If you are a student and the project is for academic credit you are applying as student and your role is as PI If you are a student but applying as a research assistant on behalf of a postdoc or professor you are applying as staff and your role is non-PI

	: eg research for a PhD should be 'student' even if teaching on the side ie. 'staff' -post doc: staff -research assistant: staff
Why does the system need to capture employer details?	This informs the REC if applicants have other affiliations relevant to the application eg: -staff with a hospital position, or -part-time students in professional employment
Why do collaborators need to be recorded?	This gives the REC information about the other members of the Research Team Students add their academic supervisor as a TCD collaborator. Non-PI applicants add the PI as a TCD Collaborator Any TCD collaborator can coedit the application in draft form and also non-TCD collaborators (they have to be pre-registered on system) can have full read access to the application. The only collaborators required to sign the application are the PI or supervisor
Do I still apply directly to the REC at Faculty or School Level?	No REAMs determines the most appropriate REC to review your application using information about your School and the risk level. You do not have to identify the REC before starting an application.
What if I click on the wrong school?	If you click on the wrong school it will automatically direct to that REC -the REAMs can reset it for you OR -you can contact the REC and ask them to override the committee to the correct one:this resets the application to draft and you have to resubmit.
Do I have to complete training (research integrity, GDPR) in advance of a REAMs application? Eg. GDPR .	The REAMs platform is neutral: -it doesn't force obligations on applicants -it doesn't present a barrier or police the applicant -it trusts that the applicant will do what is required to prepare for the research.

	If say 'yes' system will require certs as proof in the attachment list and so the application cannot proceed until this is done. If say 'no' there is no requirement for an attachment and the application can be submitted. Reports will show the extent of the issue ie. number of submissions without training completed.
Who officially signs off the application?	Applicants sign off as the last step before submission -If the applicant is a Student the Supervisor will be asked to sign-off: -If the applicant is not the PI, the PI will be asked to signoff Only one digital signature is required in REAMs rather than all researchers/collaborators in a team All sign-offs are recorded digitally on the REAMs platform.
Can colleagues collaborate to help complete my application?	In draft form, before submission, it is possible to allow collaboration on a document by team members including the PI/supervisor NB. It is possible even if collaborators are outside TCD although they can read only. NB. Take care not to override editing-best to do offline and then cut and paste into the application.
What's the difference in the definitions of risk in the: -Risk section/tab -data risk in the data protection (DP) section/tab -Risk Level of the application	Risk tab/section is about the risk a project poses to each of: -the researcher(s) -the participant(s) -the site(s) where the research is done DP risk is for data processing risk solely Risk Level is the level of review that the project requires. Projects are assigned automatically to Level 1, 2, or 3.
The word limit for a text field is not large enough for me to include all the information relevant to that field. What should I do?	Word limits are designed to encourage precision and efficiency in describing your study.

| | If the word limit for any text field is insufficient you can upload the entry as an attachment – under Document Type select 'Other Documentation' and in the text field enter 'REF Attachment [NAME]'

Where there is not enough space then:
-bundle information together/ package documents for efficiency eg methods
OR
-upload a protocol as an attachment by selecting 'other documents' from the alphabetical attachment list. |
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| Do all research projects have to go to full ethical review? | There is a pop-up banner when you click 'new ethics application' which directs you to a check list of research that does not require ethical review.

NB. Even if ethics is not required, data protection may still be so check with DPO

If your research does require ethical review, all applications in REAMs, regardless of level, must go to the REC for ethical review. |
| I've noticed that the platform requests the External Ethical Approval form but I haven't received it yet-can I get TCD approval pending receipt of this? | REAMs cannot offer any 'approval in principle'. Where external ethical approval is required it must be achieved before applying to TCD through REAMs.
All approvals must be received prior to TCD approval to ensure that the research achieves the correct level of ethical/ data protection scrutiny.
However, there may be instances where individual sites or sources require specific ethics approval-see below for how to manage these situations |
| My research requires approvals (licences/permits/ethics) from a site or source but I have yet to obtain it, what should I do? | In cases where there are several sites/sources requiring licences/permits or providing ethics approval, it is recognised that, in some instances, not all permissions will have been secured before the application is submitted to the REC.
In such cases, a REC may grant approval for the research to proceed at the sites for which licences/permits have been secured or ethics approval has been granted. |

	In Project Details, under Add Data Collection site/source select the option 'Site/Source ethics required but not yet obtained from this site' This will alert the REC that it is underway. Approval for the conduct of research at additional sites may be requested subsequently through an application for an amendment to the proposal.
What if I have made a mistake in the submission, I cannot seem to change it?	When you press SUBMIT the application cannot be edited unless it is reset to draft. Requests to reset to draft need to made by direct email to the next person in the workflow. If you are a student you can ask your supervisor to 'return to you to edit' rather than sign off. If you are not the PI you can ask your supervisor to 'return to you to edit' rather than sign off. If you are Staff and the PI you can request the REC Admin to reset to draft rather than assign to reviewers.
What's the difference between recruitment data and research data?	Recruitment data-contact information for recruiting participants whereas Research data-is the data that is collected and processed/analysed as part of the research, to be used as findings.
What is a Consent Declaration?	This is NOT the same as a consent form. It is a specific declaration required for Health Research that involves getting pre-approval from the HRDC.
What are Interventions?	These are experimental elements tested in a research setting among a participant group and can be educational, health related or medicinal.
What happens when I conduct a trial of a medicinal product or device?	You will be asked to upload a letter of compliance from the Head of Clinical Sponsorship Oversight. You should contact them here and they will review your research and provide you with a letter signifying your compliance.

What are the timelines for submission, feedback, approval?	Each REC operates to its own deadlines for submission and time-lines for review. Information should be available on the REC website.
How to I make changes to the application when I've heard back from the REC	Feedback from the REC in terms of 'make revisions' will direct you to certain sections/ question numbers to correct and your application will be reset to 'draft' form in order for you to do this. You should do these edits and resubmit your application with a cover note confirming that you have done the changes with a summary of them. The REC can see the changes as there is an icon next to each field in the application form which is red when the field has been changed. Clicking on this shows the history of changes in the field. NB. Each submission/resubmission is registered with a Version number to keep track of the changes.
What if something changes in my research protocol-how do I make an Amendment? NB. An amendment is only for small changes to your research eg. data collection dates, members of research team. Any changes that are significant require a new application eg. anything that affect the consent, form, PIL or the data protection review	When you click on 'New Ethics Application' you are asked to indicate if this is a new application or an amendment. When you click on amendment, a dropdown list appears of all your approved submissions, and you select the one that you are amending. A new title is generated (the original with an 'amendment' badge added) and a unique reference number is assigned. The original application information and all attachments are present in the new application and you can make changes and resubmit and track using the new unique-reference number. NB. In submitting the amendment you may be asked to reattach any attachments specific to a names person, method or site
How do I get an approval letter?	An approval letter will automatically appear in the attachments section once the application is approved by the REC and can be downloaded. It reminds you the researcher:

	-that the approval is valid for the timelines stated in the application only -your responsibilities regarding conducting the research with ethical principles and within GDPR law. It directs you where to find, download and send follow-up forms for: adverse events, end of project, annual reports
What follow-up documentation will I be asked to submit if any?	Prompt emails will be sent from noreply@academic.ie to remind you to submit an end of project report, annual report.
Why am I asked to enter information about the countries where I will collect data?	This simply alerts the REC if research is being conducted in 'no go' countries
Why is there no option for Northern Ireland?	If NI then choose UK even though in collecting data it is often treated like an extension of Ireland.
How does REAMs handle Phased studies (eg. 1st qual/ 2nd quant)	These can be handled in 2 different ways: -if concurrent steps within same piece of research, then all information must be entered into one application -if the steps are phased ie the 2nd phase depends on the outcome of the 1st, then 2 applications must be made with the 2nd application being linked to the parent by name (a selection drops down when you click it is a phased study)
Are my previous submissions saved?	All submissions are automatically given a version number (starting from V1) and are saved wo the attachment section on submission.
Why can't I see the name of the reviewers and their individual comments?	This anonymity in an important part of the ethical review process. You will receive the comments as a consolidated review from the REC.
Is it Ok to say no to a question eg consent?	Yes, the REC is the ultimate decision-maker and will feedback if incorrect.
How does REAMs interface with research in hospitals.	REAMs does not interface with hospital RECs.

| | JREC has special status and as a result, research with this approval does not need TCD ethical approval.

However, other hospital RECs are a separate entity and will be treated by TCD as an external REC ie approval must be granted by the hospital REC before any application can be processed by TCD. |
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| How does REAMs interface with Animal Research-lab? | REAMs forwards to AREC. This is the same process as before but REAMs now records this research for reporting purposes. |
| How to add more labs/ more countries to a study after approval has been granted? | This is done by making amendment (see Amendment FAQ) You will be asked what study you are amending to ensure the amendment is linked back to the original application |
| .I am a professional staff member conducting research with no affiliation to any school or faculty so what REC will my application be assigned to? | Research Ethics Committees are located in academic Schools and Faculties.
It is recommended that you consult with the Chair of a REC that will have the disciplinary expertise to review your research proposal and enter that School on the Applicant Collaborator section of the application.

An Appendix at the end of the REAMs Guidance document details all the RECs if you have any queries in advance of your application or would like to approach a school to find a home for your application.

NB. Where this is not obvious or you have no luck, then contact the REAMs administrator to advise. |
| If I put in multiple applications, do I have a better chance of getting approval quicker? | No.
You should work on one application, the time taken is related to the REC's processes not the REAMs platform. |
| Can I apply for ethics from a TCD REC if I am not a Staff member or registered student of TCD? | The current policy is available here: |