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# **RESEARCH APPLICATIONS**

## **INFONETICA TRAINING 2025**

Research & Innovation Team  
[research@stjames.ie](mailto:research@stjames.ie)

# QUALITY IMPROVEMENT = QSID

From August 2024 R&I no longer accepts Quality Improvement(QI) projects. They are instead registered with QSID, through the below link.  
Clinical Audit - St James's Hospital

Intranet Page → Quality Safety → Effective Care → Clinical Audit

St James's Hospital Intranet

Search the entire site... Search

A-Z of Departments: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Alerts Education On Campus Quality Safety Resources Staff

Latest News:

**Complaint Management Survey for Staff System**  
 Please share your experience of managing complaints with the Patient Experience Office by completing this survey. It takes less than 2 minutes to complete. [Read more...](#)

Alerts	Education	On Campus	Quality Safety	Resources	Staff
COVID-19	CLD	News	Safe	Useful Links	Communications
SIH Flu Fighters	DSIDC	Departments	<u>Effective Care</u>	Hospital Forms	Ethics
Medication Safety	eLearning	EPR & PAS Support	Person Centred Care	IMS Service Desk	On Call/Rotas
MEP	Post Grad Centre	STARS	Improvement	Medication Links	Phone Directory
Blood Transfusion	Research/Innovation	Staff Restaurant	QSI Programmes	Up To Date	Relocation / Rental
PCHCAI Updates	NPDU	Smartertravel	QSI Updates	IV Guidelines	Events Calendar
Safety Alerts	TCD School of Med	Staff Wellbeing	PPPGs	LabMed User Guide	Vacancies

Clinical Audit

Service Evaluation

Usual Practice Study

# INTRODUCTION

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

1. Ethical approval (from [Joint Research Ethics Committee \(JREC\)](#) or [National Research Ethics Committee \(NREC\)](#))

**AND**

2. Hospital approval via the Research & Innovation Office

**R&I applications will now be submitted through Infonetica, the same platform as JREC applications. The R&I form will be a sub-form of the JREC form.**

## **Benefits:**

- The two forms are connected, i.e. your responses to questions in the JREC form will automatically populate duplicate questions in the R&I form.
- More streamlined application process
- 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. Eg: DPIA

# APPLICATION PATHWAYS – WHAT DOES THIS MEAN?

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## PATHWAY 1

- Use this pathway when you are applying for **BOTH** JREC and R&I approval.

## 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

# TYPE OF STUDIES UNDER BOTH PATHWAYS

## PATHWAY I

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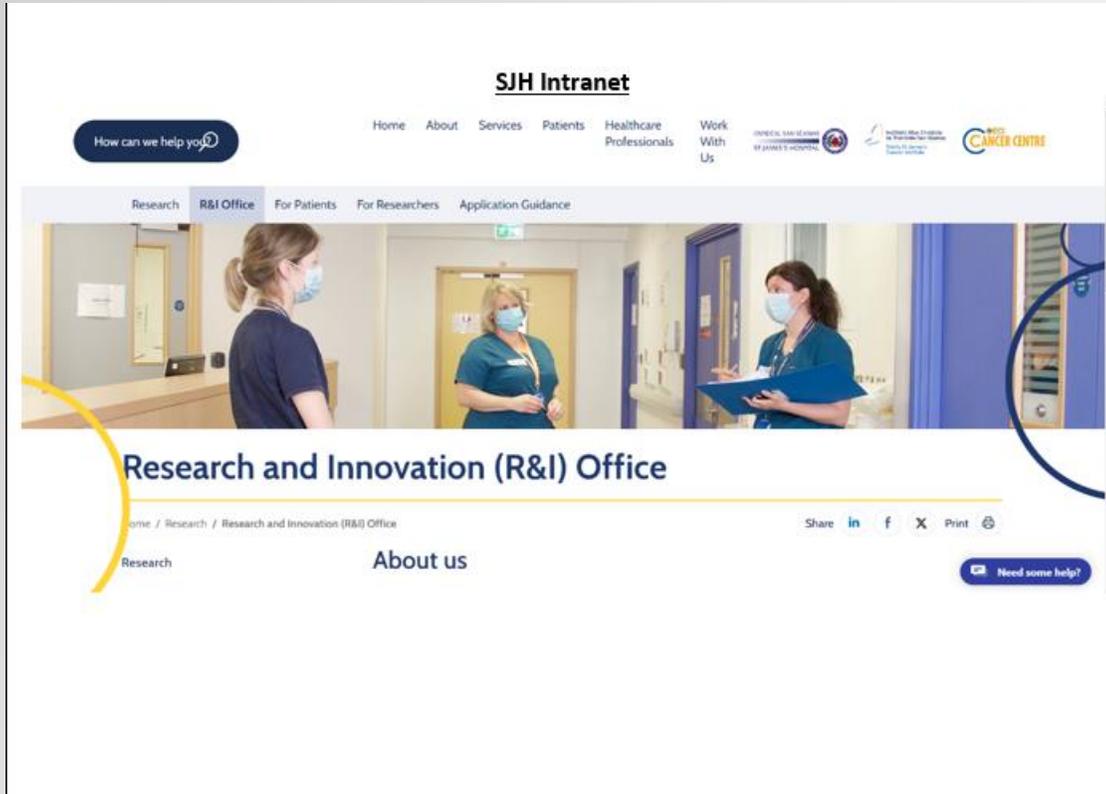
- Retrospective Chart Review
- Observational Research Study
- Translational Research Study
- Device Trial - Not subject to Medical Device Regulation
- Randomised Controlled Trial
- Pilot Study
- Feasibility Study
- Hospital Staff - Survey/Questionnaire, without ethics approval
- Hospital Staff - Interviews/Focus Groups
- Hospital Staff - ANONYMOUS Survey/Questionnaire, without ethics approval
- Patient - Survey/Questionnaire
- Patient - Interviews/Focus Groups
- Patient - ANONYMOUS Survey/Questionnaire
- Case Study (including 5 or more patients)
- Innovation Project e.g. Consultant Spark/Innovation Fund
- Systematic Review

## PATHWAY 2

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- Clinical Trial
- Medical Device Trial
- Clinical Trials involving Ionizing radiation
- Case Study (Less than 5 Patients)

# Where to find the application form ?



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 R&I Intranet page](#)

If you are not SJH Staff, the application is available on the public [R&I website](#).

**Please read the following before proceeding:**

Please only use the browser **Chrome** to access this review portal.

The system has the following functions:

**1. Research Ethics review:**

- For new studies: select "Research-Main Application Form".
- For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".
- Register the study and you will be able to submit an amendment or report.

**2. Registration of research taking place in TUH:**

- For new studies: select "Research-Main Application Form".
- For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".

**3. Clinical Audit/Service Evaluation/Quality Improvement Initiative:**

- TWO PATHWAYS:
- **TUH ONLY** - for studies taking place in TUH. Clinical Audit submitted to Sinead Palmer and Service Evaluation/Quality Improvement Initiative sent to Mary Hickey.
- **SJH ONLY** - Letter requests only: select "Non-research: Clinical Audit/Service Evaluation/Quality Improvement Initiative registration"

**4. Registration of Innovation Ideas and Projects in TUH**

- for new ideas or projects select 'Innovation' under Create Project
- Please link with innovation to discuss your idea/proposal prior to submission (innovation@tuh.ie)
- 

Please use the login button to the right (top of page) when you are ready to proceed.

Select 'Create Project' to begin your application.



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

<https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login>

# Log in or Register as a New User



The form is for logging in or registering as a new user. It features logos for Tallaght University Hospital, Ospidéal Ollscoile Thamhlachta, and Ospidéal San Séamas. The text identifies the Research Office and the St James's Hospital/Tallaght University Hospital Joint Research Ethics Committee. The login section includes fields for Email Address\* and Password\*, a Log in button, a New User button, and a link for Forgotten Password.

 **Tallaght University Hospital** | Ospidéal Ollscoile Thamhlachta  
An Academic Partner of Trinity College Dublin



**Research Office**

**St James's Hospital/Tallaght University Hospital Joint Research Ethics Committee**

**Log in**

Email Address\*

Password\*

[Log in](#) [New User](#) [Forgotten Password](#)

## Logging in

If you have already used Infonetica to submit an ethics application, you will already have an account (you can use the 'forgot password' function to reset this if needed).

If you are a new user, select 'register' to create a new account on Infonetica – **PLEASE REGISTER USING YOUR SJH/TCD/TUH/INSTITUTIONAL EMAILS.**

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

Research Ethics Applications    Work Area    Contacts    Help    **Beta Test Mode**

Create Folder    Delete Folder    Create Project

Delete Project    Duplicate Project    Move Project

Transfer

## Work Area

Notifications: 15    Signatures: 0    Transfers: 0    Shared: 0

### Projects

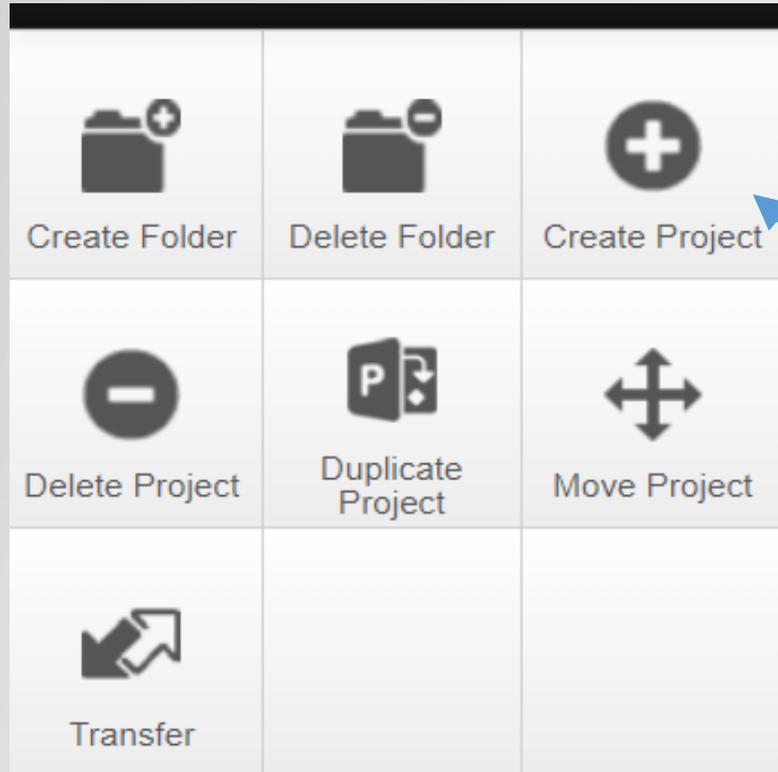
Search Projects

Project Title	Project ID	Owner	Date Created
> Test 18.09.2024	4631	Ms Danielle Keane Keane	18.Sep.2024 11:24
> Test 03092024	4610	Ms Danielle Keane Keane	03.Sep.2024 12:05
> TEST 2 31072024	4568	Ms Danielle Keane Keane	31.Jul.2024 13:13
> TEST 310724	4567	Ms Danielle Keane Keane	31.Jul.2024 13:09

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



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

A dialog box will open.

**Create Project** [X]

Project Title\* (Max 200 characters)

Form\*

Centre\*

**Create Project** [X]

Project Title\* (Max 200 characters)

Form\*

- Please select...
- Pathway 2: External Ethical Approval For Staff Studies & Regulated Clinical & Device Trials R&I App
- Research - Previously JREC Approved - Research registration Form
- Research - SJH/TUH Research Registration and JREC Form
- SJH ONLY - Clinical Audit/Quality Improvement/Service Evaluation
- TUH Innovation
- TUH ONLY - Clinical Audit/Quality Improvement Initiative/Service Evaluation

- 1) Input your project title.
- 2) Select the form you wish to complete from the drop-down box.
  - If your study requires **BOTH** JREC application and an R&I application you must select **'SJH/TUH Research Registration and JREC Form'**. This will open the JREC form.
  - The JREC application form must be completed **and** submitted before an R&I application form can be created as a **Sub Form** linked to your JREC submission. The R&I sub form is called Pathway 1: SJH R&I Application Form Clinical Research
  - Some 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 & Staff Study that has 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

# PATHWAY I

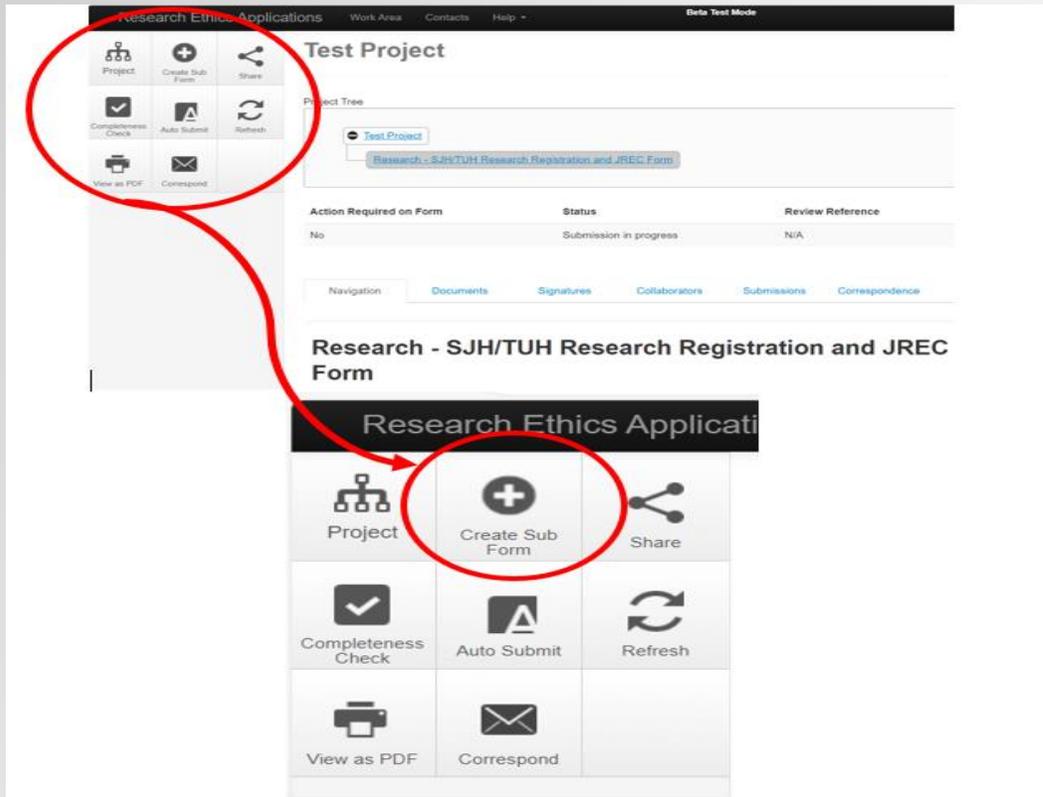
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How to create an application for projects that require **both** JREC and R&I approval

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

There are two parts:

- 1) Complete **and** submit your JREC application.
- 2) Once the JREC application is **fully submitted** the R&I application can be created as a sub form.



- 1) To create a sub-form, click the 'Create Sub Form' button in the left navigation pane.

## Create Subform ✕

Select the sub-form that you would like to apply to this form

Pathway 1: SJH R&I Application Form Clinical Research ▼

Centre

Ethics Committee - St James' ▼

[Create](#) [Close](#)

- 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'

The screenshot displays the 'Research Ethics Applications' web interface. At the top, there is a navigation bar with 'Work Area', 'Contacts', and 'Help' menus, and a user profile for 'Ms Danielle Keane Keane'. A 'Beta Test Mode' indicator is also present. The main content area shows a table with columns for 'Action Required on Form', 'Status', 'Review Reference', and 'Date Modified'. Below the table, there is a navigation menu with options like 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', 'Centre', and 'History'. The main form is titled 'SJH Research and Innovation Application Form' and includes a 'Show Inactive Sections' checkbox. The form is divided into 'Section' and 'Questions' categories. The 'Section' list includes: Background, SJH Research and Innovation Application Form, SJH Mandatory Training, Data Protection Impact Assessment (DPIA), Legal Information, Financial Details, Document Upload, and Signatures. The 'Questions' list includes: Applicant Details, General Information, Study Background Information, SJH R&I Questions, Human Resources Details, SJH Mandatory Training, Explanation of terms used in DPIA, Data Protection Impact Assessment (DPIA), Legal Information, Financial Details, Document Upload, and Sign off / Signatures. A sidebar on the left contains various utility icons such as Project, Duplicate Form, Delete Form, Share, Transfer Form, Completeness Check, Auto Submit, Refresh, View as PDF, and Correspond.

## 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.

The screenshot displays the 'Research Ethics Applications' web interface. The top navigation bar includes 'Work Area', 'Contacts', and 'Help'. The user is identified as 'Ms Danielle Keane Keane'. The interface features a left-hand sidebar with navigation and utility icons: Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Collaborators, and a Completeness Check icon. The main content area is titled 'Signatures' and contains the following elements:

- A section for 'Applicant Signature' with a blue 'Sign' button.
- An 'Important Note' section with the following text:

The applicant and Principal Investigator (PI) should not be the same person. For non clinical trial studies a hospital consultant, ADON or manager can act as PI.

The Principal Investigator must be a SJH employee (i.e. have a SJH e-mail address and personnel number).

In multisite studies a SJH clinician (as described above), involved in this study, can act as the local PI.
- A section for 'Principle Investigator signature' with 'Request Signature' and 'Sign' buttons.

## 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.

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, as you did for your ethics application.

**NOTE: The R&I application form will not be submitted until the PI has provided a signature.**

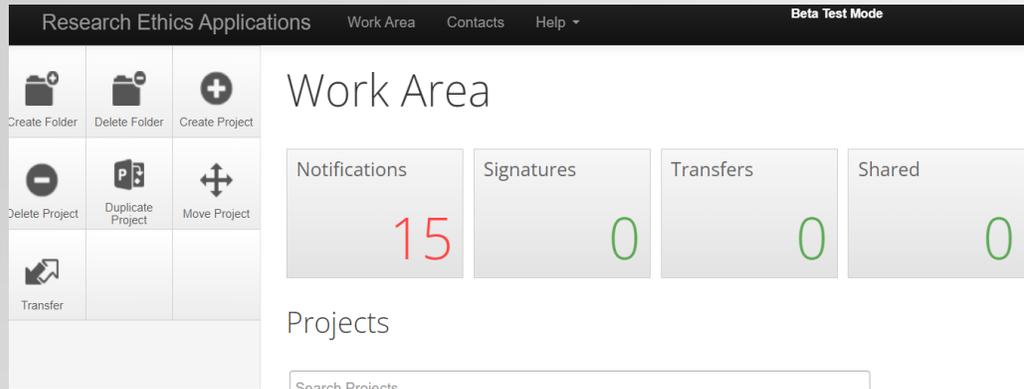
# PATHWAY 2

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How to create an application for projects that have external ethical approval but require R&I approval

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

Trials that have ethical approval from the National Research Ethics Committee (NREC) or CTIS, still require R&I approval. This application can be submitted while NREC/CTIS approval is 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'**.

The 'Create Project' dialog box is shown with the following fields and options:

- Project Title\*** (Max 200 characters): PATHWAY 2 APPLICATION FORM
- Form\***: Pathway 2: SJH R&I Regulated Clinical & Device Trials R&I Application Form
- Centre\***: Ethics Committee - St James's Hospit

At the bottom right, there are two buttons: 'Create' (highlighted in blue) and 'Close'.

The screenshot displays the 'Research Ethics Applications' web interface. At the top, there is a navigation bar with 'Work Area', 'Contacts', and 'Help' menus, along with 'Beta Test Mode' and the user name 'Ms Danielle Keane Keane'. A search bar on the right contains the number '4634'. Below the search bar is a table with the following data:

Action Required on Form	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	19.Sep.2024 13:20

Below the table is a navigation menu with options: 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', 'Centre', and 'History'. The main content area is titled 'SJH Research and Innovation Application Form' and includes a 'Show Inactive Sections' checkbox. The form is divided into two columns: 'Section' and 'Questions'. The 'Section' column lists various form sections, and the 'Questions' column lists specific questions, both with blue links indicating they are to be completed.

## Starting your application

Once created, the R&I application form will appear as follows.

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

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.

The screenshot shows the 'Research Ethics Applications' interface. The top navigation bar includes 'Work Area', 'Contacts', 'Help', 'Beta Test Mode', and the user 'Ms Danielle Keane Keane'. A left-hand sidebar contains navigation and utility icons: Previous, Next, Navigate, View as PDF, Documents, Signatures, Save, Share, Collaborators, and a checked 'Completeness Check' box. The main content area is titled 'Signatures' and features a 'Signatures' header with a notification bubble. Below this is the 'Applicant Signature' section with a blue 'Sign' button. An 'Important Note' section follows, containing the text: 'The applicant and Principal Investigator (PI) should not be the same person. For non clinical trial studies a hospital consultant, ADON or manager can act as PI. The Principal Investigator must be a SJH employee (i.e. have a SJH e-mail address and personnel number). In multisite studies a SJH clinician (as described above), involved in this study, can act as the local PI.' Below the note is the 'Principle Investigator signature' section with blue 'Request Signature' and 'Sign' buttons.

## 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.

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.

# ACTIONS

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**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!

The screenshot shows the application management interface for 'Test Pathway 2 07112024' (ID: 4710). A table highlights the 'Action Required on Form' section:

Action Required on Form	Status	Review Reference	Date Modified
Yes	SJH R&I Office requires further information	2024-Nov-39243924	07 Nov 2024 13:17

Below the table, the application form structure is visible, including sections like 'Applicant Details', 'Study Background Information', and 'Human Resources'.



## Addressing Review Comments

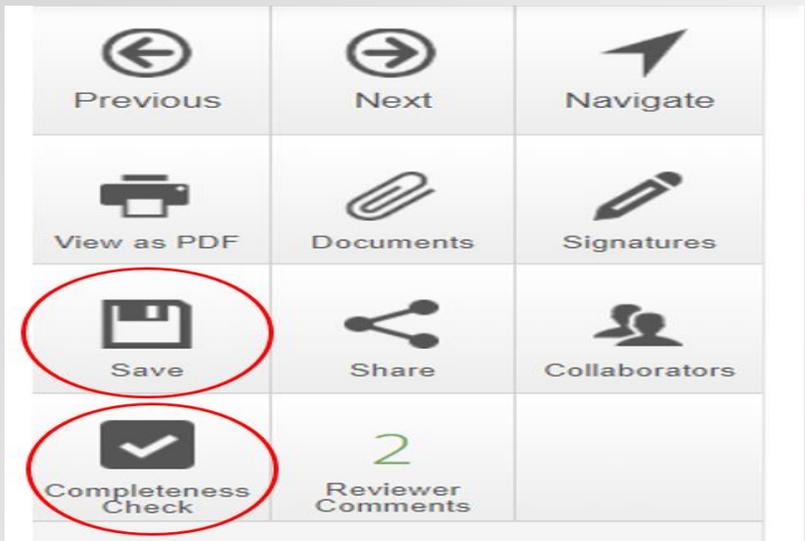
Reviewer comments will appear in your action pane on the left side of your screen.

Click 'reviewer comments' to open a dialog box containing 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 that you make.

When you have addressed all comments, resubmit your application for review.



Test Pathway 2 07112024 4710

Project Tree

- Test Pathway 2 07112024
  - SJH Regulated Clinical & Device Trials B&A Application Form

Action Required on Form	Status	Review Reference	Date Modified
No	Resubmitted to SJH DPO	2024-Nov-30253925	07 Nov 2024 13:35

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

Correspondence [New Correspondence](#)

Search correspondence...

User	Date	Message	Attachment
Review user	07 Nov 2024	Correspondence Test	

Showing 1 to 1 of 1 entries

First Previous 1 Next Last

## New Correspondence

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

This feedback is returned to the applicant in the form of a 'correspondence' within Infonetica i.e. message within the system.

Correspondence Message

Date 07.Nov.2024 2:25 PM

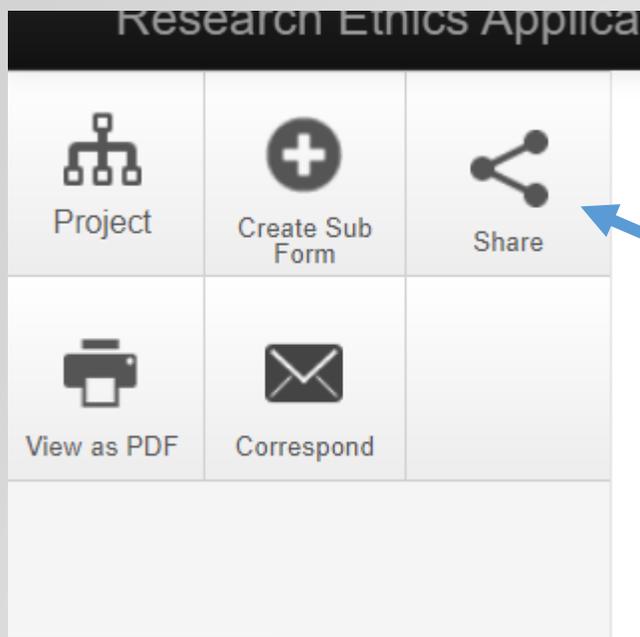
Correspondence Test

Attachment Name	Download
DSA- Data Sharing AgreementTemplate_V4_22Aug2023.docx	Download

Close

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.

### Share

Sharing a form enables others to view/edit the same form depending on the level of access you give them. Please select the users you wish to share this form with:

Collaborator email

- Read
- Write
- Submit
- Share
- Create all sub forms
- Receive notifications

**Abbreviations**

- CRF:** Clinical Research Facility
- DPIA:** Data Protection Impact Assessment
- HPRA:** Health Products Regulatory Authority
- JREC:** Joint Research Ethics Committee
- NRAC:** Nursing Research Access Committee
- PI:** Principal Investigator
- R&I:** Research and Innovation
- SJH:** St James's Hospital
- NDA:** Non Disclosure Agreement
- MTA:** Material Transfer Agreement
- DTA:** Data Transfer Agreement

**Research & Innovation Application**

I need to apply for R&I APPROVAL.

Go to Joint Research Ethics Committee (JREC) Webpage.

It is recommended to have the following documents prepared:

Garda Vetting Form/Checklist, NDA ,MTA ,DTA, Indemnity Agreements, Other applicable agreements. Templates are available in the 'help' section of the application form. All forms can also be found on [the R&I Intranet Page](#)

Note that the late submission of these documents may cause delays.

I already have:

Clinical Trial Information System Approval (CTIS)  
**OR**  
 NREC Approval  
**OR**  
 Local/University Ethics Approval

**JREC Approval required/previously obtained**

Create/ Select the JREC Application relevant to your R&I Application, The JREC must be fully submitted but does not need to be fully approved before beginning the R&I Application.

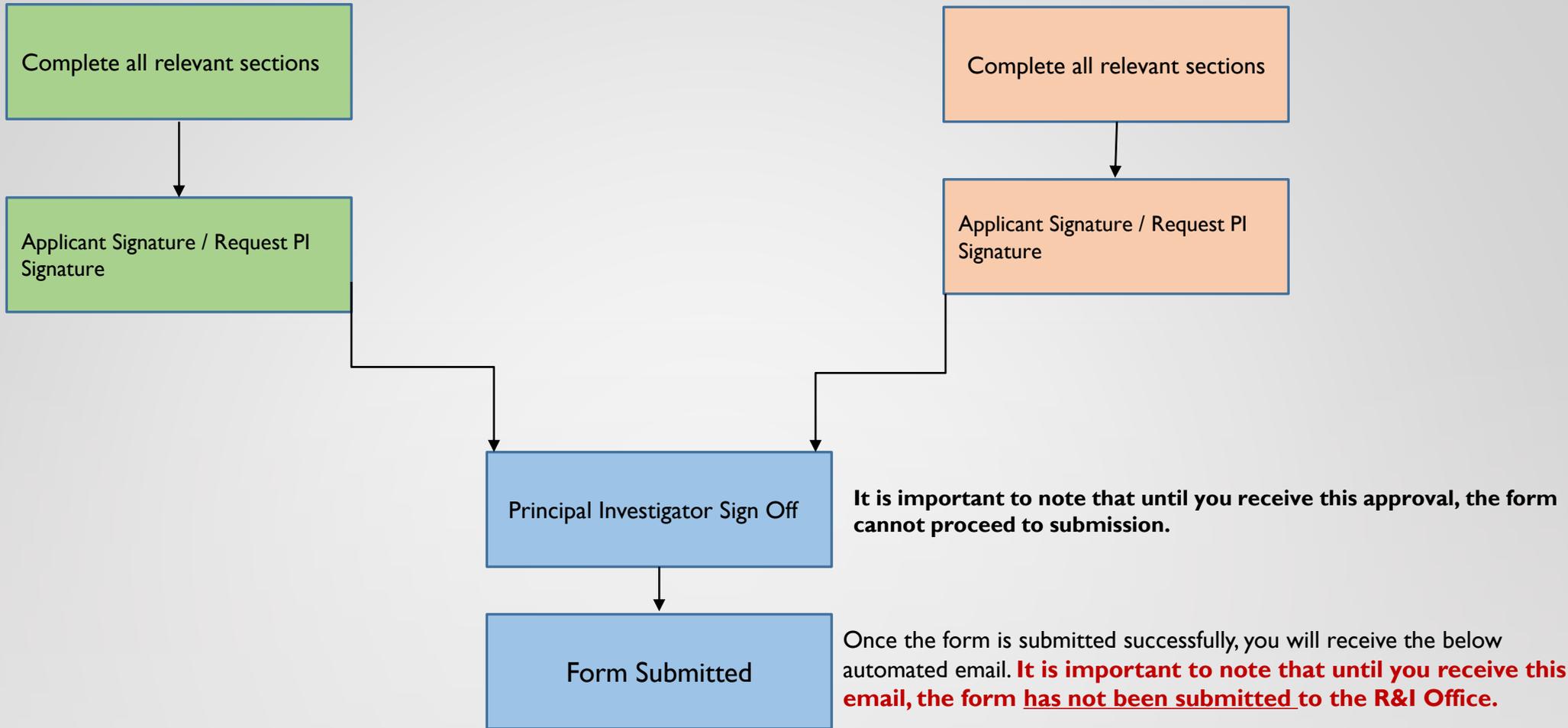
**(Pathway 1)**  
 Create the SJH R&I Application Form Clinical Research as a sub form of your JREC form

**Yes**

**(Pathway 2)**  
 External Ethical Approval For Staff Studies & Regulated Clinical & Device Trials R&I Application

Select the study type most suitable to your project. Staff Survey / Clinical Trial/ Medical Device Trial





\*\*\*\* 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%2fsh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2flogin&umid=79562d8e-6631-455e-9998-35e299a76c20&auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66>

After Application is Submitted

# R & I Review

If Applicable, Nursing Research Access Committee Review

If Applicable, Clinical Research Facility Review

If additional information is required by R&I, the form will be returned with comments. In such cases, please address **all comments** and resubmit your application for further review

## Data Protection Officer Review

If additional information is required by the DPO, the form will be returned with comments. In such cases, please address **all comments** and resubmit your application for further review

## Legal Review

**Applicant Sign Off** required for application resubmission following requested changes from R&I/DPO/Legal.

## Chief Executive Officer Sign Off

## Final R&I Sign Off

The NRAC reviews applications, where nurses and/or healthcare assistants are subjects in the study.  
<https://www.stjames.ie/intranet/ocampus/departments/nursingresearch/>

CRF reviews the application, when the study be run in tandem with the Wellcome HRB Clinical Research Facility. (<https://www.sjhcrf.ie/> )

## Questions?

For further information, contact the Research & Innovation Office -

Email: [research@stjames.ie](mailto:research@stjames.ie)

Phone Number: 01 – 415 1978

# Thank you

