

# Research and Innovation

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RESEARCH APPLICATION FORM GUIDANCE, JULY 2025

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

# Contents

<b>Explanation of Terms</b> .....	3
<b>Important Information about the New R&amp;I Application Process</b> .....	4
How does it work?.....	4
What about Clinical Trials with NREC <sup>1</sup> or CTIS <sup>2</sup> approval? .....	4
Application Pathways – what does this mean?.....	4
Choosing the Correct R&I Application Pathway .....	6
<b>Getting Started</b> .....	8
Where to find the application form.....	8
Log in or Register as a New User .....	10
<b>Creating an R&amp;I application</b> .....	12
<b>R&amp;I Application Pathway 1: Applying for JREC and R&amp;I approval (non-Clinical Trial/Medical Device Trials)</b> .....	17
How to create a sub-form .....	17
<b>Ensuring your Pathway 1 Application is Correctly Submitted</b> .....	21
1. Applicant Sign Off.....	21
2. PI Sign Off .....	21
<b>Completing a Pathway 1 R&amp;I Application Form</b> .....	25
1. Applicant Details.....	25
2. General Information .....	25
3. Study Background Information.....	27
4. SJH R&I Questions .....	27
5. Human Resources Details.....	29
6. SJH Mandatory Training .....	30
7. Explanation of terms used in DPIA .....	31
8. Data Protection Impact Assessment .....	31
9. Legal Information .....	33
10. Financial Details.....	34
11. Document Upload .....	35
<b>R&amp;I Application Pathway 2: External Ethical Approval for SJH (ONLY) Staff Studies &amp; Regulated Clinical &amp; Device Trials</b> .....	36
<b>Ensuring your Pathway 2 Application is Correctly Submitted</b> .....	39
1. Applicant Sign Off.....	39
2. PI Sign Off .....	39
<b>Filling Out a Pathway 2 R&amp;I Application Form</b> .....	43
1. Applicant Details.....	43

2. Study General Information .....	43
3. SJH R&I Questions .....	44
4. Trial Information (including interventional studies involving medicinal products, medical devices, or non-drug interventions) .....	46
5. Human Resources .....	48
6. Clinical Trial/Clinical Study Agreement.....	49
7. Legal Information .....	50
8. Financial Details.....	51
9. Document Upload .....	52
Further Information Required .....	53
New Correspondence .....	55
<b>Frequently Asked Questions .....</b>	<b>58</b>
1. Do I need an R&I application? .....	58
2. Do I choose Pathway 1 or Pathway 2? .....	58
3. What do I do if my PI is not an employee of St James’s Hospital?.....	59
4. My PI is not showing up when I use their email to request a signature .....	59
5. What do I do if I created my Infonetica account using a non-institutional email address?...	59
6. Do I need to list everyone on my research team?.....	59
7. Who counter signs my NDA?.....	59
8. How can I check if my application is fully submitted?.....	59
9. I have received an email stating that my application has been returned with comments, how do I view the comments? .....	60
10. My application has been returned with feedback/ comments but it is locked for editing, how to I unlock the form? .....	60
<b>Table: Document Upload required by Study design .....</b>	<b>61</b>

## Explanation of Terms

BI	Business Interface
CE-Marked	Conformité Européenne (complies with the relevant European Union legislation)
CIS	Clinical Indemnity Scheme
CNM	Clinical Nurse Manager
CRF	Clinical Research Facility
CTA	Clinical Trial Agreement
CTIS	Clinical Trial Information System
DPIA	Data Protection Impact Assessment
DSA	Data Sharing Agreement
EU	European Union
GDPR	General Data Protection Regulations
HCA	Health Care Assistant
HPRA	Health Products Regulatory Authority
HR	Human Resources
HRB	Health Research Board
HRCDC	Health Research Consent Declaration Committee
ICF	Informed Consent Form
JREC	Joint Research Ethics Committee
MTA	Material Transfer Agreement
NDA	Non-Disclosure Agreement
NRAC	Nursing Research Access Committee
NREC	National Research Ethics Committee
PI	Principle Investigator
PIL	Participant Information Leaflet
QI	Quality Improvement
QSID	Quality and Safety Improvement Department
R&I	Research and Innovation
SCCs	Standard Contractual Clauses
SJH	St James's Hospital
TUH	Tallaght University Hospital

# 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 via Infonetica, the same platform used for JREC applications.**

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<sup>1</sup> or CTIS<sup>2</sup> 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.

For the purposes of this guidance document, 'clinical trial' includes interventional studies involving medicinal products, medical devices, or non-drug interventions.

## 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 Tallaght University Hospital (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 / Institutional Ethics)**

⚠ Important clarification: If your study involves SJH staff only and has university ethics approval, but includes data collection, access, or processing at SJH, you must use Pathway 2. Even though patient involvement is not required, R&I approval is still mandatory due to the use of hospital infrastructure or access to identifiable staff data. A flowchart or checklist is available on the R&I intranet to help determine the appropriate pathway.

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

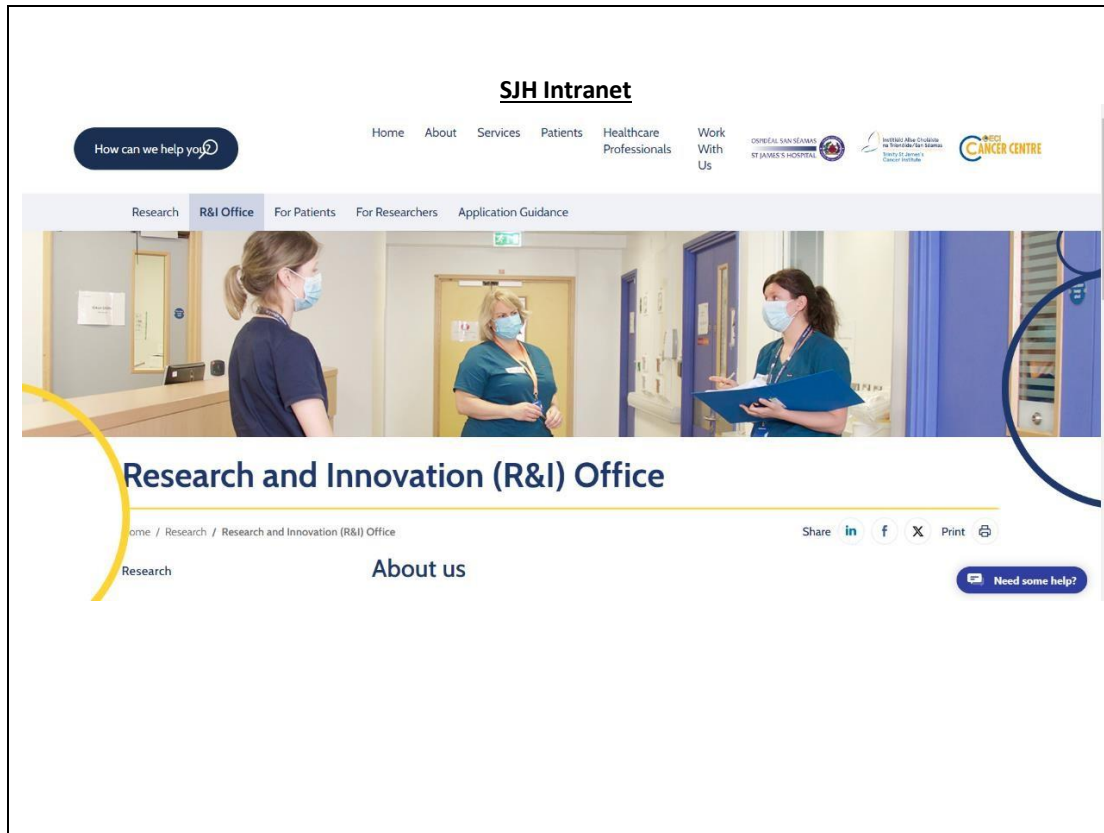
**Table 1: Choosing the Correct R&I Application Pathway**

<b>Study Type</b>	<b>SJH Staff Only</b>	<b>SJH Patients involved</b>	<b>External Ethics Approval (CTIS, NREC, Institutional ethical approval)</b>	<b>Uses SJH Data or Systems</b>	<b>Required Pathway</b>
Retrospective chart review involving SJH patients	✗	✗	✗ (JREC required)	✓	<b>Pathway 1</b>
Pilot Study, Feasibility Study	✗	✓	✗ (JREC required)	✓	<b>Pathway 1</b>
Patient survey/ interview/ focus group	✗	✓	✗ (JREC required)	✓	<b>Pathway 1</b>
Case Study with 5 or more cases	✗	✓	✗ (JREC required)	✓	<b>Pathway 1</b>
Multisite observational study with CE-marked devices	✗	✓	✓	✓	<b>Pathway 2</b>
Case Study with less than 5 cases	✗	✓	Ethics not required	✓	<b>Pathway 2</b>
Clinical Trials involving Ionising Radiation	✗	✓	✓	✓	<b>Pathway 2</b>
SJH as a site of advertisement ONLY (no recruitment)	✗	✗	✓	✗	<b>Pathway 2</b>
Staff study approved by university, no SJH systems	✓	✗	✓	✗	<b>Pathway 2</b>
Staff Survey	✓	✗	✓	✓	<b>Pathway 2</b>

Study Type	SJH Staff Only	SJH Patients involved	External Ethics Approval (CTIS, NREC, Institutional ethical approval)	Uses SJH Data or Systems	Required Pathway
Investigator-led drug trial at SJH	✗	✓	✓	✓	Pathway 2
Medical Device Trials subject to Medical Device Regulations	✗	✓	✓ (NREC and CTIS only)	✓	Pathway 2
Quality improvement project	✓	✗	✗	✗	R&I application not required, register project directly with QSID

# Getting Started

## Where to find the application form




### Where to find Infonetica

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

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](#).

<p>Research Ethics Applications    Help ▾    <b>Log in</b></p> <p><b>Please read the following before proceeding:</b></p> <p>Please only use the browser <b>Chrome</b> to access this review portal.</p> <p>The system has the following functions:</p> <ol style="list-style-type: none"><li><b>1. Research Ethics review:</b><ul style="list-style-type: none"><li>• For new studies: select "Research-Main Application Form".</li><li>• For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".</li><li>• Register the study and you will be able to submit an amendment or report.</li></ul></li><li><b>2. Registration of research taking place in TUH:</b><ul style="list-style-type: none"><li>• For new studies: select "Research-Main Application Form".</li><li>• For previously reviewed studies: select "Research-Previously Reviewed Study-Research Registration Form".</li></ul></li><li><b>3. Clinical Audit/Service Evaluation/Quality Improvement Initiative:</b><ul style="list-style-type: none"><li>• TWO PATHWAYS:</li><li>• <b>TUH ONLY</b> - for studies taking place in TUH. Clinical Audit submitted to Sinead Palmer and Service Evaluation/Quality Improvement Initiative sent to Mary Hickey.</li><li>• <b>SJH ONLY</b> - Letter requests only: select "Non-research: Clinical Audit/Service Evaluation/Quality Improvement Initiative registration"</li></ul></li><li><b>4. Registration of Innovation Ideas and Projects in TUH</b><ul style="list-style-type: none"><li>• for new ideas or projects select 'Innovation' under Create Project</li><li>• Please link with innovation to discuss your idea/proposal prior to submission (innovation@tuh.ie)</li><li>•</li></ul></li></ol> <p>Please use the login button to the right (top of page) when you are ready to proceed.</p> <p>Select 'Create Project' to begin your application.</p> 	<p>This page explains the different functions/ application forms available within Infonetica.</p> <p><a href="https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login">https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login</a></p> <p>Previously, Infonetica was only used for JREC applications for both Tallaght University Hospital and St James's Hospital.</p> <p>Now SJH R&amp;I applications are also submitted through Infonetica.</p> <p>There are two R&amp;I application forms:</p> <ol style="list-style-type: none"><li>1) Pathway One: Application for clinical research that requires <b>BOTH</b> JREC and/or R&amp;I approval</li><li>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 <b>ONLY</b> require an R&amp;I approval</li></ol> <p>To log in or create an account, click 'log in' in the top right corner</p>
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## Log in or Register as a New User



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

You can use the same login details to submit your R&I applications. If needed, use the 'Forgot Password' option to reset your password.

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

Once you've entered your details and completed registration, you will receive an email inviting you to verify your account.

**Work Area** BETA

Notifications: **86**   Signatures: **0**   Transfers: **0**   Shared: **0**

**Projects**

Search Projects 
[Create Project](#)
[Create Folder](#)
[Delete Folder](#)
[Delete Project](#)
[Duplicate Project](#)
[Move Project](#)
[Transfer](#)

Project Title	Project ID	Owner	Date Created	Date Modified
Test PR-Pathway 2	5689	Ms Danielle Keane	25 Nov 2025 12:45	25 Nov 2025 12:54
Test 2 New-Annual Progress Report- Can Submit Option On	5687	Ms Danielle Keane	24 Nov 2025 13:02	24 Nov 2025 14:52
Test 1 New-Annual Progress Report- Can Submit Option Off	5685	Ms Danielle Keane	24 Nov 2025 12:35	24 Nov 2025 15:31
Test -S/H Annual Progress Report	5664	Ms Danielle Keane	24 Nov 2025 11:20	24 Nov 2025 11:52
Testing APR- New	5682	Ms Danielle Keane	24 Nov 2025 10:10	24 Nov 2025 10:33
Test for Annual Progress Report Nov 2025	5661	Ms Danielle Keane	24 Nov 2025 09:47	24 Nov 2025 10:08
SPARK VIDEO	5654	Ms Danielle Keane	21 Nov 2025 10:53	21 Nov 2025 12:29
SPark 5	5626	Ms Danielle Keane	11 Nov 2025 10:02	14 Nov 2025 11:47
SPARK TEST 4	5625	Ms Danielle Keane	11 Nov 2025 10:00	11 Nov 2025 10:00

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
- Delete projects

## Creating an R&I application

**Work Area**

Notifications: 86   Signatures: 0   Transfers: 0   Shared: 0

**Projects**

Search Projects

[+ Create Project](#) [Create Folder](#) [Delete Folder](#) [Delete Project](#)

Project Title	Project ID	Owner	Date Created
<a href="#">Test PR-Pathway 2</a>	5669	Ms Danielle Keane	25.Nov.2025 12:45
<a href="#">Test 2 New- Annual Progress Report- Can Submit Option On</a>	5667	Ms Danielle Keane	24.Nov.2025 13:02
<a href="#">Test 1 New -Annual Progress Report - Can Submit Option Off</a>	5665	Ms Danielle Keane	24.Nov.2025 12:35
<a href="#">Test -SJH Annual Progress Report</a>	5664	Ms Danielle Keane	24.Nov.2025 11:20
<a href="#">Testing APR- New</a>	5662	Ms Danielle Keane	24.Nov.2025 10:10

To create an application form, click 'Create Project' in navigation pane on the work area page.

A dialog box will open.

**Create Project** [X]

Project Title\* (Max 200 characters)

Form\*

Centre\*

**Create Project**

Project Title\* (Max 200 characters)

Form\*

- Please select...
- Pathway 2: Case Studies (< 5 Patients), 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
- SPARK CIF Pre-Approval
- 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 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'**.

	<ol style="list-style-type: none"><li>3) <b>Centre:</b> Select 'Ethics Committee – St James's Hospital/ Tallaght University Hospital.</li><li>4) Press 'Create'.</li><li>5) Please note that if you are applying from SJH, some of the drop-down options do not apply</li></ol>
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# Tracking your Application Post-Submission

**Work Area**

Notifications: 86 | Signatures: 0 | Transfers: 0 | Shared: 0

Projects

Search Projects:

[Create Project](#)
[Create Folder](#)
[Delete Folder](#)
[Delete Project](#)
[Duplicate Project](#)
[Move Project](#)

Project Title	Project ID	Owner	Date Created	Date Modified
> Test PR-Pathway 2	5669	Ms Danielle Keane	25.Nov.2025 12:45	25.Nov.2025 12:54
> Test 2 New- Annual Progress Report- Can Submit Option On	5667	Ms Danielle Keane	24.Nov.2025 13:02	24.Nov.2025 14:52
> Test 1 New -Annual Progress Report - Can Submit Option Off	5665	Ms Danielle Keane	24.Nov.2025 12:35	24.Nov.2025 15:31

You can track the status of your application at any time throughout the application process using the status bar.

To view the status bar, first select your project from your project list.

**Test 2 New- Annual Progress Report- Can Submit Option On**

[Go Back to Work Area](#)

Project

Project Tree

- Test 2 New- Annual Progress Report- Can Submit Option On
  - Research - SJH/TUH Research Registration and JREC Form
  - Pathway 1 SJH R&I Application Form Clinical Research
    - DRAFT SJH Annual Progress Report

[Project](#)
[Duplicate Form](#)
[Share](#)
[Transfer Form](#)
[View as PDF](#)
[Correspond](#)

Navigation: Documents | Signatures | Collaborators | Submissions | Correspondence | Site | History

**DRAFT SJH Annual Progress Report**  Show Inactive Sections

Section: SJH Annual Progress Report, Data Protection Annual Report

Questions: General Information, Data Protection Annual Report

**Overview**

INSIGHTS

View Comments: 1

BASIC INFO

Project: Test 2 New- Annual Progress Report- Can Submit Option On

Project ID: 5667

Form Title: DRAFT SJH Annual Progress Report

Status: SJH R&I Manager Approved

Review Reference: 2025-Nov -50525052

Last Modified: 24.Nov.2025

Action Required: No

Second, and most importantly, please ensure you have selected the correct 'branch' from your project tree.

If you have created a pathway 1 application, the project will automatically open to your JREC application branch. Only the status of your JREC application will be visible on this branch.

You must select the R&I application branch to view the status of your R&I application.

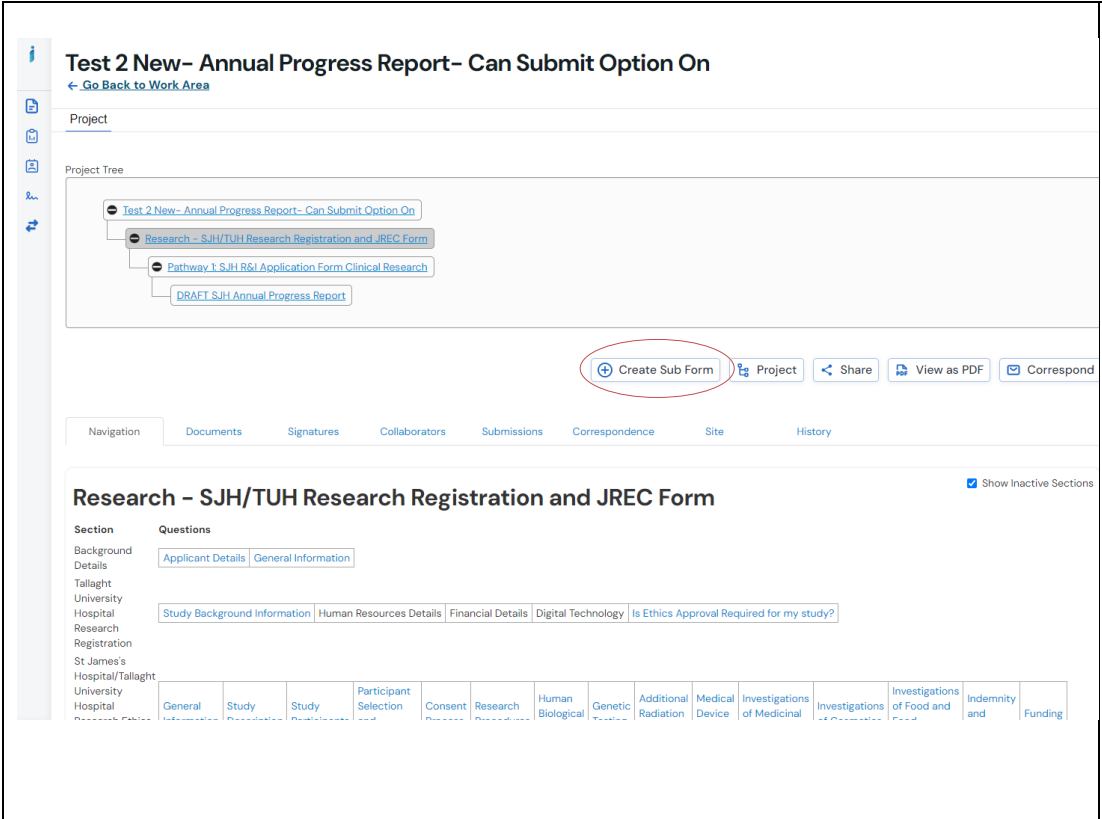
	<p>From the status bar you can see where the application is in the approval process and if any action is required from you. Actions include addressing reviewer comments, uploading documents or adding your or your Principal Investigator (PIs) signature</p>
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# 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



The screenshot displays a web application interface for managing research forms. The main content area shows a 'Project Tree' with several items, including 'Test 2 New- Annual Progress Report- Can Submit Option On', 'Research - SJH/TUH Research Registration and JREC Form', 'Pathway 1: SJH R&I Application Form Clinical Research', and 'DRAFT SJH Annual Progress Report'. Below the tree, there is a row of buttons: 'Create Sub Form' (circled in red), 'Project', 'Share', 'View as PDF', and 'Correspond'. The bottom section of the interface is titled 'Research - SJH/TUH Research Registration and JREC Form' and contains a 'Section' dropdown menu and a 'Questions' section with various tabs like 'Applicant Details', 'General Information', 'Study Background Information', etc.

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

<h2>Create Subform <span>✕</span></h2> <p>Select the sub-form that you would like to apply to this form</p> <p>Pathway 1: SJH R&amp;I Application Form Clinical Research ▼</p> <p><span>Create</span> <span>Close</span></p>	<ol style="list-style-type: none"><li>2) Then select 'Pathway 1: SJH R&amp;I Application Form Clinical Research'.</li><li>3) <b>Centre:</b> select 'Ethics Committee – St James's Hospital/ Tallaght University Hospital'.</li><li>4) Click 'Create'.</li></ol>
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**Test 2 New- Annual Progress Report- Can Submit Option On**  
 ← Go Back to Work Area

Project

Navigation Documents Signatures Collaborators Submissions Correspondence Site History

**Research – SJH/TUH Research Registration and JREC Form** Show Inactive Sections

**Section Questions**

Background Details [Applicant Details](#) [General Information](#)

Tallaght University Hospital Research Registration St James's Hospital/Tallaght University Hospital Research Ethics Standard Application Form

[Study Background Information](#) | [Human Resources Details](#) | [Financial Details](#) | [Digital Technology](#) | [Is Ethics Approval Required for my study?](#)

<a href="#">General Information</a>	<a href="#">Study Description</a>	<a href="#">Study Participants</a>	<a href="#">Participant Selection and Recruitment</a>	<a href="#">Consent Process</a>	<a href="#">Research Procedures</a>	<a href="#">Human Biological Material</a>	<a href="#">Genetic Testing</a>	<a href="#">Additional Radiation Exposure</a>	<a href="#">Medical Device Trials</a>	<a href="#">Investigations of Medicinal Products</a>	<a href="#">Investigations of Cosmetics</a>	<a href="#">Investigations of Food and Food Supplements</a>	<a href="#">Indemnity and Insurance</a>	<a href="#">Funding</a>
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Research Data Protection [Research Data Protection](#)

Document Upload [Document Upload](#)

SJH Research and Innovation Disclaimer [SJH Research and Innovation Disclaimer](#)

Signatures [Signatures](#)

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Terms and Conditions | Data Controller Privacy Policy | Data Processor Privacy Policy

### 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: It is very important to ensure that the PI has signed off on your application as the R&I application form will not be submitted until the PI has provided a signature.**

**Testing APR- New**

Project

Completeness Check | Navigate | View as PDF | Documents | Signatures | Save | More

**Important Note**

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.

Type of Submission

This is the first time that this R&I application form is being submitted.  
 This is a resubmission of this R&I Application in response to feedback.

Applicant Signature

Sign

Principle Investigator signature (PI has to be current SJH employee registered with Infonetica)

Request Signature | Sign

< Previous | Next >

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 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.**

**Testing APR- New**

Project

Completeness Check | Navigate | View as PDF | Documents | Signatures | Save | More

Signatures

**Important Note**

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.

Type of Submission

This is the first time that this R&I application form is being submitted.  
 This is a resubmission of this R&I Application in response to feedback.

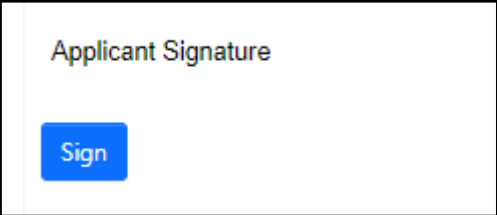
You can also use the 'completeness check' button to ensure you have completed all sections of the form.

# Ensuring your Pathway 1 Application is Correctly Submitted

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

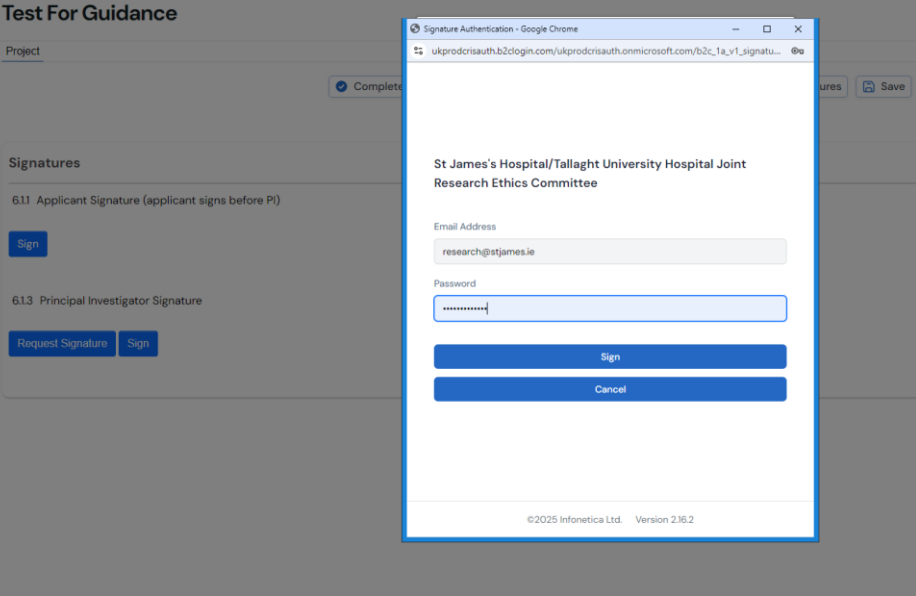

1. Applicant Sign off AND
2. PI sign off.

## 1. Applicant Sign Off

	<p>The Applicant Signature/sign off section appears at the bottom of the last page of the R&amp;I application.</p> <p>Please Click “Sign” and provide your Infonetica username (email) and password to successfully sign off the R&amp;I application.</p>
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## 2. PI Sign Off

			<p>The R&amp;I application form will not be submitted to the R&amp;I Office for review <b>UNTIL</b> the PI has also provided a signature/signed off on the application.</p> <p>To request the PI signature/sign off click on “Request Signature”.</p>
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			<p>Provide the PI email address in the box that pops up (see image below) and click "Request".</p>
	<p>Research &amp; Innovation  FW: Your Signature Request  Blanaid Mee PhD Interim</p>  <p>12:29</p>		<p>If the Request Signature section of the form is completed correctly the PI will receive an email inviting them to sign off on your application.</p>
	<p>**** This is an automated email from infonectica****</p> <p>Dear MsKeane</p> <p>Your signature request has been accepted by Dr Blanaid Mee.</p> <p>To view the status of your signature requests, please access your account in Infonectica, the online review portal of the SJH/TUH JREC (link below).</p> <p>Link to Infonectica: <a href="https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fslh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=79562d8e-6631-455e-9998-35e299a76c20&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66">https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fslh%2dtuh.forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=79562d8e-6631-455e-9998-35e299a76c20&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66</a></p>		<p>This email will contain a link for the PI to follow to provide a signature/sign off for the application.</p>

# Work Area

Notifications **26**      Signatures **1**      Transfers **0**      Shared **0**

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

### Signatures

Search signatures

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Principle Investigator	Test For Guidance	5708	Ms Danielle Keane		03.Dec.2025 15:42		Requested	<a href="#">View Form</a>
Principle Investigator	Test PR-Pathway 2	5669	Ms Danielle Keane		25.Nov.2025 12:52	25.Nov.2025 12:52	Signed	<a href="#">PDF being Generated</a>
Principle Investigator	Test 2 New- Annual Progress Report- Can Submit Option On	5667	Ms Danielle Keane		24.Nov.2025 13:14	24.Nov.2025 13:14	Signed	<a href="#">View PDF</a>

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

The PI should click "View Form" to review the R&I application form.

<p><b>Signatures</b></p> <p>6.1.1 Applicant Signature (applicant signs before PI)</p> <p><b>Sign</b></p> <p><b>Signed:</b> This form was signed by Ms Danielle Keane (research@stjames.ie) on 03.Dec.2025 3:41 PM</p> <p>6.1.3 Principal Investigator Signature</p> <p><b>Request Signature</b> <b>Sign</b></p> <p><b>Signature Request:</b> Signature requested from Mr Athul Kumbrote on 03.Dec.2025 3:42 PM</p>	<p>The PI can sign off the R&amp;I application form by clicking the “Sign” icon on the left of the Signatures page.</p>
<p>**** This is an automated email from Infonetica****</p> <p>Dear MsKeane</p> <p>Your signature request has been accepted by Dr Blanaid Mee.</p> <p>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).</p> <p>Link to Infonetica: <a href="https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2f%2fsjh%2dtuh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffc51cd36b98b07">https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2f%2fsjh%2dtuh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffc51cd36b98b07</a></p>	<p>When the PI has successfully signed off the R&amp;I application form the Applicant will receive the following email and the form will proceed through the R&amp;I approval system.</p>

# Completing a Pathway 1 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

<b>Unique R&amp;I study title</b>	Please create a unique study title for each R&I Application, different from the JREC application and/or other R&I applications, as this is the means by which your R&I application will be tracked.
<b>Full study title</b>	Type out your full study title in the text box.
<b>Please select YES if:</b> <ol style="list-style-type: none"><li>1. Your study is a retrospective chart review, or</li><li>2. Involves the recruitment of Human Participants (either staff or patients).</li></ol>	Auto-populated from JREC Application
<b>Please select NO if:</b> <ol style="list-style-type: none"><li>1. The above 2 points <u>are not true</u></li><li>2. TUH and/or SJH is <u>only a site of advertisement</u> for the study and NOT a site of recruitment</li><li>3. Your study is a <u>case study involving &lt;5 patients (SJH ONLY)</u></li><li>4. Your study population is <u>ONLY SJH employee's</u> survey/questionnaire and you have Research Ethics Committee approval from an Academic Research Ethics Committee</li></ol>	The answer you provide will determine whether your study requires R&I approval <b>AND</b> JREC approval <b>or</b> if you are just applying for R&I approval.  Selecting 'YES' opens the JREC form and indicates that your project requires both JREC approval <b>AND</b> R&I approval.  Selecting 'NO' indicates that your project does NOT require JREC approval, <b>ONLY</b> R&I APPROVAL.
<b>Please select the nature of the study</b>	Choose from the drop down
<b>Please provide a brief lay (plain English) description of the study</b>	Provide a summary of the trial in plain English. Include a study description referring to:

	<ul style="list-style-type: none"> <li>- Study background</li> <li>- Aims and objectives</li> <li>- Hypothesis</li> <li>- Participants – inclusion/exclusion criteria</li> <li>- Any testing.</li> </ul> <p>Ensure to clearly outline your research design.</p>
<b>Please confirm that this study is taking place at St James's Hospital</b>	<p>If no, please stop filling in the form and contact <a href="mailto:research@stjames.ie">research@stjames.ie</a></p> <p>If yes, select 'yes' and fill in the subsequent questions relating to department and directorate.</p>
<b>Please list the departments in which the study is taking place.</b>	Type the relevant departments in the box provided
<b>What SJH Directorate is this study taking place in?</b>	Choose the relevant department from the drop down list
<b>Is this study being undertaken as part of an academic qualification?</b>	Auto populated from JREC
<b>If yes, is the study being conducted as part of an undergraduate or postgraduate qualification?</b>	Auto populated from JREC
<b>What is the academic qualification?</b>	Auto populated from JREC
<b>Please provide the name of the academic institution</b>	Auto populated from JREC
<b>Is this a multi-site study?</b>	Auto populated from JREC
<b>Who is the PI in SJH?</b>	In this section, you must populate the details of the SJH PI, 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.
<b>Please select the discipline that best represents the PI</b>	Select from drop down menu
<b>Where the applicant is NOT the PI could the applicant please confirm that the PI is happy for their name and email address to appear on the R&amp;I BI Database:</b>	The BI database is an internal dashboard use to visualise and track research in SJH.
<b>Is the applicant also the PI (Clinical Research Studies)?</b>	Auto populated from JREC
<b>Please select what best describes why you are completing this application (tick all that apply)</b>	Select all options that are applicable

### 3. Study Background Information

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

<b>Is this study cancer related?</b>	<b>We ask this question to track cancer related research taking place in SJH.</b>
<b>Was this study part of a previous Clinical Audit/Service Evaluation/Usual Practice project?</b>	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 <u>OR</u> title of the previous QI project. This allows us to link the QI initiative with the current R&I application.

<p><b>Clinical Research Facility (CRF): Will the study be run using the Wellcome HRB Clinical Research Facility?</b></p>	<p>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.</p>
<p><b>If you select Yes to 'will the study be run in the Wellcome HRB Clinical Research Facility, the following questions will open up:</b></p>	<ul style="list-style-type: none"> <li>• <b>Please list the Research Team including Sub-Investigators and other Research Staff</b> 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.</li> <li>• <b>Please select the project type</b></li> <li>• <b>Please select the type of support required</b> We ask this to define the resources that the project will require. Please select from the options listed.</li> <li>• <b>CRF Project Number</b> This is used to liaise with the CRF regarding your CRF application.</li> </ul>
<p><b>Pharmacy: Will this study require support from either the hospital or CRF pharmacy?</b></p>	<p>We ask this to define the resources that the project will require.</p>
<p><b>Hospital Resources: Select the hospital resources that will be used for this study</b></p>	<p>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.</p>
<p><b>Nursing Research Access Committee: Are nurses or healthcare assistants participants in this study? Are nurses or healthcare assistants subjects in the study?</b></p>	<p>If your project involves Nurses or Healthcare Assistants (HCAs) your application it will need to be reviewed and approved by NRAC.</p> <p>Selecting 'yes' here opens the NRAC specific questions that <b>must be completed</b> if Nurses or HCAs are the subject of your application.</p>
<p><b>If 'yes' the following questions will open up:</b></p> <p>Responses in this section will be reviewed by the Nursing Research Access Committee.</p>	<ul style="list-style-type: none"> <li>• <b>Short Study Title</b> (same as in general information section)</li> <li>• <b>Full Study Title</b> (same as in general information section)</li> <li>• <b>Please provide a brief lay (plain English) description of the study</b></li> <li>• <b>List the study aims and objectives</b></li> </ul>

- **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.

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**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.

The required Garda Vetting documents and a template NDA are available on Infonetica in the 'Help' tab, under 'Templates'

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](mailto: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](mailto: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.

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## 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](http://www.hseland.ie)

## 7. Explanation of terms used in DPIA

<b>This page explains common terms used in the Data Protection Impact Assessment (DPIA)</b>	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.
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## 8. Data Protection Impact Assessment

<b>Did you complete the Data Protection Impact Assessment (DPIA) section of the JREC application?</b>	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.  <b>Please review and manually complete the sections not auto-populated.</b>  These are additional questions, specific to SJH. If you did not complete a JREC application form, you will need to complete the DPIA manually
<b>Do you have a DPIA that is reviewed and signed by the Data Controller/Joint Data Controllers?</b>	<b>Select 'Yes' if you</b> have already had a DPIA for this project reviewed and approved by the Data Controller's DPO. <b>You can upload this DPIA and the SJH DPO will review it.</b> If you select yes, you will be prompted to upload the document.  <b>Select 'No' if you</b> do not have an approved DPIA.

<b>UPLOAD</b>	<b>DPIA Upload Requirements Checklist:</b> <ul style="list-style-type: none"><li><input checked="" type="checkbox"/> If you have a completed DPIA signed by the Data Controller/DPO you can upload this, otherwise we will use the DPIA section of the R&amp;I form</li><li><input checked="" type="checkbox"/> Data Flow Diagram (from data collection to deletion)</li><li><input checked="" type="checkbox"/> Case Report Form</li><li><input checked="" type="checkbox"/> Data Sharing Agreement (DSA) (if multisite or involving third parties)</li></ul>
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Material Transfer Agreement (if materials are leaving SJH)

Standard Contractual Clauses (SCCs), if applicable

Participant Information Leaflet (PIL) and Consent Form

 **Need help? Templates are available on Infonetica! Click on the help tab and select templates.**

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## 9. Legal Information

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### Who are you employed by?

All SJH staff are covered by the Clinical Indemnity Scheme (CIS). Please use this information to answer the questions below.

If you are Trinity staff and unclear how to answer the indemnity questions below, please see footnote.

If you are unclear how to answer the indemnity questions below, please contact your Institution's Legal Office.

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### Are all researchers and medical staff covered by the Clinical Indemnity Scheme (CIS)?

The 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, see footnote.

TCD Researchers can contact Dr Ruben Eavan Keane, Head of Clinical Sponsorship Oversight (TR&I Administration) at [keaner4@tcd.ie](mailto:keaner4@tcd.ie) and Tony Dowling, Insurance Manager at [tony.dowling@tcd.ie](mailto: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.

<p><b>Is Indemnity in place for all NON-SJH researchers?</b></p>	<p>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.</p> <p>If you are unsure about the indemnity in place for non-SJH researchers, you must contact their institutions legal department.</p> <p>PLEASE NOTE: If you are unsure, it is possible to proceed with this application and add the indemnity information after submission.</p>
<p><b>Hospital sign off: Do any contracts with third party organisations associated with this study require execution by the hospital (hospital sign off)?</b></p>	<p>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.</p> <p>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.</p>
<p><b>Where applicable, please download, complete &amp; return a SJH MTA (Material Transfer Agreement) from the HELP SECTION. The completed form can be uploaded here.</b></p>	<p>A Material Transfer Agreement is an agreement that regulates how parties can share materials such as blood samples and tissue samples. A template MTA is available on Infonetica in the 'Help' tab, under 'Templates'</p>

## 10. Financial Details

<p><b>Is there funding in place for this study?</b></p>	<p>If you select "Yes", further questions will be opened. If you select "No", you will move to the next section.</p>
<p><b>What is the nature of the funding?</b></p>	<p>Tick the relevant box.</p>
<p><b>What is the source of funding for this study?</b></p>	<p>Who is providing the funding?</p>
<p><b>What is the amount of funding?</b></p>	<p>Please respond in numeral values.</p>
<p><b>What organisation will the funder be depositing funds into?</b></p>	<p>What institution will hold the funds</p>

<p><b>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?</b></p>	<p>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</p>
<p><b>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</b></p>	<p>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.</p>

## 11. Document Upload

<p><b>In this section you have the opportunity to upload any additional supporting documents.</b></p>	<p>For example, you may choose to upload protocols.</p> <p>For more information on what documents may be required for a particular study type, please see our <a href="#">Document Guidance Table</a></p>
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## R&I Application Pathway 2: External Ethical Approval for SJH (ONLY) Staff Studies & Regulated Clinical & Device Trials

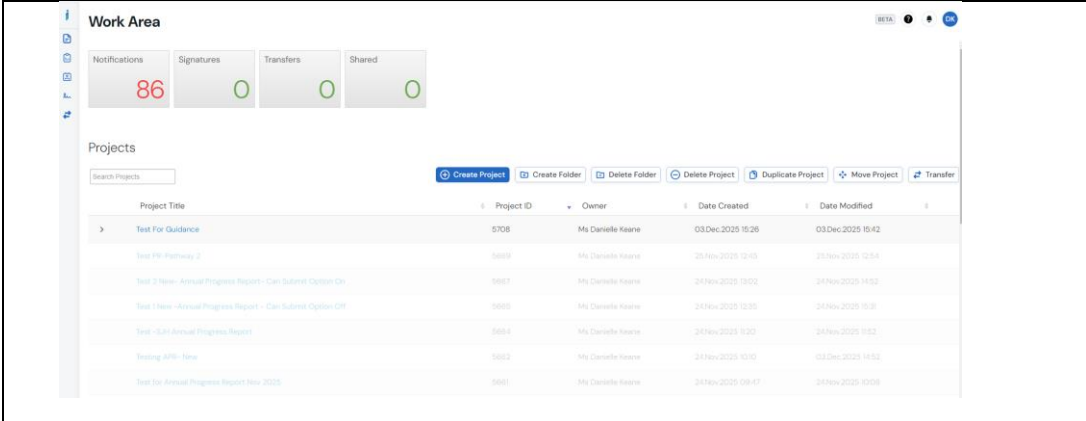
This pathway is for

- 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.



The screenshot shows a 'Work Area' interface. On the left is a navigation pane with a 'Create Project' button. The main content area displays a table of projects with columns for Project Title, Project ID, Owner, Date Created, and Date Modified. The table contains several rows of project data.

Project Title	Project ID	Owner	Date Created	Date Modified
Test For Guidance	5708	Ms Danielle Keane	03 Dec 2025 15:26	03 Dec 2025 16:42
Test PR Pathway 2	5695	Ms Danielle Keane	25 Nov 2025 12:05	25 Nov 2025 12:54
Test 2 New - Annual Progress Report - Can Submit Option On	5687	Ms Danielle Keane	24 Nov 2025 13:00	24 Nov 2025 14:02
Test 1 New - Annual Progress Report - Can Submit Option Off	5686	Ms Danielle Keane	24 Nov 2025 12:30	24 Nov 2025 13:31
Test - SJH Annual Progress Report	5684	Ms Danielle Keane	24 Nov 2025 11:20	24 Nov 2025 11:52
Training ePR - New	5682	Ms Danielle Keane	24 Nov 2025 10:30	03 Dec 2025 16:52
Test for Annual Progress Report Nov 2025	5681	Ms Danielle Keane	24 Nov 2025 09:47	24 Nov 2025 10:08

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

## Create Project ✕

Project Title\* (Max 200 characters)

Form\*

**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.

**Testing APR- New**

Project

Completeness Check | Navigate | View as PDF | Documents | Signatures | Save | More

**Important Note**

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.

Type of Submission

This is the first time that this R&I application form is being submitted.  
 This is a resubmission of this R&I Application in response to feedback.

Applicant Signature

Sign

Principle Investigator signature (PI has to be current SJH employee registered with Infonetica)

Request Signature | Sign

Previous | Next

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.

**Testing APR- New**

Project

Completeness Check | Navigate | View as PDF | Documents | Signatures | Save | More

Signatures

**Important Note**

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.

Type of Submission

This is the first time that this R&I application form is being submitted.  
 This is a resubmission of this R&I Application in response to feedback.

You can also use the 'Completeness Check' button to ensure you have completed all sections of the form.

## Ensuring your Pathway 2 Application is Correctly Submitted

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

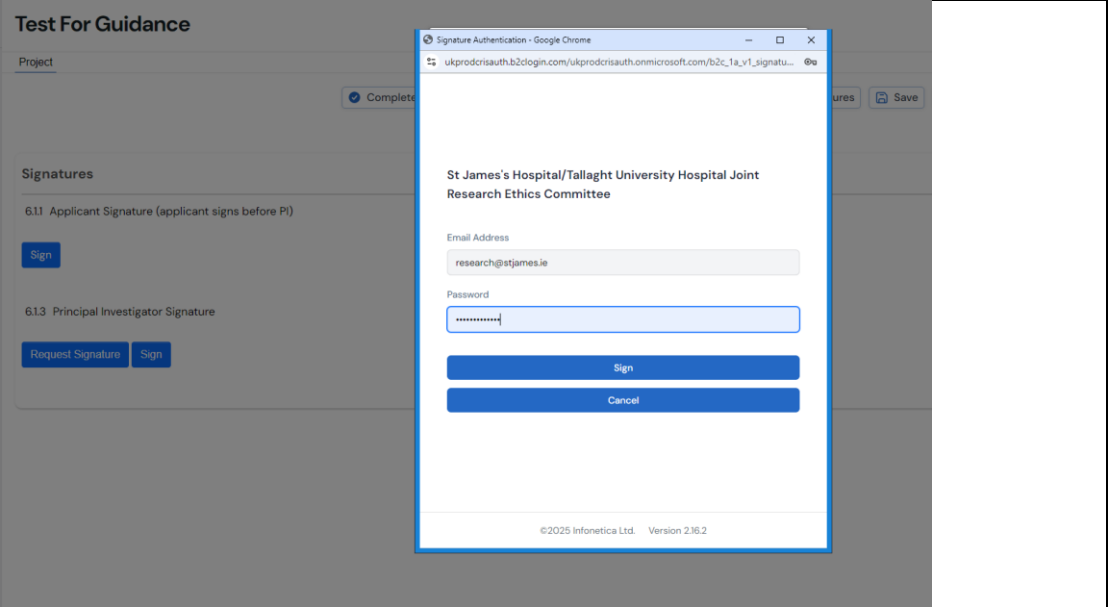

1. Applicant Sign off AND
2. PI sign off.

### 1. Applicant Sign Off

	<p>Applicant Signature</p> <p><a href="#">Sign</a></p>		<p>The Applicant Signature/sign off section appears at the bottom of the last page of the R&amp;I application.</p> <p>Please Click “Sign” and provide your Infonetica username (email) and password to successfully sign off the R&amp;I application</p>
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### 2. PI Sign Off

	<p>Principal Investigator Signature</p> <p><a href="#">Request Signature</a> <a href="#">Sign</a></p>		<p>The R&amp;I application form will not be submitted to the R&amp;I Office for review UNTIL the PI has also provided a signature/signed off on the application.</p> <p>To request the PI signature/sign off click on “Request Signature”</p>
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		<p>Provide the PI email address in the box that pops up (see image below) and click “Request”.</p>
		<p>If the Request Signature section of the form is completed correctly the PI will receive an email inviting them to sign off on your application.</p>
	<p>**** This is an automated email from Infonetica****</p> <p>Dear MsKeane</p> <p>Your signature request has been accepted by Dr Blanaid Mee.</p> <p>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).</p> <p>Link to Infonetica: <a href="https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fjrh%2dtuh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=79562d8e-6631-455e-9998-35e299a76c20&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66">https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=https%3a%2f%2fjrh%2dtuh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=79562d8e-6631-455e-9998-35e299a76c20&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-8f6ce6522e45dd69574ad4f3ea5e6cc272620d66</a></p>	<p>This email will contain a link for the PI to follow to provide a signature/sign off for the application.</p>

# Work Area

Notifications

26

Signatures

1

Transfers

0

Shared

0

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

Type	Project Title	Project ID	Requesting User	Message	Requested Date	Response Date	Status	Action
Principle Investigator	Test For Guidance	5708	Ms Danielle Keane		03.Dec.2025 15:42		Requested	<a href="#">View Form</a>
Principle Investigator	Test PR-Pathway 2	5669	Ms Danielle Keane		25.Nov.2025 12:52	25.Nov.2025 12:52	Signed	<a href="#">PDF being Generated</a>
Principle Investigator	Test 2 New- Annual Progress Report- Can Submit Option On	5667	Ms Danielle Keane		24.Nov.2025 13:14	24.Nov.2025 13:14	Signed	<a href="#">View PDF</a>

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

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

<p><b>Signatures</b></p> <p>6.1.1 Applicant Signature (applicant signs before PI)</p> <p><a href="#">Sign</a></p> <p>Signed: This form was signed by Ms Danielle Keane (research@stjames.ie) on 03.Dec.2025 3:41 PM</p> <p>6.1.3 Principal Investigator Signature</p> <p><a href="#">Request Signature</a> <a href="#">Sign</a></p> <p>Signature Request: Signature requested from Mr Athul Kumbrote on 03.Dec.2025 3:42 PM</p>	<p>The PI can sign off the R&amp;I application form by clicking the “Sign” icon on the left of the Signatures page.</p>
<p>**** This is an automated email from Infonetica****</p> <p>Dear MsKeane</p> <p>Your signature request has been accepted by Dr Blanaid Mee.</p> <p>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).</p> <p>Link to Infonetica: <a href="https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v:1/query?url=https%3a%2f%2fsih%2dnh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffe51cd36b98b07">https://ddec1-0-en-ctp.trendmicro.com:443/wis/clicktime/v:1/query?url=https%3a%2f%2fsih%2dnh_forms.ethicalreviewmanager.com%2fAccount%2fLogin&amp;umid=0aef82dc-e1b0-43a4-9ae5-0a0501e8db50&amp;auth=79a182f17a61d2ad61a86c6ae2351ca92b1d6b54-698a46b527216aa53ede00c79ffe51cd36b98b07</a></p>	<p>When the PI has successfully signed off the R&amp;I application form, the Applicant will receive the following email, and the form will proceed through the R&amp;I approval system.</p>

## Filling Out a Pathway 2 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 (including interventional studies involving medicinal products or non-drug interventions) 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

<b>Short trial Title</b>	<b>Please insert the shortened trial title</b>
<b>Full Trial Title</b>	Please insert the full trial title
<b>Please provide a short lay description of the study</b>	Provide a summary of the trial in plain English. Include a study description referring to: <ul style="list-style-type: none"> <li>- Study background</li> <li>- Aims and objectives</li> <li>- Hypothesis</li> <li>- Participants – inclusion/exclusion criteria</li> <li>- Any testing.</li> </ul> Ensure to clearly outline your research design.
<b>Please list the departments in which the study is taking place.</b>	Type the relevant departments in the box provided
<b>What SJH Directorate is this study taking place in?</b>	Choose the relevant department from the drop down list
<b>What is the target disease area?</b>	Please select one or more target disease areas from the options
<b>Is this a multisite Trial?</b>	If the trial is taking place in a location other than SJH, please select yes.
<b>Please provide details of the PI at SJH</b>	The local PI must be and SJH employee.

<b>Where the applicant is NOT the PI could the applicant please confirm that the applicant please confirm that the PI is happy for their name and email address to appear on the R&amp;I BI Database</b>	The BI database is an internal dashboard use to visualise and track research in SJH.
<b>How many participants are to be included/recruited in total from SJH?</b>	Numerical response.
<b>How will explicit consent be obtained from participants?</b>	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.
<b>What is the expected start date of the Trial at SJH?</b>	Response to be specific to your project.
<b>Who is the target population for this Study?</b>	Please select from the list provided
<b>Is this study a Clinical Trial or a Medical Device Trials?</b>	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

<b>Cancer: Is this trial cancer related?</b>	We ask this question to track cancer related research taking place in SJH.
<b>Clinical Research Facility (CRF): Will the trial be run using the Welcome HRB Clinical Research Facility?</b>	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.
<b>If you select Yes to 'will the study, be run in the Wellcome HRB Clinical research Facility', the following questions will open up:</b>	<ul style="list-style-type: none"> <li>• <b>Please list the Research Team including Sub-Investigators and other Research Staff</b> 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.</li> <li>• <b>Please select the project type</b></li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Please select the type of support required</b> We ask this to define the resources that the project will require., please select from the options listed</li> <li>• <b>CRF Project Number</b> This is used to liaise with the CRF regarding your CRF application</li> </ul>
<b>Pharmacy: Will the trial require support from either the hospital or CRF pharmacy?</b>	We ask this to define the resources that the project will require. If yes, choose which pharmacy in the next question.
<b>Hospital Resources: Select the hospital resources that will be used for this trial</b>	We ask this to define the resources that the project will require.
<b>Nursing Research Access Committee: Are nurses or healthcare assistants participants in the trial?</b>	<p>If your project involves Nurses or Healthcare Assistants (HCAs) your application it will need to be reviewed and approved by NRAC.</p> <p>Selecting 'yes' here opens the NRAC specific questions that <b>must be completed</b> if Nurses or HCAs are the subject of your application.</p>
<p><b>If 'yes' the following questions will open up:</b></p> <p>Responses in this section will be reviewed by the Nursing Research Access Committee.</p>	<ul style="list-style-type: none"> <li>• <b>Short Study Title</b> (same as in general information section)</li> <li>• <b>Full Study Title</b> (same as in general information section)</li> <li>• <b>Please provide a brief lay (plain English) description of the study</b></li> <li>• <b>List the study aims and objectives</b></li> <li>• <b>Describe the research design/methodology of the study</b> – explain your research design</li> <li>• <b>Please provide details on the study sample &amp; the sampling technique</b> – be specific here, name the wards, number of staff, how you will access staff</li> <li>• <b>Who is the Gatekeeper for this study?</b> Please provide; full name, work position &amp; Dept/Directorate – this should <u>ALWAYS</u> be an SJH employee</li> <li>• <b>List the inclusion criteria of the study</b></li> <li>• <b>List the exclusion criteria of the study</b></li> <li>• <b>Does this study require ethics approval? Ethical approval is required for ALL NRAC applications.</b></li> </ul>

- 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 (including interventional studies involving medicinal products, medical devices, or non-drug interventions)

**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?

Please select which of the following options apply to your project.

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**

Each option will open a sub question.

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**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.

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**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.

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**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

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**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.

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**Is the Sponsor located in the EU?**

Select Yes or No

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**Has an EU legal Representative been appointed?**

Select Yes or No

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

## 5. Human Resources

<b>Will any research staff NOT employed by SJH be on-site in SJH as part of this Trial (excluding monitors, auditors and inspectors)?</b>	<p><b>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.</b></p> <p><b>The required Garda Vetting documents and a template NDA are available on Infonetica in the ‘Help’ tab, under ‘Templates’</b></p> <p><b>You must upload the signed NDA for each external researcher who will be accessing SJH patients or patient data.</b> If you are unsure whether you will require an NDA. It is possible to proceed and add your NDA after submission.</p> <p><b>Each external researcher must complete the Garda Vetting invitation form and contact <a href="mailto:research@stjames.ie">research@stjames.ie</a> to arrange to have their IDs validated</b></p> <p><b>Please note: If you are unsure about whether you will need to undergo Garda Vetting, please contact HR at <a href="mailto:humanresources@STJAMES.IE">humanresources@STJAMES.IE</a> and proceed with the application. If HR determine that Garda Vetting is required, this can be added to your application after submission.</b></p>
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<b>If YES, please provide the; Name, Affiliated Institution(s) and Contact Details (email &amp; mobile phone number), of non- SJH staff that form part of the research team or act as Co-investigators at SJH.</b>	Enter relevant details in the text box.
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**Will non-SJH staff require access to SJH patients and/or SJH patient data?**

<b>SJH Mandatory Training:</b>	Mandatory training for all researchers in SJH are: <ul style="list-style-type: none"><li>- GDPR</li><li>- Hand Hygiene</li><li>- Children first (if your project involves children)</li></ul> Mandatory training can be completed on HSELandD: <a href="http://www.hseland.ie">www.hseland.ie</a>
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## 6. Clinical Trial/Clinical Study Agreement

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<b>Please upload the most up to date version of the agreement.</b>	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'.
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## 7. Legal Information

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### Who are you employed by?

All SJH staff are covered by the CIS. Please use this information to answer the questions below.

If you are unclear how to answer the indemnity questions below, please contact your Institution's Legal Office. Please see footnote for TCD researchers.

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### Are all researchers and medical staff covered by the Clinical Indemnity Scheme (CIS)?

The 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, see footnote.

If you select no, you will be prompted to give further information about the cover in place for researchers NOT covered by CIS.

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**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.

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**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

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## 8. Financial Details

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**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.

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**If yes, What is the nature of the funding?  
If yes, What is the source of the funding?**

Tick relevant box  
Who is providing the funding?

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<b>If no, will there be additional costs to SJH outside of patient standard of care or normal working hours e.g. overtimes?</b>	If there are additional costs, you will be prompted to answer whether alternative funding is available.
<b>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</b>	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

For more information on what documents may be required for a particular study type, please see our [Document Guidance Table](#)

<b>Research Ethics Approval/ National Research Ethics Committee Approval/CTIS Part 2 Approval</b>	CTIS covers ethics AND HPRA If you have university ethics for a staff study, upload here.
<b>Health Products Regulatory Authority Approval</b>	If CTIS is provided, HPRA is not necessary.
<b>Health Research Consent Declaration Committee Approval</b>	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 <b>and</b> approval letter; these are required documents if your project involves individuals unable to provide consent.
<b>Site Specific Assessment/Site Assessment Template</b>	
<b>Data Protection Impact Assessment</b>	
<b>Data Protection Agreement(DPA)/Data Sharing Agreement (DSA)</b>	
<b>Additional Data Protection Documents</b>	<ul style="list-style-type: none"> <li>• Standard Contractual Clauses (SCCs)</li> <li>• Participant Information Leaflet (PIL)</li> <li>• Participant Consent Form (CF)</li> </ul>
<b>Letter of Authorisation</b>	

## Actions

	<p><b>Project ID:</b> 4710 <b>Submission Number:</b> 3920: <b>Submission Date:</b> 07.Nov.2024 12:20</p> <p>Dear Danielle Keane, The SJH R&amp;I Office has reviewed your R&amp;I application and further information is required. The following comments were made:</p> <table border="1"><thead><tr><th colspan="2">Title</th></tr></thead><tbody><tr><td>2.1.2 Full Trial Title</td><td>spelling</td></tr><tr><td>Please select the Class 1 sub class</td><td>test comment</td></tr></tbody></table> <p><b>Please resubmit once all comments have been addressed.</b> Link: <a href="https://SJH-TUH.forms.ethicalreviewmanager.com/ProjectView/Index/4710">https://SJH-TUH.forms.ethicalreviewmanager.com/ProjectView/Index/4710</a></p> <p>Kind regards, <b>SJH R&amp;I Office</b></p>	Title		2.1.2 Full Trial Title	spelling	Please select the Class 1 sub class	test comment	<h3>Further Information Required</h3> <p>When you have submitted your application, it is possible that a reviewer may request further information or leave comments to be addressed.</p> <p>When this happens, you will receive an email inviting you to address this request by following the link.</p> <p>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</p> <p><b>Tip:</b> You can also use this area to check the status of your application.</p>
Title								
2.1.2 Full Trial Title	spelling							
Please select the Class 1 sub class	test comment							

Research Ethics Applications

Test Pathway 2 07112024 4710

Project 2 Reviewer Comments Share

Completeness Check Auto Submit Refresh

View as PDF Correspond

Project Tree

- Test Pathway 2 07112024
  - SJH Regulated Clinical & Device Trials R&I Application Form

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

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

SJH Regulated Clinical & Device Trials R&I Application Form  Show Inactive Sections

Section Questions

Applicant Details Applicant Details

SJH Research Registration Study Background Information Human Resources

Clinical Trial & Studies Contracts Clinical Trial/Clinical Study Agreement Legal Information Financial Details Regulatory Documentation Site Specific Assessment/Site Suitability Data Protection Miscellaneous Agreements/Contracts

Signatures Signatures

Research Ethics Applica

Project 2 Reviewer Comments Share

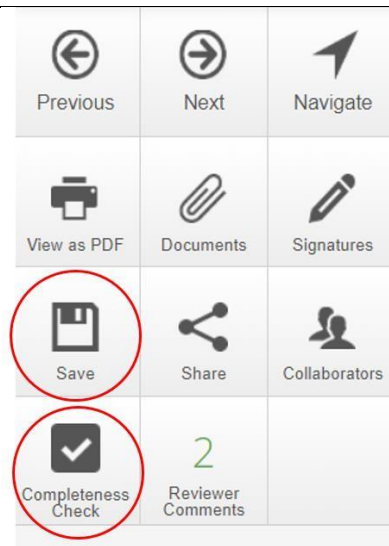
Completeness Check Auto Submit Refresh

View as PDF Correspond

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

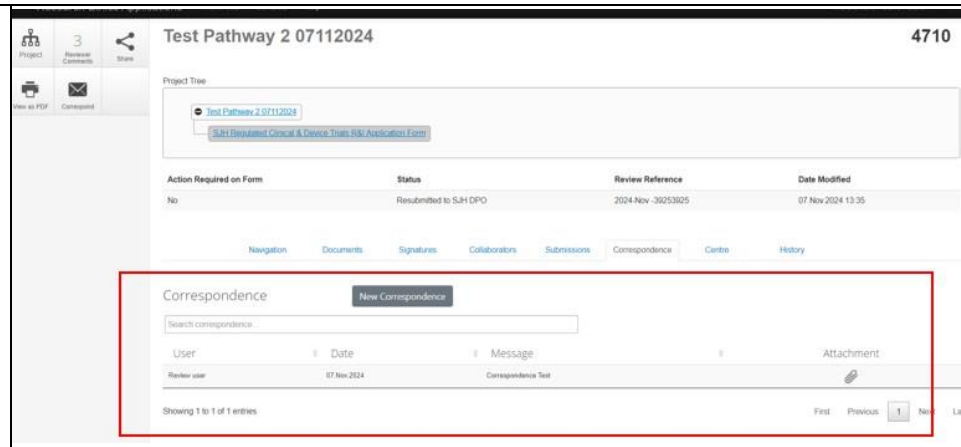
Click 'reviewer comments' to open a dialog box of all comments on your application.

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.

<p>Correspondence Message <span>✕</span></p> <p>Date <b>07.Nov.2024 2:25 PM</b></p> <p>Correspondence Test</p> <p>Attachment Name <span>Download</span></p> <p>DSA- Data Sharing AgreementTemplate_V4_22Aug2023.docx <span>Download</span></p> <p><span>Close</span></p>	<p>Re-upload the <b>updated documents</b> as a 'new correspondence'</p>
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Research Ethics Applica		
 Project	 Create Sub Form	 Share
 View as PDF	 Correspond	

### 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

<input type="text" value="Collaborator email"/>	<input type="checkbox"/>	Read	
	<input type="checkbox"/>	Write	
	<input type="checkbox"/>	Submit	
	<input type="checkbox"/>	Share	
	<input type="checkbox"/>	Create all sub forms	
	<input type="checkbox"/>	Receive notifications	

## 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.

# Frequently Asked Questions

## 1. Do I need an R&I application?

If you are completing a project that is research based in St James's Hospital, you are required to submit an R&I application.

If your project is non-research (quality improvement/ service evaluation/ clinical audit) you will not require an R&I application, instead you must register your project with QSID.

Research <sup>‡</sup>	Non-research
Registration with: Research & Innovation	Registration with: QSID
<ul style="list-style-type: none"> <li>• Clinical Trial</li> <li>• Medical Device Trial</li> <li>• Retrospective Chart Review</li> <li>• Observational Research Study</li> <li>• Translational Research Study</li> <li>• Device Trial (Not Subject to Medical Device Regulation)</li> <li>• Pilot Study</li> <li>• Feasibility Study</li> <li>• Case Studies<sup>^</sup></li> <li>• Pre-screening*</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical audit</li> <li>• Service evaluation</li> <li>• Usual practice project</li> <li>• Quality Improvement Initiative</li> </ul>
<p>The following projects can be classified as research <u>and/or</u> non-research depending on the purpose of the project;</p> <ul style="list-style-type: none"> <li>• Hospital Staff – Survey/Questionnaire</li> <li>• Hospital Staff – Interview/Focus Group</li> <li>• Patient – Survey/Questionnaire</li> <li>• Patient – Interview/Focus Group</li> </ul> <p><i>It is important to correctly classify your project as either research or non-research, as projects classified as research require ethics approval, as per the Health Research Regulations 2018. <u>Failure to obtain ethics approval may impact on insurance and Clinical Indemnity.</u></i></p> <p>If you are unsure whether your project is research, please contact the Research &amp; Innovation Team at <a href="mailto:research@stjames.ie">research@stjames.ie</a></p>	

## 2. Do I choose Pathway 1 or Pathway 2?

### PATHWAY 1

**When to choose:** Pathway 1 is for applications that require both JREC approval and R&I approval.

Examples include: Retrospective Chart Review, Observational Research Study, Translational Research Study, Device Trial - Not subject to Medical Device Regulation, Randomised Controlled Trial, Pilot Study, Feasibility Study

**Method:** First create and complete your JREC application, then create your R&I application as a sub-form. Any duplicated questions will auto-populate using the answers you added to your JREC applications.

**Benefit:** This pathway allows you to complete both applications in the same place.

### PATHWAY 2

**When to choose:** Pathway 2 is for studies that have external ethics and are now applying for R&I approval. Example include: Staff studies with institutional ethics, Clinical Trials with NREC or CTIS, Case studies with less than 5 participants, Requests to use St James’s as a site of advertisement or a study.

**Method:** From your work area, select ‘Create Project’ and go straight to ‘Pathway 2’ in the drop down menu.

**Benefit:** Pathway 2 bypasses the JREC form, and allows you to upload existing external ethics.

### 3. What do I do if my PI is not an employee of St James’s Hospital?

It is a requirement that all studies have an SJH employee as a local supervisor. If your PI is not an employee of SJH, you can nominate a member of your research team who is employed by SJH with appropriate seniority to act as a local supervisor. Alternatively, you can reach out to other suitable SJH staff members to request support for your study.

### 4. My PI is not showing up when I use their email to request a signature

If they are not showing up, this means they have not created an account with Infonetica. They can do so by clicking this link: <https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login?returnUrl=/ActivityForm/Index> and selecting ‘New User’. Please ensure they sign up using their institutional email address.

### 5. What do I do if I created my Infonetica account using a non-institutional email address?

If you previously created your Infonetica account with a non-institutional email, you can fill in your own details in the section asking for details of the research team and list your institutional email as a contact.

### 6. Do I need to list everyone on my research team?

You must list everyone who will be coming on site at SJH and anyone who will be accessing SJH patients or patient data.

### 7. Who counter signs my NDA?

When you sign and re-upload the NDA, the R&I programme manager will countersign the NDA on behalf of the hospital.

### 8. How can I check if my application is fully submitted?

You can check the status of your application by clicking on the application title, then selecting the R&I branch of the project tree and viewing the status bar:

Action Required on Form	Status	Review Reference	Date Modified
Yes	Not Submitted	N/A	27 Jun 2025 17:53

In the screenshot above, you can see that the status is ‘Not Submitted’. You will also see that under ‘Action Required’, the status shows ‘Yes’. By clicking on ‘Yes’, a dialogue box will open outlining the action that are required.

## 9. I have received an email stating that my application has been returned with comments, how do I view the comments?

You can view the comments on your application by clicking on the application that has been returned with feedback. Then, click 'Reviewer Comments' in the action pane on the left side of your screen. This will open a dialog box displaying all comments on your application.

Each comment must be addressed. If an application is resubmitted with unanswered queries remaining, it will be returned to the applicant again, which will delay the approval process.

When the form is returned with feedback, it is unlocked for editing, allowing you to update the information in response to the comments.

Please ensure you save any changes by clicking the 'Save' button in the left pane.

## 10. My application has been returned with feedback/comments, but it is locked for editing. How do I unlock the form?

When you open your project, it is important to ensure you are viewing the correct branch of the project tree.

At the top of the tree is the main form. From the main form the applicant can create sub-forms, for example progress reports, amendments, annual reports.

For those completing a Pathway 1 application, make sure you have selected the R&I application sub-form branch. If not, you may be viewing your JREC submission instead.



Table 2: Document Upload required by Study Type

Study Type	Pathway	Participant Information leaflet/ Consent form	MTA*/ DSA*	External Ethics Approval Upload (CTIS, NREC, Institutional ethical approval)	HPRA#	HRCDC	Contract
Retrospective chart review involving SJH patients	Pathway 1	✗	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	✗ JREC only	✗	✗	✗
Pilot Study, Feasibility Study	Pathway 1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> If data or material is being shared outside of SJH a DSA	✗ JREC only	May be required if the pilot study involves human medicines or clinical investigations of medical devices	May be required if explicit consent cannot be obtained	May be required if a sponsor is involved in the pilot/ feasibility trial
Patient survey/ interview/ focus group	Pathway 1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	✗ JREC only	✗	✗	✗

Study Type	Pathway	Participant Information leaflet/ Consent form	MTA*/ DSA*	External Ethics Approval Upload (CTIS, NREC, Institutional ethical approval)	HPRA#	HRCDC	Contract
Case Study with 5 or more cases	Pathway 1	✓	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	<input checked="" type="checkbox"/> JREC only	✗	May be required if explicit consent cannot be obtained	✗
Multisite observational study with CE-marked devices	Pathway 2	✓	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	May be required if explicit consent cannot be obtained	<input checked="" type="checkbox"/>
Case Study with less than 5 cases	Pathway 2	✓	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	Ethics not required	✗	May be required if explicit consent cannot be obtained	✗
Clinical Trials involving Ionising Radiation	Pathway 2	✓	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	May be required if explicit consent	May Be required

Study Type	Pathway	Participant Information leaflet/ Consent form	MTA*/ DSA*	External Ethics Approval Upload (CTIS, NREC, Institutional ethical approval)	HPRA#	HRCDC	Contract
			If data is being shared outside of SJH a DSA	Institutional ethics		cannot be obtained	
SJH as a site of advertisement ONLY (no recruitment)	Pathway 2	✗	✗	<input checked="" type="checkbox"/> Institutional ethics	✗	✗	✗
Staff study	Pathway 2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	<input checked="" type="checkbox"/> Institutional ethics OR JREC acceptable	✗	✗	✗
Investigator-led drug trial at SJH	Pathway 2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> If data is being shared outside of SJH a DSA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	May be required if explicit consent cannot be obtained	<input checked="" type="checkbox"/>

Study Type	Pathway	Participant Information leaflet/ Consent form	MTA*/ DSA*	External Ethics Approval Upload (CTIS, NREC, Institutional ethical approval)	HPRA#	HRCDC	Contract
Medical Device Trials subject to Medical Device Regulations	Pathway 2	☑	☑ If data is being shared outside of SJH a DSA	☑	☑	May be required if explicit consent cannot be obtained	☑

*MTA = Material Transfer Agreement, DSA = Data Sharing Agreement. Applies to studies where SJH is the data controller.  
# HPRA = Health Products Regulatory Authority. If you are submitting through CTIS, this covers your HPRA requirements.*