Research and Innovation

RESEARCH APPLICATION FORM GUIDANCE, JANUARY 2025

Research and Innovation (R&I)
ST. JAMES'S HOSPITAL | RESEARCH@STJAMES.IE

Contents

Important Information about the New R&I Application Process

To carry out research in St James's Hospital (SJH) researchers must be granted;

1. Ethical approval (from the St James's Hospital/ Tallaght University Hospital Joint Research Ethics Committee (JREC) or National Research Ethics Committee (NREC))
2. Hospital approval via the Research & Innovation Office

Previously, the Research & innovation (R&I) application form and JREC Approval form were two forms that researchers completed separately.

R&I applications will now be submitted through Infonetica, the same platform as JREC applications.

The R&I application form will now be available on the same platform as the JREC application form. We have transitioned to this platform with the goal of creating one consolidated process with a view to removing barriers to research in SJH.

By moving the R&I application to the same platform as the current JREC application, the two forms are connected, meaning your responses to questions in the JREC form will automatically populate duplicate questions in the R&I form.

How does it work?

The new R&I application form exists as a 'sub-form' from the JREC approval form. Once you have completed your JREC form, you can then create a sub form to apply to the R&I office for approval, on Infonetica.

It is envisaged that this will benefit the research community by creating a more streamlined application process and reducing the need for duplication between application forms.

This is beneficial because both forms are available in one location, both forms are available to external researchers outside SJH campus and questions duplicated across the forms auto-populate. For example, the Data Protection Impact Assessment (DPIA) completed as part of the JREC application form automatically populates in the R&I application form. Therefore, researchers are no longer required to populate two DPIA documents.

What about Clinical Trials with NREC[1] or CTIS[2] approval?

Clinical Trials with NREC approval or CTIS approval do not require JREC approval but **R&I approval is required**.

The R&I Office created a separate **Application Pathway** for Clinical trials and Regulated Medical Device Trials that bypasses the JREC application and allows you to upload your NREC or CTIS approval letter.

[1]NREC – National Research Ethics Committee in Ireland. The remit of the NREC-CTs is to review the submission of ethics applications related to Clinical Trials of Investigational Medicinal Products (CTIMP). The National Research Ethics Committee for Clinical Trials (NREC-CT) is recognised by the Department of Health under the S.I. No. 190/2004 - European Communities (Clinical Trials on Medicinal Products For Human Use) Regulations, 2004 and the S.I. No. 41/2022 European Union (Clinical Trials on Medicinal Products for Human Use) (National Research Ethics Committees) Regulations 2022

[2]CTIS - The Clinical Trials Information System (CTIS) is the online system for the regulatory submission, authorisation and supervision of clinical trials in the European Union and the European Economic Area

Application Pathways – what does this mean?

There are now two application pathways for R&I applications.

Pathway 1: Use this pathway when you are applying for **BOTH** JREC and R&I approval. Some examples of applications that would follow pathway one includes:

- A patient survey in SJH
- A retrospective chart review in SJH
- A staff study including staff from TUH

Pathway 1: Does NOT include clinical trials or medical device trials.

Pathway 2: Use this pathway for Clinical Trials, Medical Device Trial, SJH Staff Studies or Clinical Trials involving Ionizing radiation that have **EXTERNAL ETHICAL APPROVAL (NREC / CTIS / University Ethics)**

Pathway 2 bypasses the JREC application and allows you to upload your NREC or CTIS approval letter. Examples of pathway 2 applications include:

- Any regulated clinical/medical device where ethical approval is being sought from **NREC or CTIS**
- Any study where the participants are **staff only,** and university ethics has been granted
- Multi-site Clinical Trials involving ionizing radiation, where one site has already received ethical approval

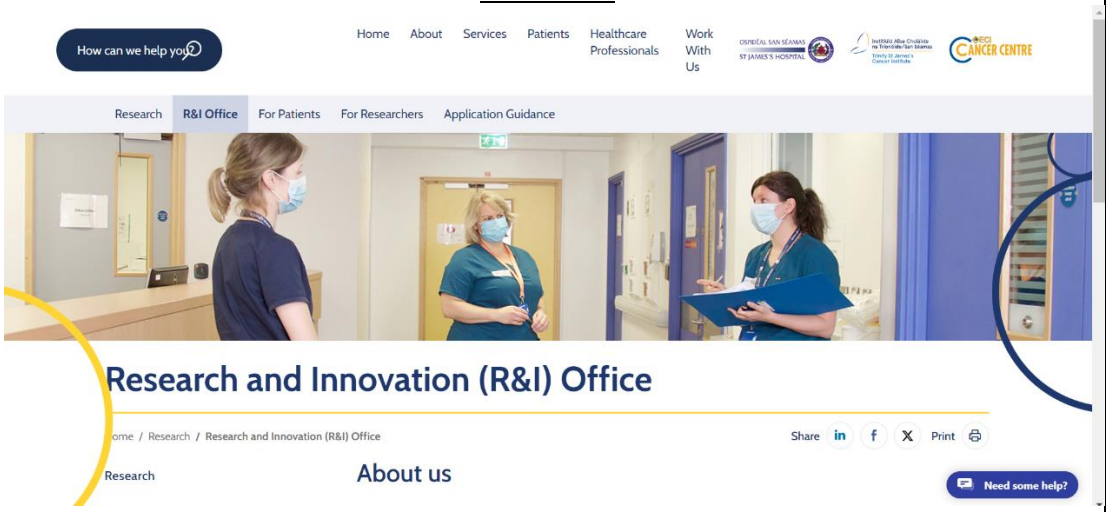
[3] SJH/TUH staff surveys that require JREC approval

[4]Studies involving staff **ONLY** (no patient participants) can be approved with university ethics. Any study involving patient participants MUST have JREC approval.

Getting Started

Where to find the application form

SJH Intranet

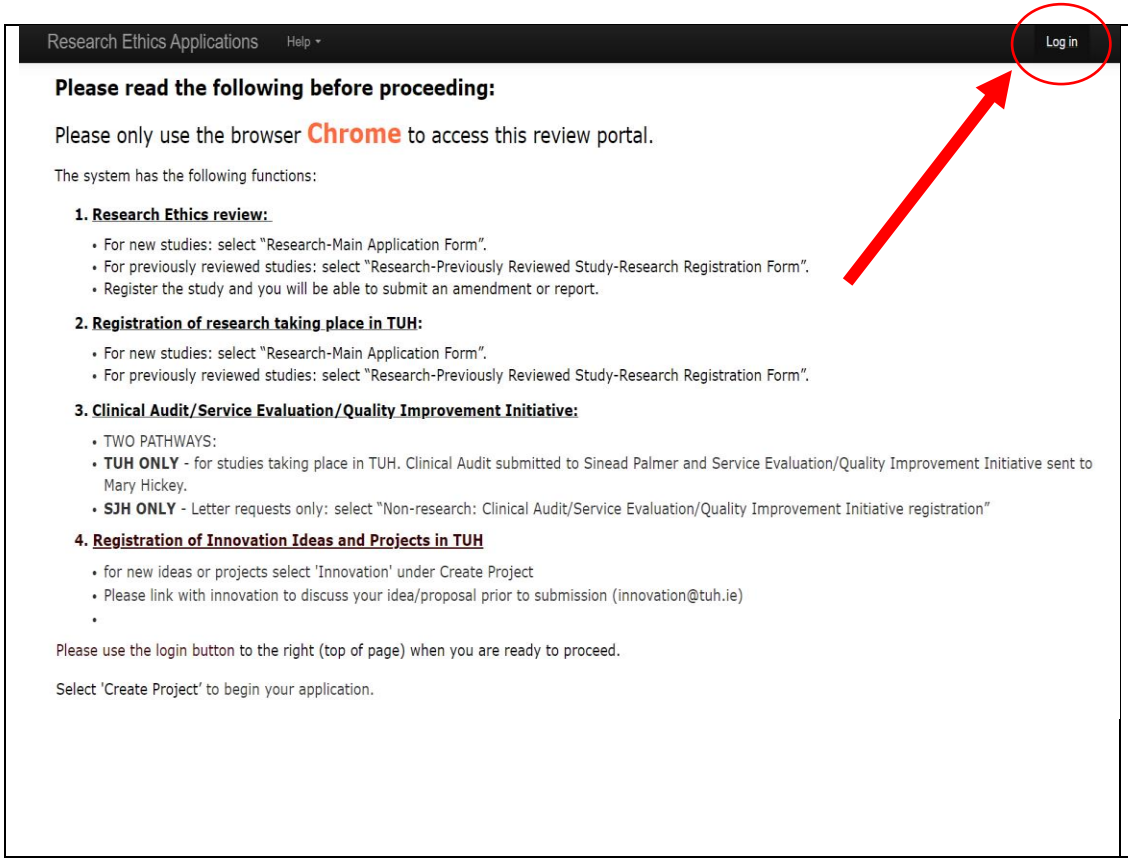


Where to find Infonetica

To get started with an R&I application, you can click the R&I Application Form link.

If you are SJH staff, the form is available on the The R&I Intranet page

If you are not SJH Staff, the application is available on the public R&I website.



This page explains the different functions/ application forms available within Infonetica.
https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login

Previously, Infonetica was only used for JREC applications for both Tallaght University Hospital and St James's Hospital.

Now R&I applications are also submitted through Infonetica.

There are two R&I application forms:

1) Pathway One: Application for clinical research that requires **BOTH** JREC and/or R&I approval

2) Pathway Two: Application for Clinical trials (including ionizing radiation trials), Regulated Medical Device Trials and SJH staff studies that have external ethical approval and ONLY require an R&I approval

To log in or create an account, click 'log in' in the top right corner

Log in or Register as a New User

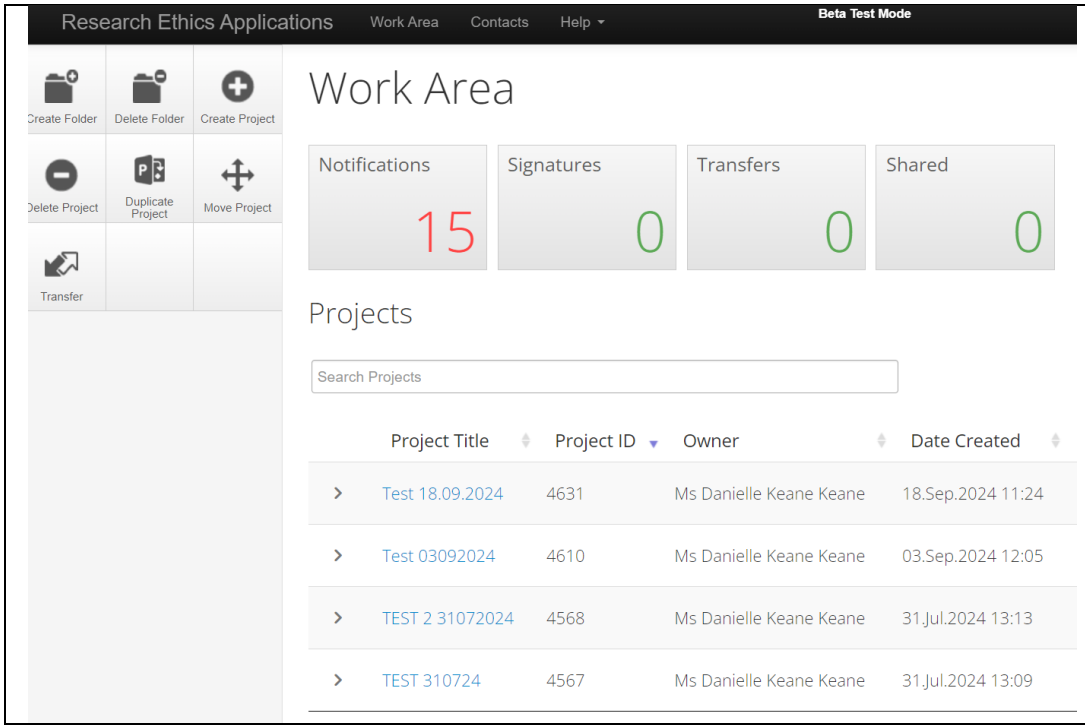
Logging in

If you already used Infonetica to submit an ethics application, you will already have an account.

You can use the same account to submit your R&I applications (you can use the 'forgot password' function to reset if needed).

If you are a new user, select 'register' to create a new account on Infonetica.

When you have provided your details and registered your account, you will receive an email inviting you to verify your account.

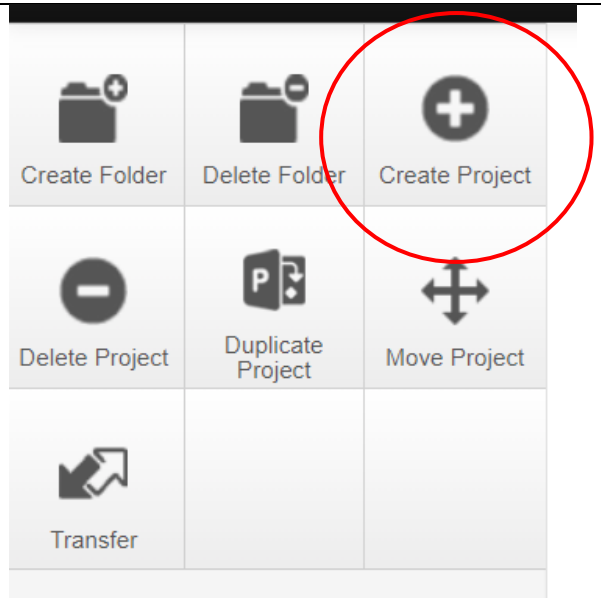


Once logged in, you will be in the Work Area.

In the work area you can:

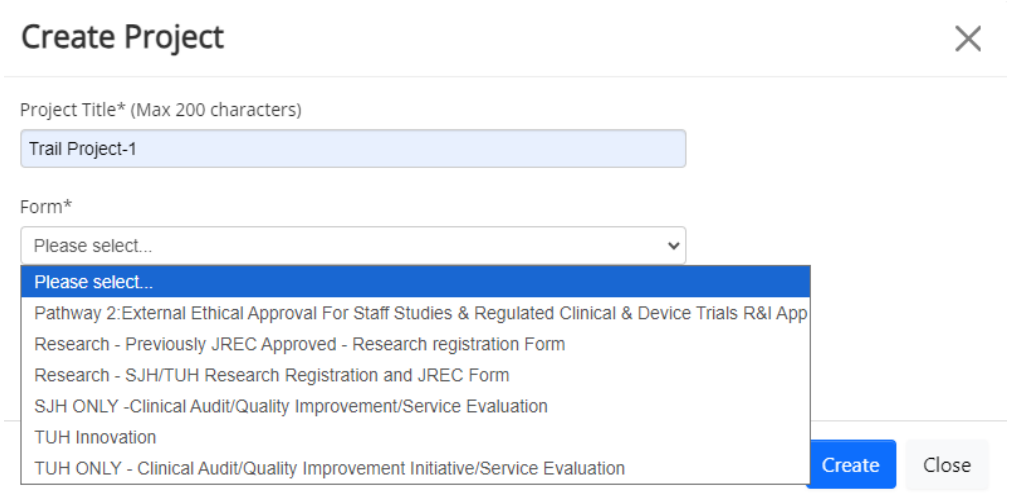
- Create application forms
- View submitted forms
- Review forms that have been returned to you for further information, clarification of details, or with comments from reviewers.
- Share your forms with co-investigators

Creating an R&I application



To create an application form, click ‘create project’ in the left pane.

A dialog box will open.



1) Input your project title.

2) Select the form you wish to complete from the drop-down box.

- If you are creating an application form for clinical research (non-clinical trial) that requires both JREC approval and R&I approval you must select 'SJH/TUH Research Registration and JREC Form'.
  - The JREC application form must be completed ***and*** submitted before the R&I application can be created as a **Sub Form** linked to your JREC submission. The R&I sub form is called a Pathway 1: SJH R&I Application Form Clinical Research
  - Information provided in the JREC application form will automatically populate the R&I application form.

- If you are applying for R&I approval for a Clinical Trial, Regulated Medical Device trial that has external ethical approval e.g., NREC **OR** CTIS **OR** a Clinical Trial involving Ionizing radiation **OR** a Staff Study with external ethical approval, e.g., university ethics, you must select 'Pathway 2: External Ethical Approval for Staff Studies & Regulated Clinical & Device Trials R&I App.

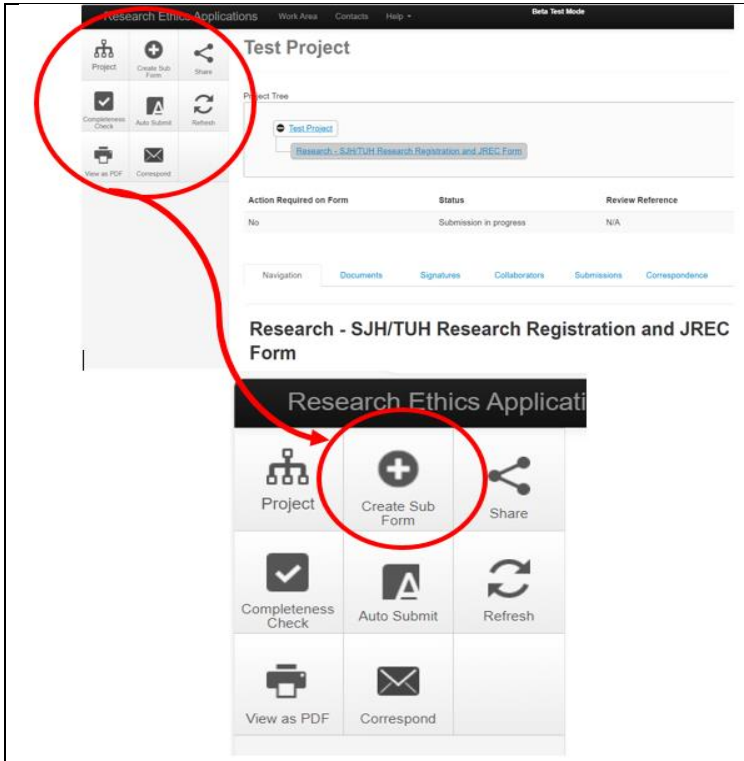
	3) **Centre**: Select 'Ethics Committee – St James's Hospital/ Tallaght University Hospital. 4) Press 'Create'. 5) Please note that if you are applying from SJH, some of the drop-down options do not apply

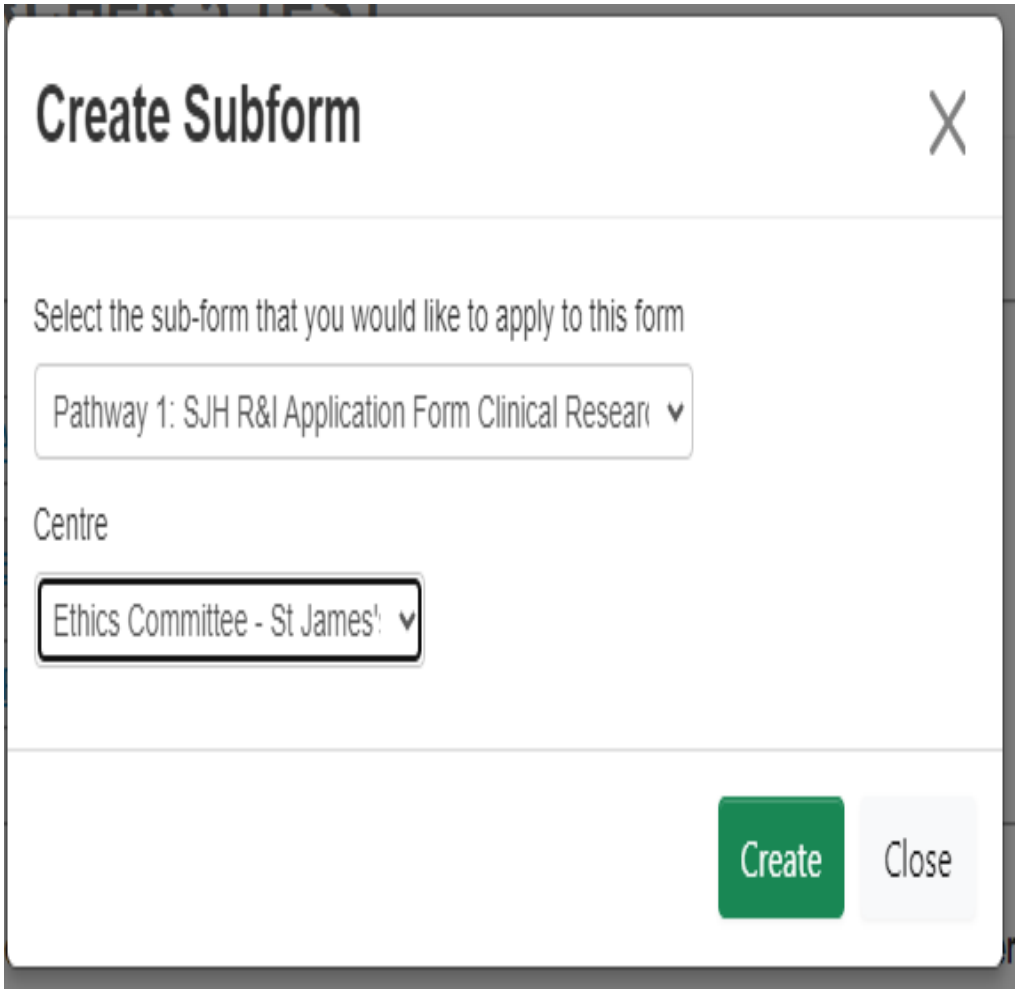
R&I Application Pathway 1: Applying for JREC and R&I approval (non-Clinical Trial/Medical Device Trials)

This pathway is for clinical research that requires ethical approval from JREC. There are two parts:

1) Complete **and** submit your JREC application – this should include your signature **and** your PI signature.
2) Once the JREC application is **fully submitted** proceed to the R&I application which can be created as a sub form. JREC approval is not required to proceed to this step.

How to create a sub-form

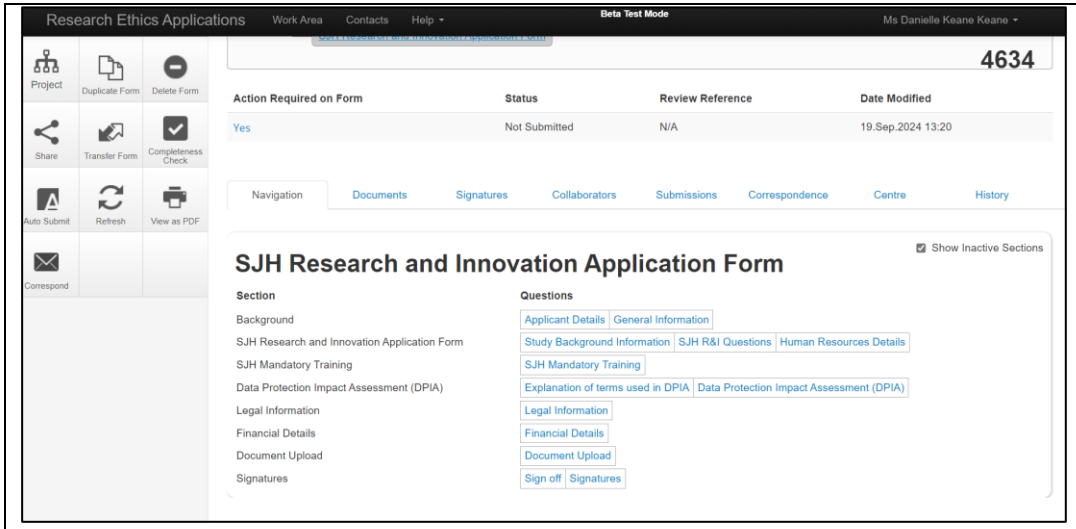
<table>
<tr>
<td> 
</td>
<td>1) To create a sub-form, click the ‘Create Sub Form’ button in the left navigation pane.</td>
</tr>
</table>



2) Then select 'Pathway 1: SJH R&I Application Form Clinical Research'.

3) **Centre:** select 'Ethics Committee – St James's Hospital/ Tallaght University Hospital.

4) Click 'Create'.



Starting your application

The R&I application form will appear as follows.

The sections to be completed are denoted by the blue font.

Many sections will have automatically populated with data from your JREC application.

To begin completing the form, select applicant details and use the 'Next Page' buttons to navigate through the application form.

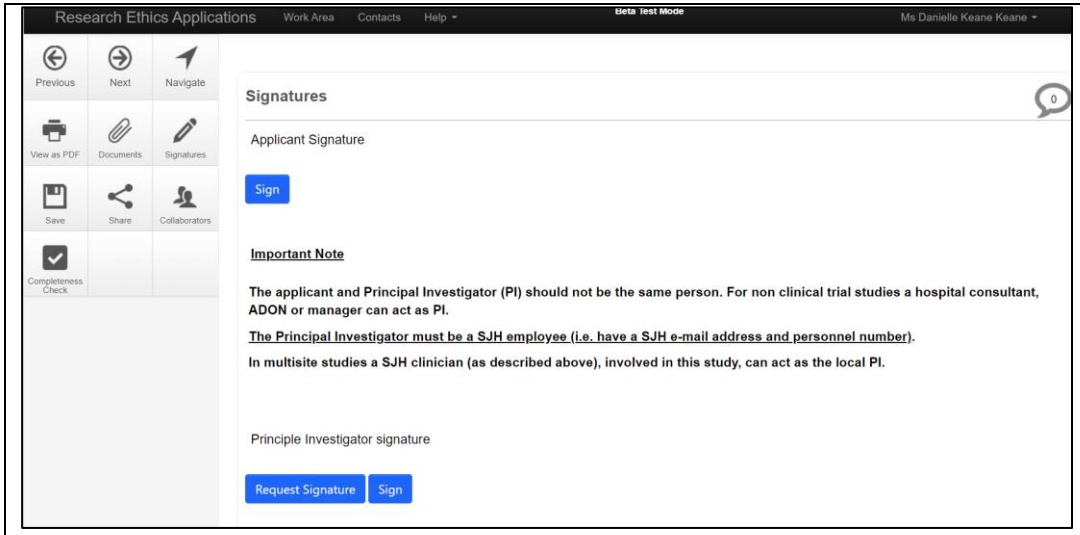
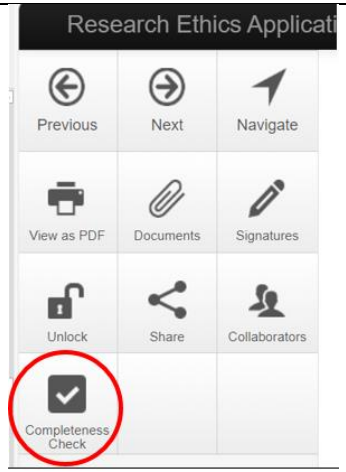
The form questions are explained in more detail in the **guidance document** and by clicking on the **information icons** throughout the form.

Submitting your application

Once you have completed all the sections, you will be invited to sign off and submit your application form by adding your signature. Your signature is your email and Infonetica password.

The first time you submit the R&I application, your PI will also be required to sign off on the application. You must request your PIs signature, as you did for your ethics application.

NOTE: The R&I application form will not be submitted until the PI has provided a signature. This is a very important step.

<table>
<tr>
<td> 
</td>
<td>You must request your PIs signature using the email associated with their Infonetica account. If they do not have an account, they will need to register for in order to sign off your R&I application form. If the PI has more than one account provide your PI with details on the email to which the signature request is sent.</td>
</tr>
<tr>
<td> 
</td>
<td>You can also use the ‘completeness check’ button to ensure you have completed all sections of the form.</td>
</tr>
</table>

Ensuring your Pathway One Application is Correctly Submitted

The successful submission of an R&I application will require:

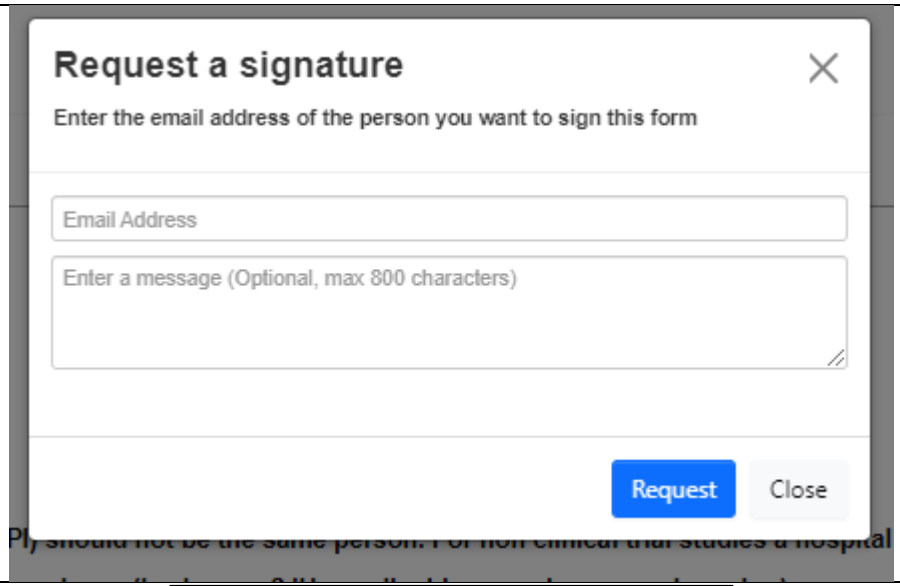
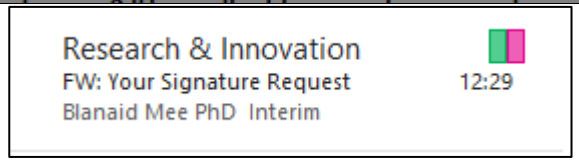
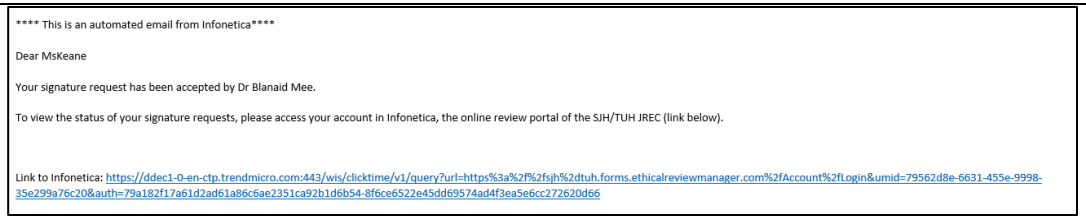
1. Applicant Sign off AND
2. PI sign off.

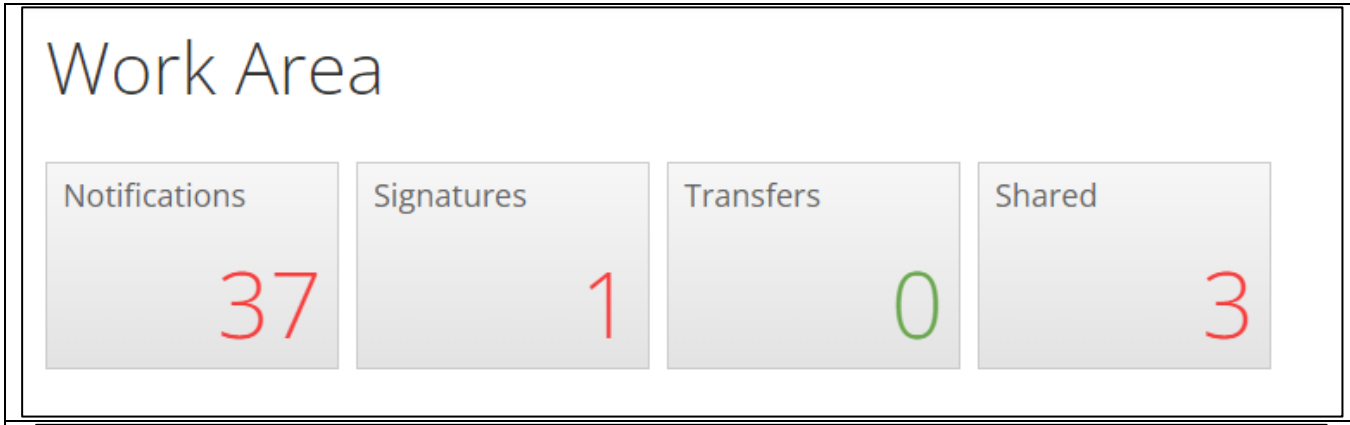
1. Applicant Sign Off

	The Applicant Signature/sign off section appears at the bottom of the last page of the R&I application. Please Click "Sign" and provide your Infonetica username (email) and password to successfully sign off the R&I application.

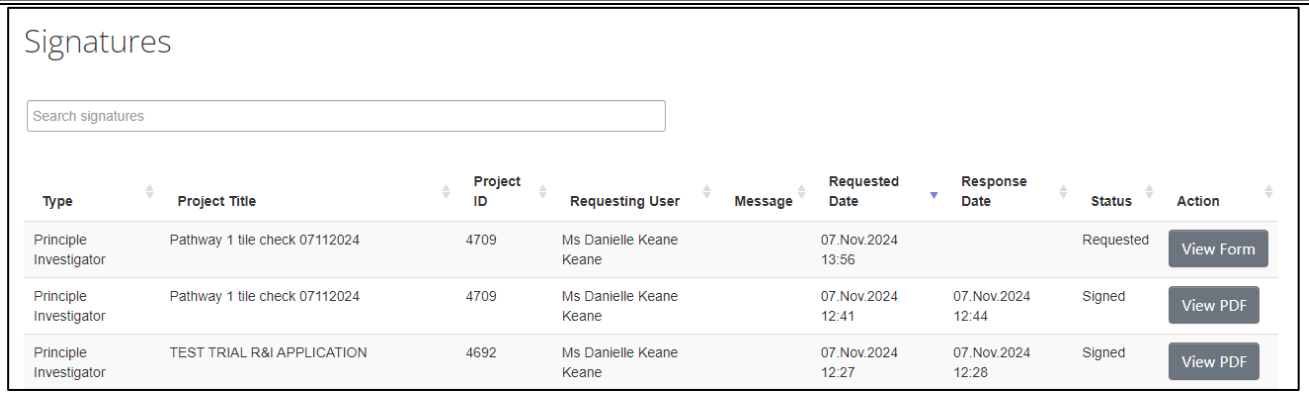
2. PI Sign Off

	The R&I application form will not be submitted to the R&I Office for review **UNTIL** the Principal Investigator has also provided a signature/signed off on the application. To request the Principal Investigator signature/sign off click on "Request Signature".

	Provide the Principal Investigator email address in the box that pops up (see image below) and click “Request”.
	If the Request Signature section of the form is completed correctly the Principal Investigator will receive an email inviting them to sign off on your application.
	This email will contain a link for the Principal Investigator to follow to provide a signature/sign off for the application.

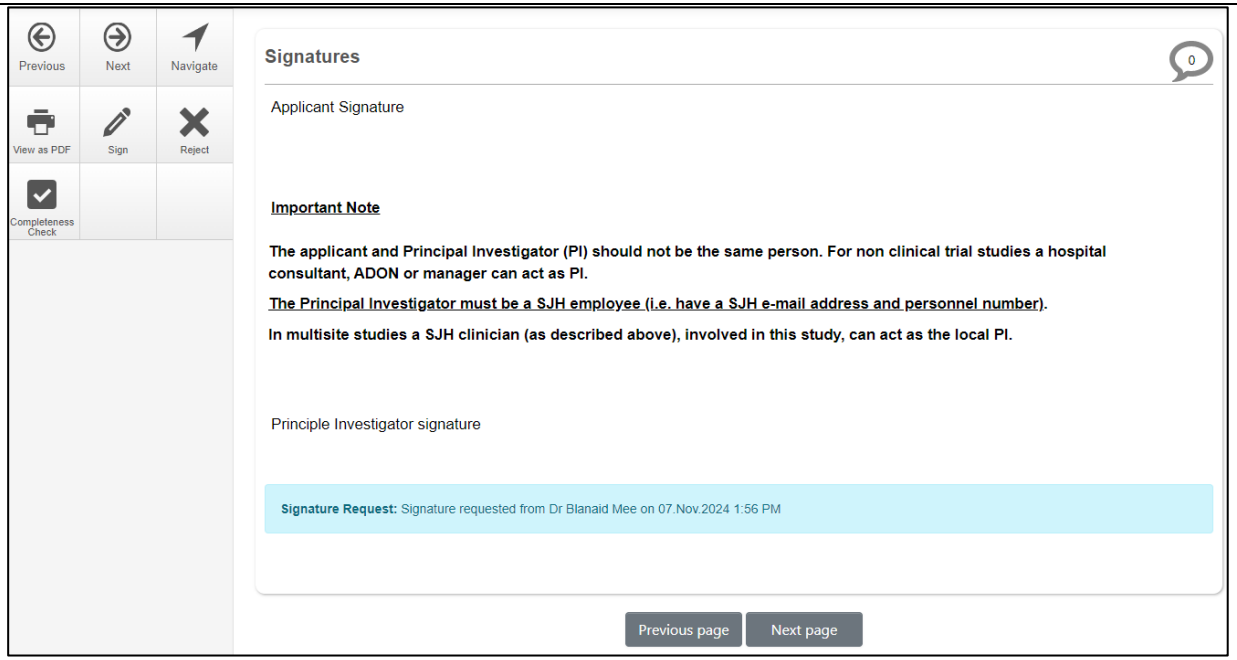


When the Principal Investigator clicks on the link and provides their Infonetica login information (email & password) it will lead to the Work Area as demonstrated (left pane);



Clicking on Signatures will lead to the Signatures section where all Requested and previously signed applications are located.

The Principal Investigator should click “View Form” to review the R&I application form.



The Principal Investigator can sign off the R&I application form by clicking the "Sign" icon on the left of the Signatures page.

**** This is an automated email from Infonetica****

Dear MsKeane

Your signature request has been accepted by Dr Blanaid Mee.

To view the status of your signature requests, please access your account in Infonetica, the online review portal of the SJH/TUH JREC (link below).

Link to Infonetica: https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fsjh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2fLogin&umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffc51cd36b98b07

When the Principal Investigator has successfully signed off the R&I application form the Applicant will receive the following email and the form will proceed through the R&I approval system.

Completing a Pathway One R&I Application Form

In this section, the questions in Pathway One will be explained.

Please note that pathway one refers to applications that require **both** JREC and R&I approval. **This pathway does not include clinical trials or medical device trials**. These are covered in Pathway Two.

1. Applicant Details

These are your details that are automatically populated using the information in your Infonetica account

2. General Information

Unique R&I study title	Please create a unique study title for each R&I Application, different from the JREDC application and/or other R&I applications, as this is the means by which your R&I application will be tracked.
Full study title	Type out your full study title in the text box.
Please select YES if: **1. Your study is a retrospective chart review, or** **2. Involves the recruitment of Human Participants (either staff or patients).** **Please select NO if:** **1. The above 2 points are not true** **2. TUH and/or SJH is only a site of advertisement for the study and NOT a site of recruitment** **3. Your study is a case study involving <5 patients (SJH ONLY)** **4. Your study population is ONLY SJH employee's survey/questionnaire and you have Research Ethics Committee approval from an Academic Research Ethics Committee**	Auto-populated from JREC Application The answer you provide will determine whether your study requires R&I approval **AND** JREC approval **or** if you are just applying for R&I approval. Selecting 'YES' opens the JREC form and indicates that your project requires both JREC approval **AND** R&I approval. Selecting 'NO' indicates that your project does NOT require JREC approval, **ONLY** R&I APPROVAL.
Please select the nature of the study	Choose from the drop down
Please provide a brief lay (plain English) description of the study	Provide a summary of the trial in plain English. Include a study description referring to:

	- Study background - Aims and objectives - Hypothesis - Participants – inclusion/exclusion criteria - Any testing. Ensure to clearly outline your research design.
Please confirm that this study is taking place at St James's Hospital	If no, please stop filling in the form and contact research@stjames.ie If yes, select 'yes' and fill in the subsequent questions relating to department and directorate.
Please list the departments in which the study is taking place.	Type the relevant departments in the box provided
What SJH Directorate is this study taking place in?	Choose the relevant department from the drop down list
Is this study being undertaken as part of an academic qualification?	Auto populated from JREC
If yes, is the study being conducted as part of an undergraduate or postgraduate qualification?	Auto populated from JREC
What is the academic qualification?	Auto populated from JREC
Please provide the name of the academic institution	Auto populated from JREC
Is this a multi-site study?	Auto populated from JREC
Who is the Principle Investigator in SJH?	In this section, you must populate the details of the SJH Principle Investigator, including their discipline. If the study is multisite, this section is for the local supervisor in SJH. There must be a nominated local supervisor who is an SJH employee.
Please select the discipline that best represents the Principal Investigator	Select from drop down menu
Where the applicant is NOT the Principal Investigator (PI) could the applicant please confirm that the PI is happy for their name and email address to appear on the Research & innovation BI Database:	The BI database is an internal dashboard use to visualise and track research in SJH.
Is the applicant also the Principal Investigator (Clinical Research Studies)?	Auto populated from JREC
Please select what best describes why you are completing this application (tick all that apply)	Select all options that are applicable

3. Study Background Information

What is the anticipated start date of this study?	Auto populated from JREC
What is the anticipated end date of the study?	Auto populated from JREC
How many participants are to be included/recruited in total from SJH?	Auto populated from JREC
How will explicit consent be obtained from participants?	Please explain in detail how you intend to consent participants, e.g. consent forms. Template consent forms and patient information leaflets are available on the R&I Intranet Page. The R&I Team can review your documents before you submit JREC. In this section you will be asked to upload the Participant Information Leaflet and Informed Consent Form, these are required documents.
Are participants lacking capacity to consent included in this study?	Any research involving participants who are unable to provide informed consent requires HRCDC approval.
If yes: **Have you applied or do you intend to apply to the Health Research Consent Declaration Committee (HRCDC)?**	If you select applied or intend to apply, you must upload a copy of the Health Research Consent Declaration Committee (HRCDC) application **and** approval letter, these are required documents if your project involves individuals unable to provide informed consent.
Please upload a the Participant Information Leaflet (PIL) & Consent Form (CF)	Upload the requested documents here (if applicable to your application) so they can be reviewed as supporting documents for your application

4. SJH R&I Questions

Is this study cancer related?	**We ask this question to track cancer related research taking place in SJH.**
Was this study part of a previous Clinical Audit/Service Evaluation/Usual Practice project?	We ask this to track the transition between quality improvement projects and implementation of findings. If you select 'yes' here, you will be asked to input the R&I number OR title of the previous QI project. This allows us to link the QI initiative with the current R&I application.

Clinical Research Facility: Will the study be run using the Wellcome HRB Clinical Research Facility?	We ask this to ensure the CRF is aware of any upcoming projects. Selecting 'Yes' here means that your application will also be reviewed and approved by our CRF manager.
If you select Yes to 'will the study be run in the Wellcome HRB Clinical research Facility, the following questions will open up:	• **Please list the Research Team including Sub-Investigators and other Research Staff** We ask this to maintain oversight of researchers coming on site at SJH or accessing patient data. It is especially important to list any non-SJH staff as they are required to submit a non-disclosure agreement (NDA) and may also need to undergo Garda Vetting. • **Please select the project type** • **Please select the type of support required** We ask this to define the resources that the project will require., please select from the options listed • **CRF Project Number** This is used to liaise with the CRF regarding your CRF application
Pharmacy: Will this study require support from either the hospital or CRF pharmacy?	We ask this to define the resources that the project will require.
Hospital Resources: Select the hospital resources that will be used for this study	Similar to above, this question aims to define the resources that the project will require. You also have the option to provide further details in a text box.
Nursing Research Access Committee: Are nurses or healthcare assistants participants in this study? Are nurses or healthcare assistants subjects in the study?	If your project involves Nurses or Healthcare Assistants (HCAs) your application it will need to be reviewed and approved by NRAC. Selecting 'yes' here opens the NRAC specific questions that **must be completed** if Nurses or HCAs are the subject of your application.
If 'yes' the following questions will open up: Responses in this section will be reviewed by the Nursing Research Access Committee.	• **Short Study Title** (same as in general information section) • **Full Study Title** (same as in general information section) • **Please provide a brief lay (plain English) description of the study** • **List the study aims and objectives**

	• **Describe the research design/methodology of the study** – explain your research design
	• **Please provide details on the study sample & the sampling technique** – be specific here, name the wards, number of staff, how you will access staff
	• **Who is the Gatekeeper for this study**? Please provide; full name, work position & Dept/Directorate – this should ALWAYS be an SJH employee
	• **List the inclusion criteria of the study**
	• **List the exclusion criteria of the study**
	• **Does this study require ethics approval? Ethical approval is required for ALL NRAC applications.**
	  ○ If yes, give the name of the ethics committee and application date
	  ○ If no, please explain why ethical approval is not required
	• **Please provide details on how data will be managed to ensure confidentiality & security**
	• **Outline your plan for the dissemination of the study findings**
	• **Has the local CNM/Manager been informed of this study**? If yes, please provide details (Name, Work position, Dept/Directorate)
	• **Please provide a reference list/bibliography**
	• **Please select the study documents that have been uploaded**
	• **Upload survey if applicable**

5. Human Resources Details

Will non-SJH staff be on site?	We ask this to maintain oversight of researchers on the SJH campus. If you select yes, the follow up question will open.

If yes: Will non-SJH staff require access to SJH patients and/or SJH patient data?	We ask this because non-SJH staff accessing patients or patient data, are required to undergo Garda Vetting by SJH and are required to sign a non-disclosure agreement. If you select yes, you must provide the details of external researchers who will be accessing SJH patients or patient data. You must upload the signed NDA for each external researcher who will be accessing SJH patients or patient data. If you are unsure whether you will require an NDA. It is possible to proceed and add your NDA after submission. Each external researcher must complete the Garda Vetting invitation form and contact research@stjames.ie to arrange to have their IDs validated **Please note:** If you are unsure about whether you will need to undergo Garda Vetting, please contact HR at humanresources@STJAMES.IE and proceed with the application. If HR determine that Garda Vetting **is** required, this can be added to your application after submission.

6. SJH Mandatory Training

Mandatory training for all researchers in SJH are:	- GDPR - Hand Hygiene - Children first (if your project involves children) Mandatory training can be completed on HSELandD: www.hseland.ie

7. Explanation of terms used in DPIA

This page explains common terms used in the Data Protection Impact Assessment (DPIA)	It is important to read this section carefully so that you can understand common data protection terms. Once you have read the glossary of terms, please select 'I confirm' at the bottom of the page**.**

8. Data Protection Impact Assessment

Did you complete the Data Protection Impact Assessment (DPIA) section of the JREC application?	Select yes or no. If you completed a JREC application prior to the R&I application, the data from your JREC application will auto populate the majority of sections in the SJH DPIA. **Please review and manually complete the sections not auto-populated.** These are additional questions, specific to SJH. If you did not complete a JREC application form, you will need to complete the DPIA manually
Do you have a DPIA that is reviewed and signed by the Data Controller/Joint Data Controllers?	**Select 'Yes' if you** have already had a DPIA for this project reviewed and approved by the Data Controller's DPO. **You can upload this DPIA and the SJH DPO will review it.** If you select yes, you will be prompted to upload the document. **Select 'No' if you** do not have an approved DPIA.
UPLOAD	- Please upload a flow diagram of the dataflow detailing how the data is processed throughout the lifecycle of the study from collection to deletion. - Please upload the case report form - Please upload a copy of the Data Sharing Agreement (this is required if data is being shared with a third party, or if this project is multisite)

9. Legal Information

Who are you employed by?	All SJH staff are covered by the Clinical Indemnity Scheme. Please use this information to answer the questions below. If you are Trinity staff and unclear how to answer the indemnity questions below, please contact Dr. Ruben Eavan Keane, Head of Clinical Sponsorship Oversight (TR&I Administration) at keaner4@tcd.ie and Tony Dowling, Insurance Manager at tony.dowling@tcd.ie. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission. If you are unclear how to answer the indemnity questions below, please contact your Institution's Legal Office.
Are all researchers and medical staff covered by the Clinical Indemnity Scheme (CIS)?	The Clinical Indemnity Scheme (CIS) covers clinical research undertaken by SJH staff or persons engaged by SJH to carry out clinical research at SJH. **ALL SJH STAFF ARE COVERED BY CIS** If you select no, you will be prompted to give further information about the cover in place for researchers NOT covered by CIS. If you are Trinity staff and unclear how to answer the indemnity questions below, please contact Dr. Ruben Eavan Keane, Head of Clinical Sponsorship Oversight (TR&I Administration) at keaner4@tcd.ie and Tony Dowling, Insurance Manager at tony.dowling@tcd.ie. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission.
Is Indemnity in place for all NON-SJH researchers?	This is for insurance purposes. If you select no, you will be prompted to explain why Indemnity is NOT in place for all NON-SJH researchers.

	If you are unsure about the indemnity in place for non-SJH researchers, you must contact their institutions legal department. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission.
Hospital sign off: Do any contracts with third party organisations associated with this study require execution by the hospital (hospital sign off)?	The following studies are often associated with contracts for hospital sign off; multi-site studies, studies with sponsor funding, studies with grant awarded funding etc. It is essential that any research contracts are reviewed by the SJH Legal Office. If you select yes here, you will be prompted to upload the agreement/ contract so that the SJH Legal Office can review and arrange execution.
Where applicable, please download, complete & return a SJH MTA (Material Transfer Agreement) from the HELP SECTION. The completed form can be uploaded here.	A Material Transfer Agreement is an agreement that regulates how parties can share materials such as blood samples and tissue samples.

10. Financial Details

Is there funding in place for this study?	If you select "Yes", further questions will be opened. If you select "No", you will move to the next section.
What is the nature of the funding?	Tick the relevant box.
What is the source of funding for this study?	Who is providing the funding?
What is the amount of funding?	Please respond in numeral values.
What organization will the funder be depositing funds into?	What institution will hold the funds
If funding will not be deposited directly into a SJH research account, is there an agreement in place to recoup the funds due to SJH?	This section is reviewed by the Research Finance Manager, it is essential that funds owed to SJH are recouped – therefore, it is essential that agreements are in place.

	Respond in the text box
I confirm that the PI has provided study costing details to the SJH Research Finance Manger (researchfinance@stjames.ie) and that these costings have been validated by the SJH Research Finance Manger	This is an essential step for any research funding. All research funding MUST go through an SJH research bank account. As the SJH Research Finance Manager sets up the research account and internal order number for invoices.

11. Document Upload

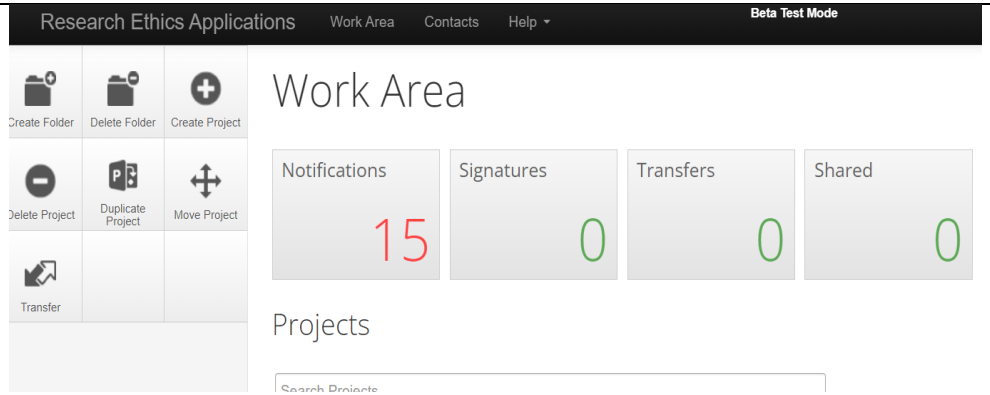
In this section you have the opportunity to upload any additional supporting documents.	For example, you may choose to upload protocols.

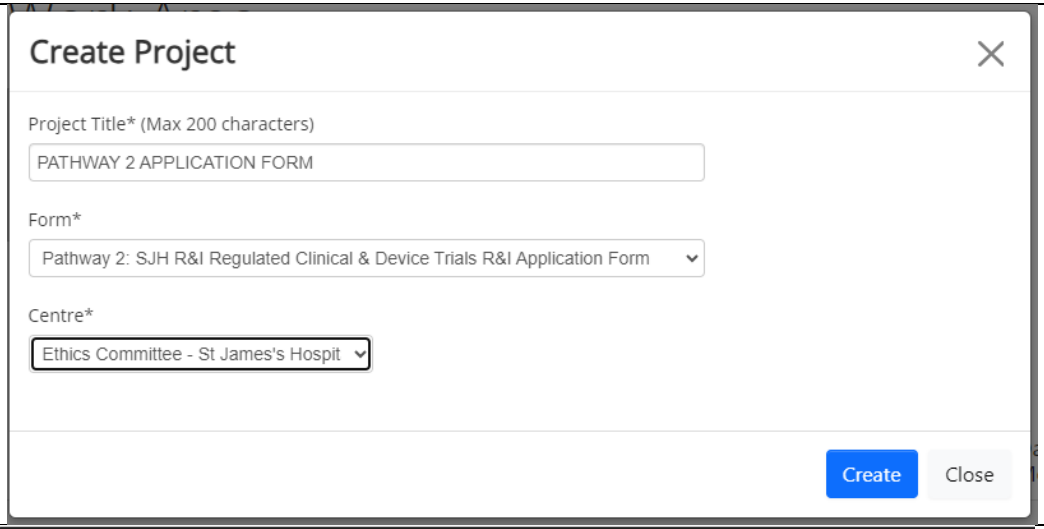
R&I Application Pathway 2: External Ethical Approval for SJH (ONLY) Staff Studies & Regulated Clinical & Device Trials

This pathway is for

1) Clinical Trials (including ionising radiation trials)/ Regulated Medical Device Trials that have ethical approval from the National Research Ethics Committee (NREC) or CTIS.
   OR
2) SJH (ONLY) Staff Studies with external ethical approval e.g., university ethical approval

R&I applications can be submitted while NREC/CTIS approval is still pending.

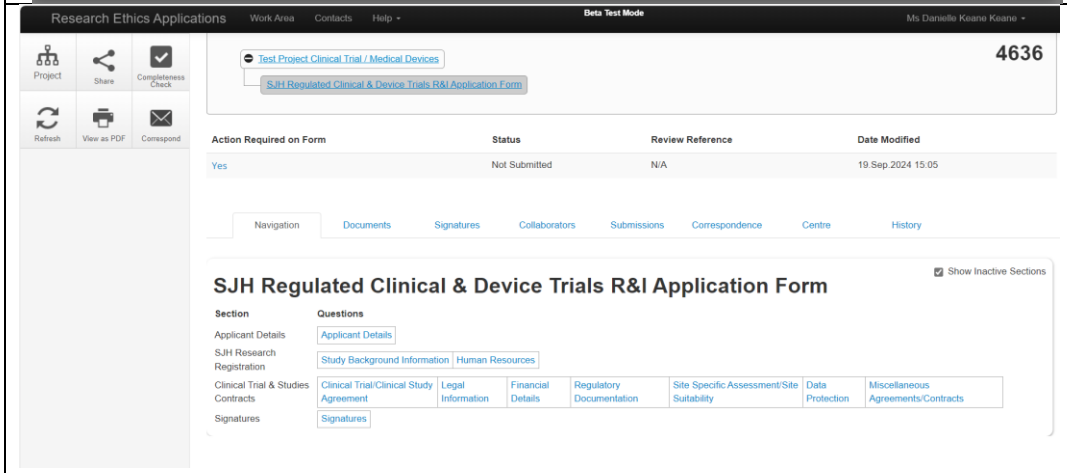
	From the work area, select 'Create Project' in the navigation pane on the left.



Form: If you are applying for R&I approval for a Clinical Trial or Regulated Device with NREC/CTIS approval or pending approval, Clinical Trial involving Ionizing radiation or a staff study that has been granted university ethics, you must select **'Pathway 2: External Ethical Approval for Staff Studies & Regulated Clinical & Device Trials R&I App'**

Centre: You must select 'Ethics Committee – St James's Hospital/ Tallaght University Hospital.

Select 'Create'.

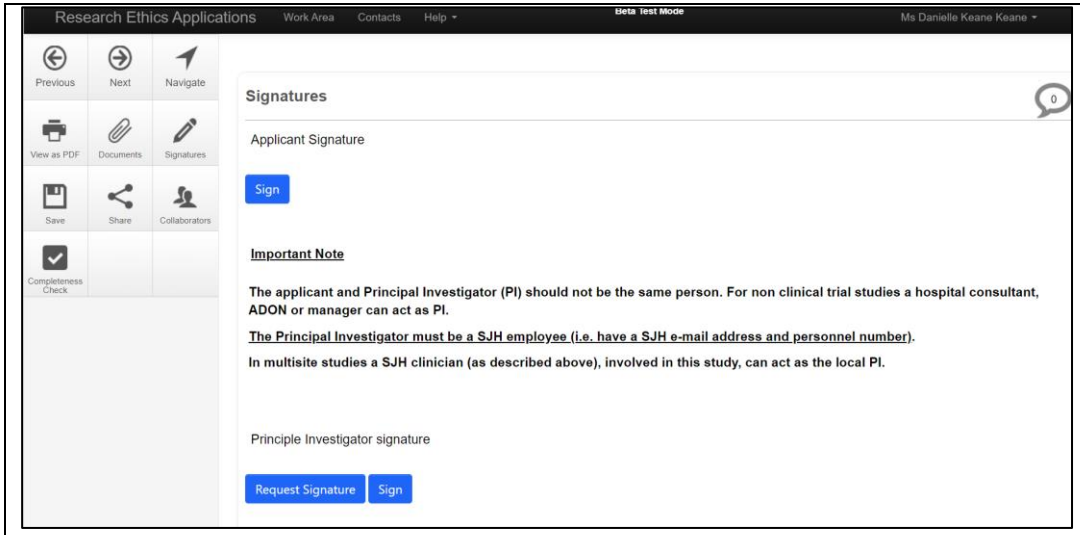


This R&I Application Form will appear as illustrated in the left pane.

The blue font denotes sections of the R&I Application Form to be completed.

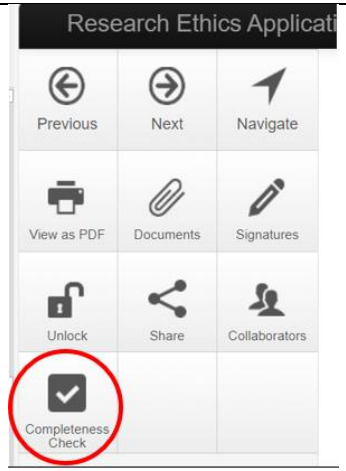
To begin completing the form, select "Applicant Details" and use the 'next page' buttons to navigate through the application form.
The form questions are explained in more detail in the **guidance document** and by clicking on the **information icons** throughout the form.

Once you have completed **all the sections**, you will be invited to sign off using your signature and submit your application form by adding your signature.

<table>
<tr>
<td> 
</td>
<td>Your signature is your email and Infonetica password.

If this is the first time you have submitted this R&I application, your PI will also be required to sign off on the application. You must request your PIs signature.

NOTE: The R&I application form will not be submitted until the PI has provided a signature. This is a very important step.

You must request your PIs signature using the email associated with their Infonetica account. If they do not have an account, they will need to register with Infonetica in order to sign off on your application form.</td>
</tr>
<tr>
<td> 
</td>
<td>You can also use the ‘Completeness Check’ button to ensure you have completed all sections of the form.</td>
</tr>
</table>

Ensuring your Pathway Two Application is Correctly Submitted

The successful submission of an R&I application will require:

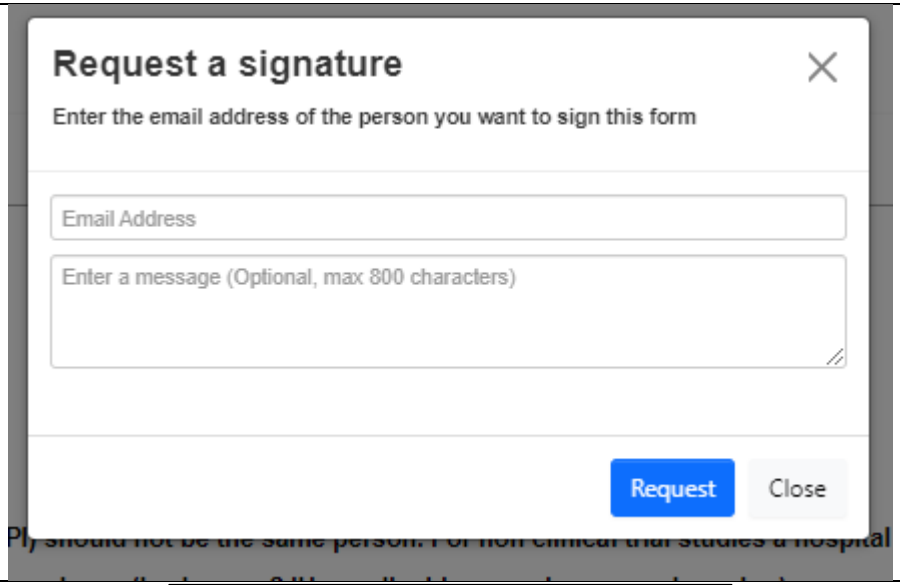
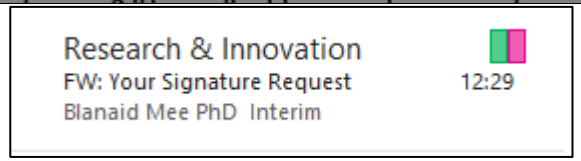
1. Applicant Sign off AND
2. PI sign off.

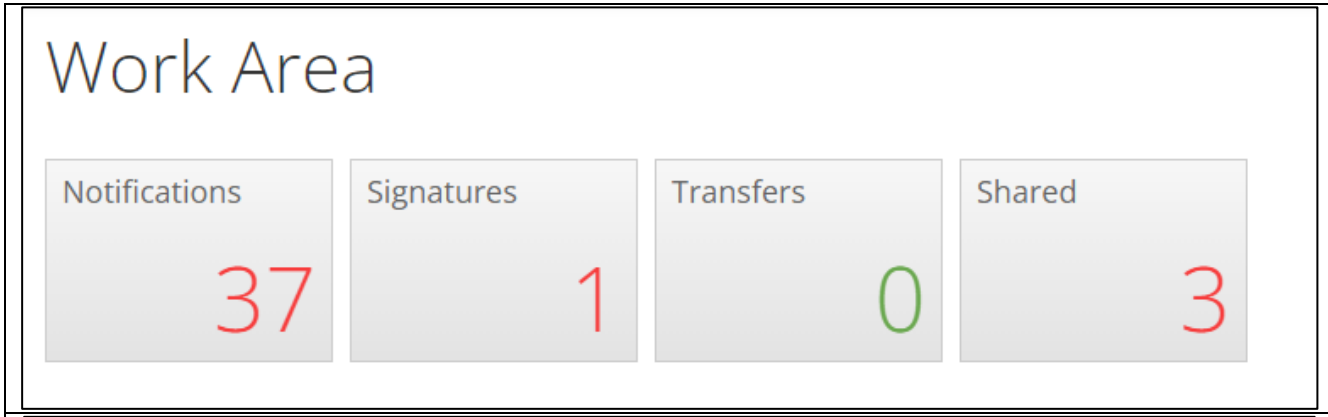
1. Applicant Sign Off

	The Applicant Signature/sign off section appears at the bottom of the last page of the R&I application. Please Click “Sign” and provide your Infonetica username (email) and password to successfully sign off the R&I application

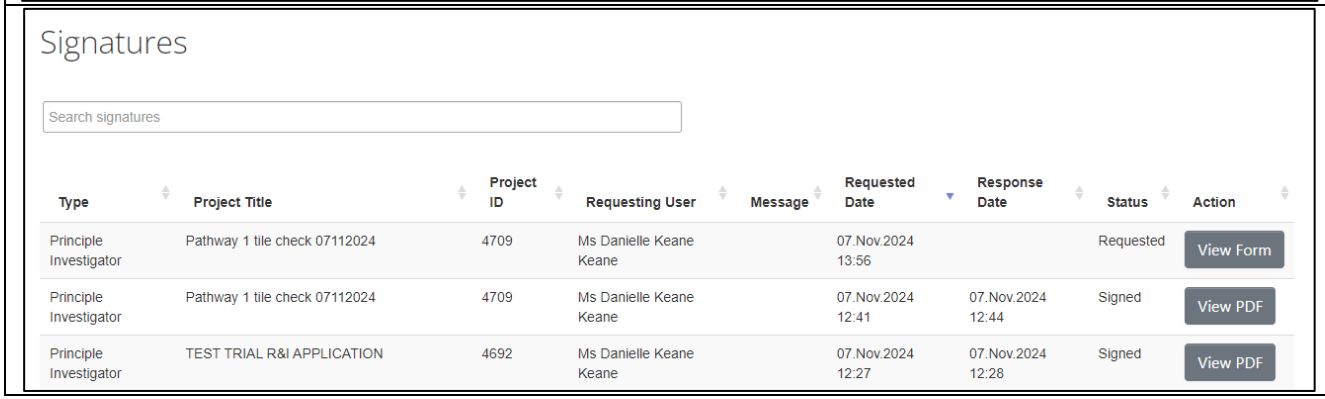
2. PI Sign Off

	The R&I application form will not be submitted to the R&I Office for review UNTIL the Principal Investigator has also provided a signature/signed off on the application. To request the Principal Investigator signature/sign off click on “Request Signature”

	Provide the Principal Investigator email address in the box that pops up (see image below) and click “Request”.
	If the Request Signature section of the form is completed correctly the Principal Investigator will receive an email inviting them to sign off on your application.
**** This is an automated email from Infonetica**** Dear MsKeane Your signature request has been accepted by Dr Blanaid Mee. To view the status of your signature requests, please access your account in Infonetica, the online review portal of the SJH/TUH JREC (link below). Link to Infonetica: https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fsjh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2fLogin&umid=79562d8e-6631-455e-9998-35e299a76c20&auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66	This email will contain a link for the Principal Investigator to follow to provide a signature/sign off for the application.

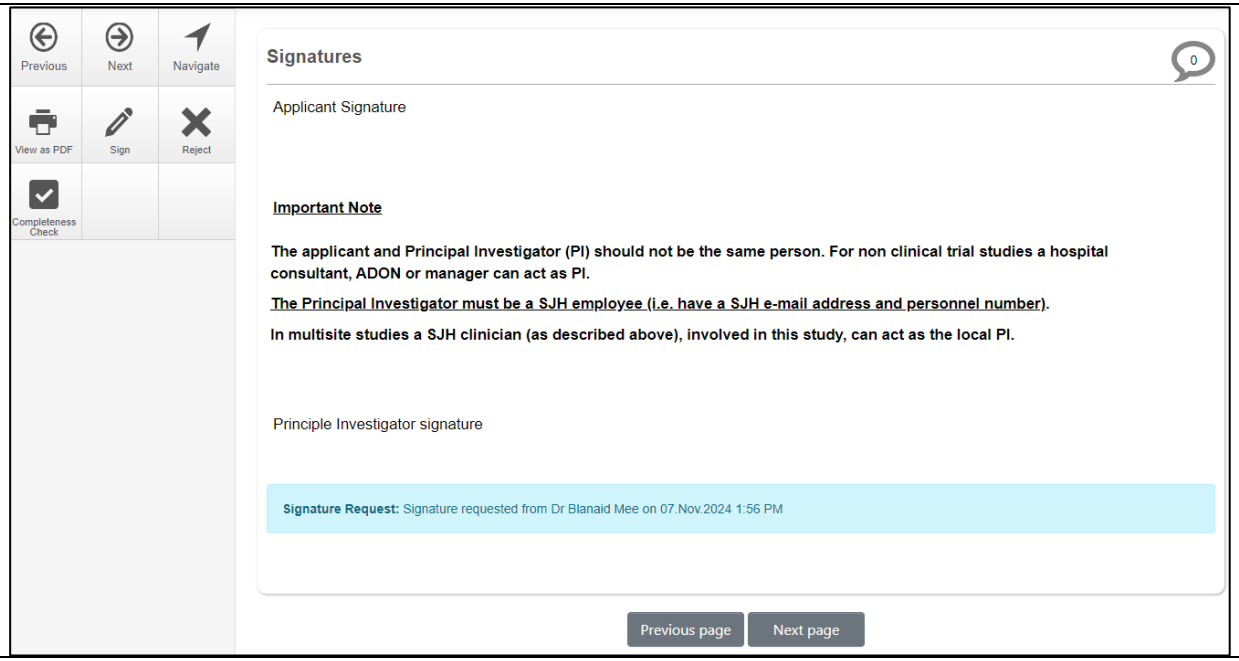


When the Principal Investigator clicks on the link and provides their Infonetica login information (email & password) it will lead to the Work Area as demonstrated below;



Clicking on Signatures will lead to Signatures section where all Requested and previously signed applications are located.

The Principal Investigator should click “View Form” to review the R&I application form.



The Principal Investigator can sign off the R&I application form by clicking the "Sign" icon on the left of the Signatures page.

**** This is an automated email from Infonetica****

Dear MsKeane

Your signature request has been accepted by Dr Blanaid Mee.

To view the status of your signature requests, please access your account in Infonetica, the online review portal of the SJH/TUH JREC (link below).

Link to Infonetica: https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fsjh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2fLogin&umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffc51cd36b98b07

When the Principal Investigator has successfully signed off the R&I application form the Applicant will receive the following email and the form will proceed through the R&I approval system.

Filling Out a Pathway Two R&I Application Form

In this section, the questions in Pathway two will be explained.

Please note that pathway two refers to applications that are clinical trials or regulated medical device trials. These applications **do not** require JREC approval, as they need approval from the National Research Ethics Committee.

This pathway includes the R&I form only and the NREC approval must be uploaded in order for R&I approval to be granted.

1. Applicant Details

These are your details that are automatically populated using the information in your Infonetica account

2. Study General Information

Short trial Title	**Please insert the shortened trial title**
Full Trial Title	Please insert the full trial title
Please provide a short lay description of the Trial	Provide a summary of the trial in plain English. Include a study description referring to: - Study background - Aims and objectives - Hypothesis - Participants – inclusion/exclusion criteria - Any testing. Ensure to clearly outline your research design.
Please list the departments in which the study is taking place.	Type the relevant departments in the box provided
What SJH Directorate is this study taking place in?	Choose the relevant department from the drop down list
What is the target disease area?	Please select one or more target disease areas from the options
Is this a multisite Trial?	If the trial is taking place in a location other than SJH, please select yes.
Please provide details of the Principal Investigator at SJH	The local PI must be and SJH employee.
Where the applicant is NOT the Principal Investigator (PI) could the applicant please confirm that the applicant please confirm that the PI is	The BI database is an internal dashboard use to visualise and track research in SJH.

happy for their name and email address to appear on the Research & Innovation BI Database	
How many participants are to be included/recruited in total from SJH?	Numerical response.
How will explicit consent be obtained from participants?	Please explain in detail how you intend to consent participants, e.g. consent forms. Template consent forms and patient information leaflets are available on the R&I Intranet Page. The R&I Team can review your documents before you submit to ethics. In this section you will be asked to upload the Participant Information Leaflet and Informed Consent Form, these are required documents.
What is the expected start date of the Trial at SJH?	Response to be specific to your project.
Who is the target population for this Study?	Please select from the list provided
Is this study a Clinical Trial or a Medical Device Trials?	If you select yes here, specific questions for Clinical Trials and Medical Device Trials will open later in the form. Only select no if your study is an SJH Staff Study.

3. SJH R&I Questions

Cancer: Is this trial cancer related?	We ask this question to track cancer related research taking place in SJH.
Clinical Research Facility (CRF): Will the trial be run using the Welcome HRB Clinical Research Facility?	We ask this so ensure the CRF is aware of upcoming projects. Selecting 'Yes' here means that your application will also be reviewed and approved by our CRF manager.
If you select Yes to 'will the study, be run in the Wellcome HRB Clinical research Facility', the following questions will open up:	• **Please list the Research Team including Sub-Investigators and other Research Staff** We ask this to maintain oversight of researchers coming on site at SJH or accessing patient data. It is especially important to list any non-SJH staff as they are required to submit a non-disclosure agreement (NDA) and may also need to undergo Garda Vetting. • **Please select the project type**

	• **Please select the type of support required** We ask this to define the resources that the project will require., please select from the options listed • **CRF Project Number** This is used to liaise with the CRF regarding your CRF application
Pharmacy: Will the trial require support from either the hospital or CRF pharmacy?	We ask this to define the resources that the project will require. If yes, choose which pharmacy in the next question.
Hospital Resources: Select the hospital resources that will be used for this trial	We ask this to define the resources that the project will require.
Nursing Research Access Committee: Are nurses or healthcare assistants participants in the trial?	If your project involves Nurses or Healthcare Assistants (HCAs) your application it will need to be reviewed and approved by NRAC. Selecting 'yes' here opens the NRAC specific questions that **must be completed** if Nurses or HCAs are the subject of your application.
If 'yes' the following questions will open up: Responses in this section will be reviewed by the Nursing Research Access Committee.	• **Short Study Title** (same as in general information section) • **Full Study Title** (same as in general information section) • **Please provide a brief lay (plain English) description of the study** • **List the study aims and objectives** • **Describe the research design/methodology of the study** – explain your research design • **Please provide details on the study sample & the sampling technique** – be specific here, name the wards, number of staff, how you will access staff • **Who is the Gatekeeper for this study**? Please provide; full name, work position & Dept/Directorate – this should ALWAYS be an SJH employee • **List the inclusion criteria of the study** • **List the exclusion criteria of the study** • **Does this study require ethics approval? Ethical approval is required for ALL NRAC applications.**

	○ If yes, give the name of the ethics committee and application date ○ If no, please explain why ethical approval is not required • **Please provide details on how data will be managed to ensure confidentiality & security** • **Outline your plan for the dissemination of the study findings** • **Has the local CNM/Manager been informed of this study**? If yes, please provide details (Name, Work position, Dept/Directorate) • **Please provide a reference list/bibliography** • **Please select the study documents that have been uploaded** • **Upload survey if applicable**
Does this study require ethics approval?	If you select yes, you will be prompted to provide the following details: name of the Ethics Committee, date of application & date of approval (specify if pending)

4. Trial Information

Please provide the EudraCT /CTIS number	**Clinical Trials Information System (CTIS) is the online system for the regulatory submission, authorisation and supervision of clinical trials in the European Union and the European Economic Area. This is a requirement.**
Which of the following best describes your Trial? 1. **Clinical Trial of an Investigation Medicinal Product - Regulation 536/2014** 2. **Medical Device - Regulation (EU) 2017/745** 3. **In Vitro Diagnostic Medical Device - Regulation (EU) 2017/746**	Please select which of the following options apply to your project. Each option will open a sub question.

If 1. Clinical Trial of an Investigation Medicinal Product - Regulation 536/2014

Please select the trial category • Phase I • Phase II • Phase III • Phase IV	If your project is a Clinical Trial of an Investigation Medicinal Product - Regulation 536/2014, please select the appropriate phase.
If 2. Medical Device - Regulation (EU) 2017/745 **Please select the article under which your medical device trial falls** • Article 62: Non-CE Marked medical device/Medical device with existing CE Mark for use outside intended purpose • Article 74: CE Marked medical device & intended purpose involves additional burdensome procedures for patient • Article 82: Medical device trial does not fall under Articles 62 or 74	If your project is a Medical Device - Regulation (EU) 2017/745 please select the appropriate article under which your medical device trial falls.
If 3. In Vitro Diagnostic Medical Device - Regulation (EU) 2017/746 Please select subcategory of In Vitro Diagnostic Medical Device • Companion Diagnostic: Medical device intended for use in combination with IMP during routine diagnostics • Performance Study	If your project is in Vitro Diagnostic Medical Device - Regulation (EU) 2017/746 please select the appropriate subcategory
Please provide the name and address of the Sponsor, who is legally responsible for the Trial	Response to be specific to your project. The "Sponsor" in relation to a Clinical Trials/Medical Device Trials, is the legal entity responsible for the initiation and management of, and the financing for that Clinical Trial/Medical Device Trial.
Is the Sponsor located in the EU?	Select Yes or No
Has an EU legal Representative been appointed?	Select Yes or No
If yes, Please provide the name and address of the EU Legal Representative	Response to be specific to your project

Is there a Contract Research Organisation (CRO) involved in this study?	Select Yes or No
If yes, Please provide the name and address of the CRO	Response to be specific to your project

5. Human Resources

Will any research staff NOT employed by SJH be on-site in SJH as part of this Trial (excluding monitors, auditors and inspectors)?	**We ask this because non-SJH staff accessing patients or patient data, are required to undergo Garda Vetted by SJH and sign a non-disclosure agreement. If you select yes, you must provide the details of external researchers who will be accessing SJH patients or patient data.** **You must upload the signed NDA for each external researcher who will be accessing SJH patients or patient data.** If you are unsure whether you will require an NDA. It is possible to proceed and add your NDA after submission. **Each external researcher must complete the Garda Vetting invitation form and contact research@stjames.ie** to arrange to have their IDs validated **Please note: If you are unsure about whether you will need to undergo Garda Vetting, please contact HR at humanresources@STJAMES.IE** and proceed with the application. If HR determine that Garda Vetting is required, this can be added to your application after submission.
If YES, please provide the; Name, Affiliated Institution(s) and Contact Details (email & mobile phone number), of non- SJH staff that form part of the research team or act as Co-investigators at SJH.	Enter relevant details in the text box.
Will non-SJH staff require access to SJH patients and/or SJH patient data?	
SJH Mandatory Training:	Mandatory training for all researchers in SJH are: - GDPR - Hand Hygiene

	- Children first (if your project involves children) Mandatory training can be completed on HSELandD: www.hseland.ie

6. Clinical Trial/Clinical Study Agreement

Please upload the most up to date version of the agreement.	This is necessary in order for the SJH Legal Office to review the agreement. Proposed changes to the agreement this will be noted with track changes. SJH Legal Office queries will take the form of comments. The SJH Legal Office will return the Clinical Trial Agreement (CTA) with feedback via 'Correspondences'.

7. Legal Information

Who are you employed by?	All SJH staff are covered by the Clinical Indemnity Scheme. Please use this information to answer the questions below. If you are Trinity staff and unclear how to answer the indemnity questions below, please contact Dr. Ruben Eavan Keane, Head of Clinical Sponsorship Oversight (TR&I Administration) at keaner4@tcd.ie and Tony Dowling, Insurance Manager at tony.dowling@tcd.ie. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission. If you are unclear how to answer the indemnity questions below, please contact your Institution's Legal Office.
Are all researchers and medical staff covered by the Clinical Indemnity Scheme (CIS)?	The Clinical Indemnity Scheme (CIS) covers clinical research undertaken by SJH staff or persons engaged by SJH to carry out clinical research at SJH. ALL SJH STAFF ARE COVERED BY CIS If you are Trinity staff and unclear how to answer the indemnity questions below, please contact Dr. Ruben Eavan Keane, Head of Clinical Sponsorship

	Oversight (TR&I Administration) at keaner4@tcd.ie and Tony Dowling, Insurance Manager at tony.dowling@tcd.ie. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission. If you select no, you will be prompted to give further information about the cover in place for researchers NOT covered by CIS.
Is Indemnity in place for all NON-SJH researchers?	This is for insurance purposes. If you select no, you will be prompted to explain why Indemnity is NOT in place for all NON-SJH researchers. This is for insurance purposes. If you select no, you will be prompted to explain why Indemnity is NOT in place for all NON-SJH researchers. If you are unsure about the indemnity in place for non-SJH researchers, you must contact their institutions legal department. PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission.
Hospital sign off: Do any contracts with third party organisations associated with this study require execution by the hospital (hospital sign off)?	The following studies are often associated with contracts for hospital sign off; multi-site studies, studies with sponsor funding, studies with grant awarded funding etc. It is essential that any research contracts are reviewed by the SJH Legal Office. If you select yes here, you will be prompted to upload the agreement/ contract so that the SJH Legal Office can review and arrange execution.
Document upload	- Clinical Trial Indemnity Form - Insurance certificate - AON Approval

8. Financial Details

Is there funding in place for this study?	If you select yes, further questions will be opened. If you select no, you can move to the next section.
If yes, What is the nature of the funding? **If yes, What is the source of the funding?** **If no, will there be additional costs to SJH outside of patient standard of care or normal working hours e.g. overtimes?**	Tick relevant box Who Is providing the funding? If there are additional costs, you will be prompted to answer whether alternative funding is available.
I confirm that the PI has provided study costing details to the SJH Research Finance Manger (researchfinance@stjames.ie) and that these costings have been validated by the SJH Research Finance Manger	This is an essential step for any research funding. All research funding MUST go through an SJH research bank account. As the SJH Research Finance Manager sets up the research account and internal order number for invoices.

9. Document Upload

Research Ethics Approval/ National Research Ethics Committee Approval/CTIS Part 2 Approval	CTIS covers ethics AND HPRA If you have university ethics for a staff study, upload here.
Health Products Regulatory Authority Approval	If CTIS is provided, HPRA is not necessary.
Health Research Consent Declaration Committee Approval	Research involving participants who are unable to provide informed requires HRCDC approval for the protection of the participants and researchers. You must upload a copy of the Health Research Consent Declaration Committee (HRCDC) application **and** approval letter; these are required documents if your project involves individuals unable to provide consent.
Site Specific Assessment/Site Assessment Template	

Data Protection Impact Assessment	
Data Protection Agreement(DPA)/Data Sharing Agreement (DSA)	
Additional Data Protection Documents	• Standard Contractual Clauses (SCCs) • Participant Information Leaflet (PIL) • Participant Consent Form (CF)
Letter of Authorisation	
Study Protocol	

Actions

Project ID: 4710

Submission Number: 3920:

Submission Date: 07.Nov.2024 12:20

Dear Danielle Keane,

The SJH R&I Office has reviewed your R&I application and further information is required.

The following comments were made:

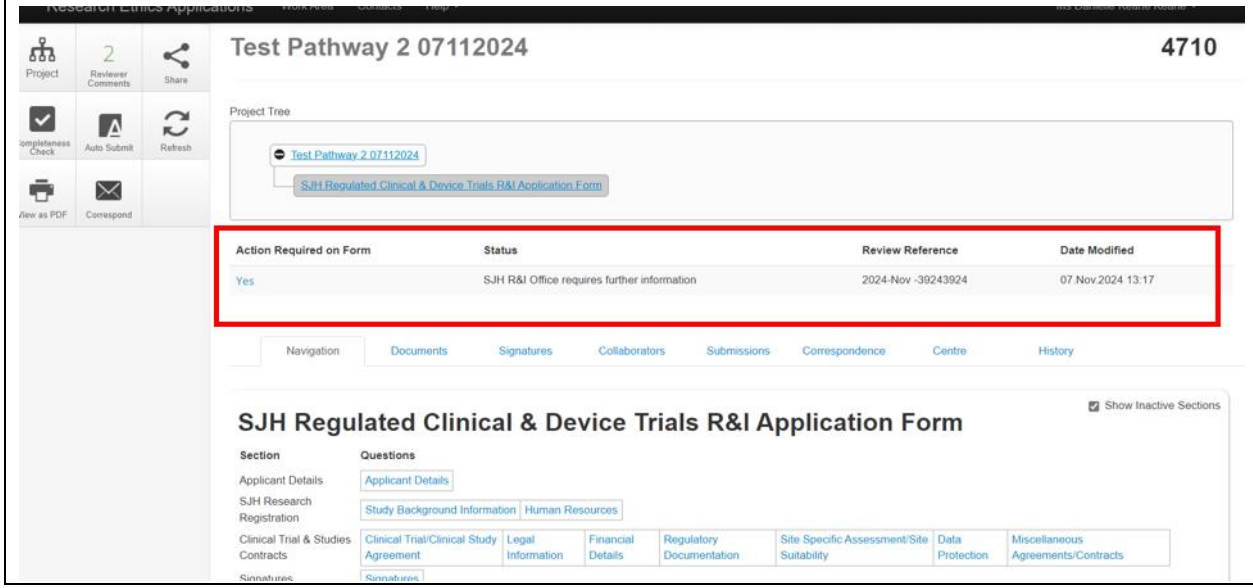
Title	
2.1.2 Full Trial Title	spelling
Please select the Class 1 sub class	test comment

Please resubmit once all comments have been addressed.

Link: https://SJH-TUH.forms.ethicalreviewmanager.com/ProjectView/Index/4710

Kind regards,

SJH R&I Office



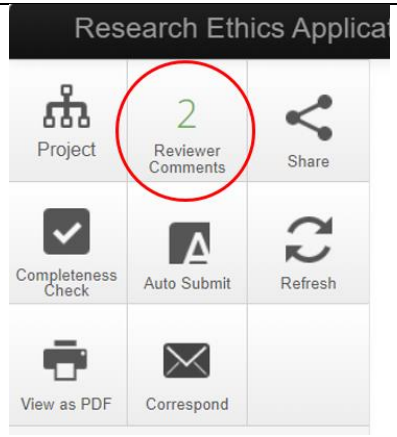
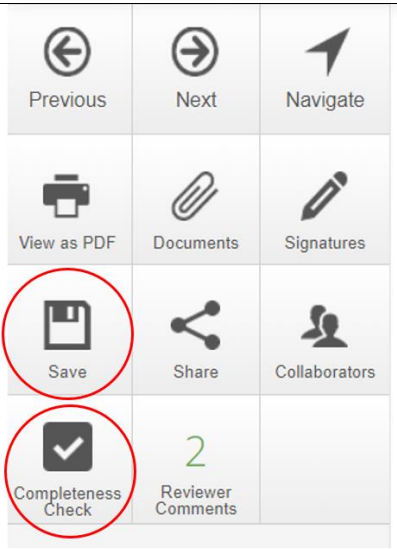
Further Information Required

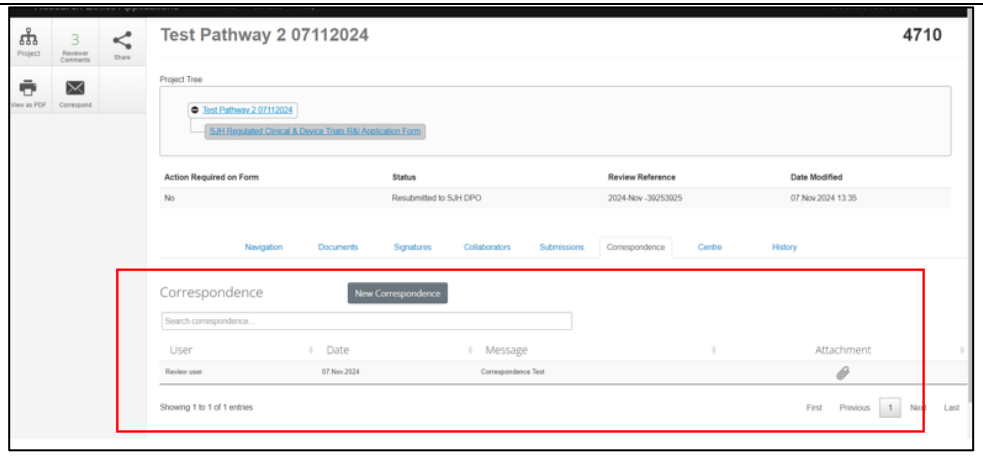
When you have submitted your application, it is possible that a reviewer may request further information or leave comments to be addressed.

When this happens, you will receive an email inviting you to address this request by following the link.

When an action on the form is required from the applicant, such as further information, this will also appear on your Infonetica account when you click on the application

Tip: You can also use this area to check the status of your application!

	Reviewer comments will appear in your action pane on the left side of your screen. Click 'reviewer comments' to open a dialog box of all comments on your application. Use this dialog box to click on a comment and address it. Please address **ALL comments** before resubmitting your application.
	While you are addressing comments, ensure that you save all the changes you make. When you have addressed all comments, select 'completeness check' to resubmit your application for review.



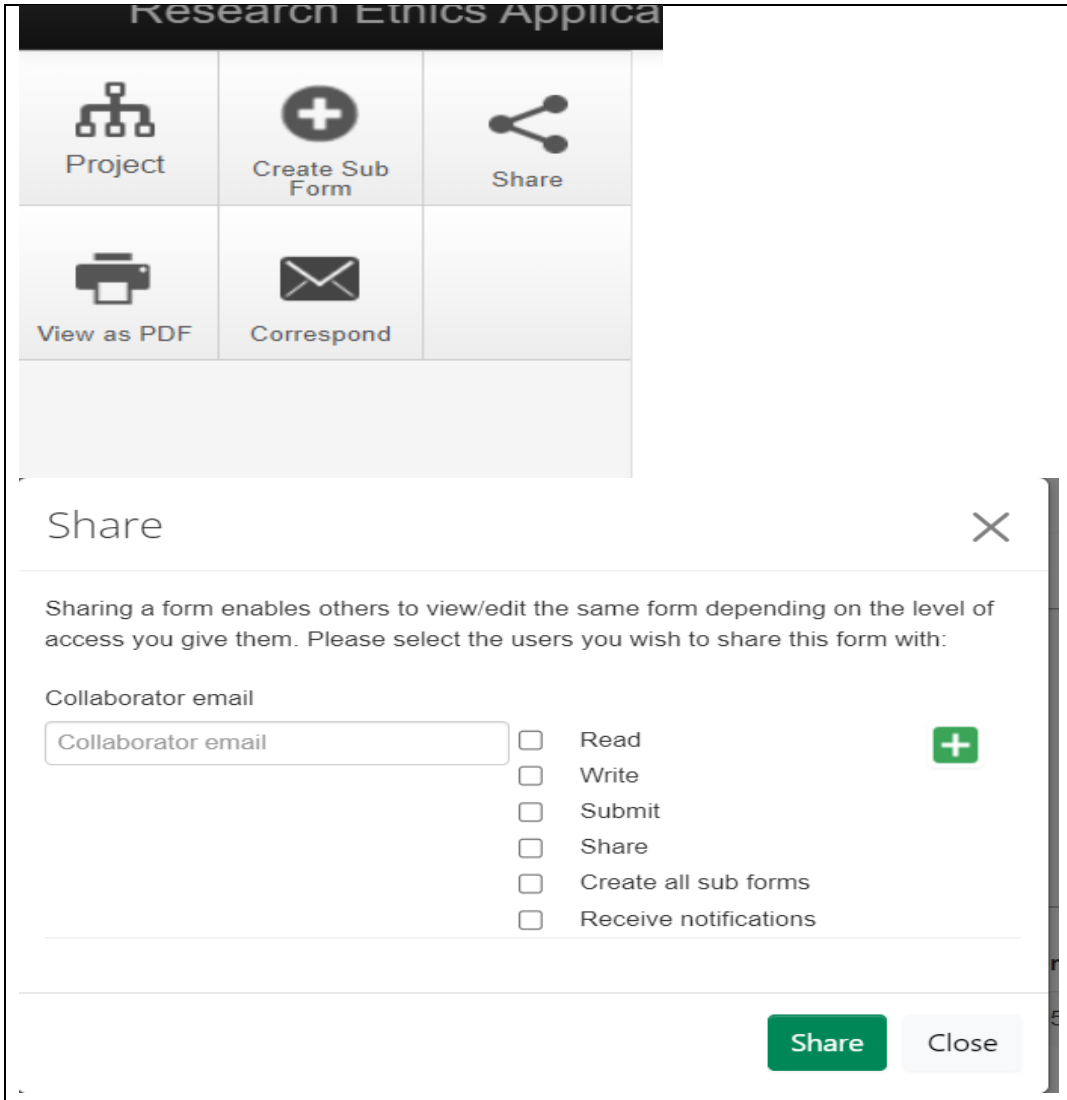
New Correspondence

Documents uploaded as part of an application are reviewed as part of this process. Reviewers can leave feedback and comments on documents.

This feedback is returned to the applicant in the form of a ‘correspondence’ within Infonetica

Download the document and address the feedback and all comments.

Re-upload the **updated documents** as a ‘new correspondence’



Sharing your Application Form

Applicants can share the R&I application with their team at any phase of the study.

Click '**share'** from the navigation pane on the left to open a dialog box containing options to enter the collaborator email and level of access to provide.

When sharing a form, you can enable others to **view/edit** the same form depending on the **level of access** you give them**.**

Use the dialog box to enter the information and click share.

Note: the application can only be shared with registered Infonetica users.