ST JAMES'S HOSPITAL

RESEARCH AND INNOVATION APPLICATION PROCESS

An overview of the research application process at St James's Hospital

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RESEARCH & INNOVATION ST JAMES'S HOSPITAL

TOPICS

Role of the Research & Innovation (R&I) Office

Research vs. Non-Research

R&I Application Process

The R&I Review Process

Key Tips for successfully navigating the application process

Data Protection Impact Assessment (DPIA) FAQs

RESEARCH & INNOVATION ST JAMES'S HOSPITAL

ROLE OF THE RESEARCH & INNOVATION OFFICE

- The Research and Innovation Office oversees all hospital-based research applications.
- It works to support and strengthen the research culture across the campus.
- The R&I Office liaises between researchers and the Data Protection and Legal offices to provide researchers with useful and timely advice.
- The R&I Office reviews and approves research proposals and provides comprehensive research support to all staff.

SUPPORT PROVIDED BY R&I OFFICE

The R&I Team supports researchers by:

- Guiding the submission of successful Research & Innovation applications
- Assisting in developing research ideas
- Helping identify a suitable Principal Investigator (PI)
- Promoting and disseminating research impact
- Signposting to relevant resources
- Organising training sessions and events
- Sharing up to date information on funding opportunities on our webpage

IS MY PROJECT A RESEARCH OR NON-RESEARCH STUDY

What is a research study?

- Designed to generate new, generalisable knowledge.
- **Aim:** to answer a question that is new and unknown, usually involves testing a hypothesis, evaluating an intervention or exploring associations
- Results are applicable **beyond the population or service**
- **Requires ethical approval**

Examples:

- Observational research
- Randomised controlled trial
- Clinical trial
- Patient surveys/ interviews to generate new knowledge

IS MY PROJECT A RESEARCH OR NON-RESEARCH STUDY

What are non-research studies?

- Non-research studies do not require ethical approval
- Non-research studies are registered with QSID
- Typically fall into **two categories:**
  - Clinical Audit
  - Service Evaluation

Clinical Audit

- **Aim:** To see if current practice meets an agreed and defined standard. The result is binary, yes or no.
- Only applicable to a single site or service
- Does not require ethics

Service Evaluation

- **Aim:** To assess what is happening in a service, describing current care without comparison to a standard.
- Focus on effectiveness, efficiency or acceptability of a service

SUMMARY TABLE

Feature	Research	Audit	Service Evaluation
Main Aim	Generate new, generalisable knowledge	Measure care against a standard	Understand how a service is working
Generalisable (beyond SJH)	Yes	No	No
Reference point	Research question	Predefined standard/guideline	No standard — describes current service
Ethics approval	Required	Not Required	Not Required
Governance	Ethical approval + Hospital R&I Approval	QSID Registration	QSID Registration
Example	Retrospective chart Review to see if patients on one medication had better outcomes than another Patient survey on unmet needs Randomised controlled trial on efficacy of an intervention	Checking compliance with infection control guidelines, Auditing compliance with antibiotic prescribing guidelines	Patient satisfaction survey Retrospective Chart Review to check compliance with allergy documentation policy Reviewing referral patterns to see how many patients are seen within 6 weeks

RESEARCH IN SJH

All research taking place in SJH requires:

1. **Ethical Approval** – from either:
   - Joint Research Ethics Committee (JREC)
   - National Research Ethics Committee (NREC)
   - Clinical Trial Information System (CTIS)
   - University/ Institutional Ethics

2. **Hospital approval** – from the R&I office (ethical approval must be in place before hospital approval can be granted)

Before your project can begin you must have ethical approval **AND** hospital approval.
The R&I application is **mandatory.**

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INTRODUCTION TO R&I APPLICATION PROCESS

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FINDING THE R&I APPLICATION

The R&I application is available:

- Internally on the R&I intranet page
- Externally on the R&I Webpage
- Apply directly using this link: R&I Infonetica Platform

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LOGGING IN TO YOUR INFONETICA ACCOUNT

If you have submitted an application to the Joint Research Ethics Committee (JREC), you already have an Infonetica account that can be used for your R&I applications!

If you are a new user, please sign up using your **institutional email.**

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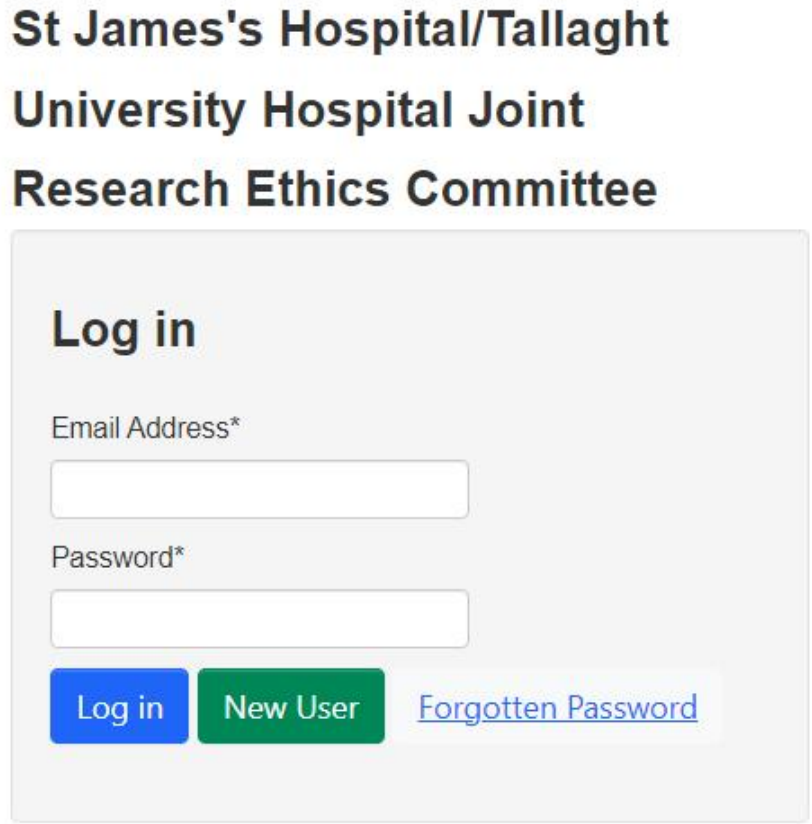
Tallaght University Hospital | Ospidéal Ollscoile Thamhlachta

An Academic Partner of Trinity College Dublin

Research Office

Ospidéal San Séamas – Seirbhís Dé agus A Phobail



APPLICATION PATHWAYS

Your application Pathway will be determined by the type of research planned and the type of ethical approval required

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PATHWAY 1

Pathway 1 is for projects requiring JREC approval **AND** R&I approval

Pathway 1 consists of **two connected applications:**

1. JREC application
2. R&I application

First the applicant must create and complete their JREC application.

Then, the R&I Pathway 1 form is created as a sub-form of your JREC application, and auto populates duplicated questions using the information input on the JREC application

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PATHWAY 1: RESEARCH TYPES

(ALL REQUIRE JREC AND R&I APPROVAL)

- Retrospective Chart Review
- Observational Research Study
- Patient Interviews, Focus Groups or Surveys
- Device Trial - Not subject to Medical Device Regulation
- Hospital Staff Study – where university/ institutional ethics is not available

- Case Study – five or more patients
- Randomised Controlled Trial
- Pilot Study
- Feasibility Study
- Translational Research Study

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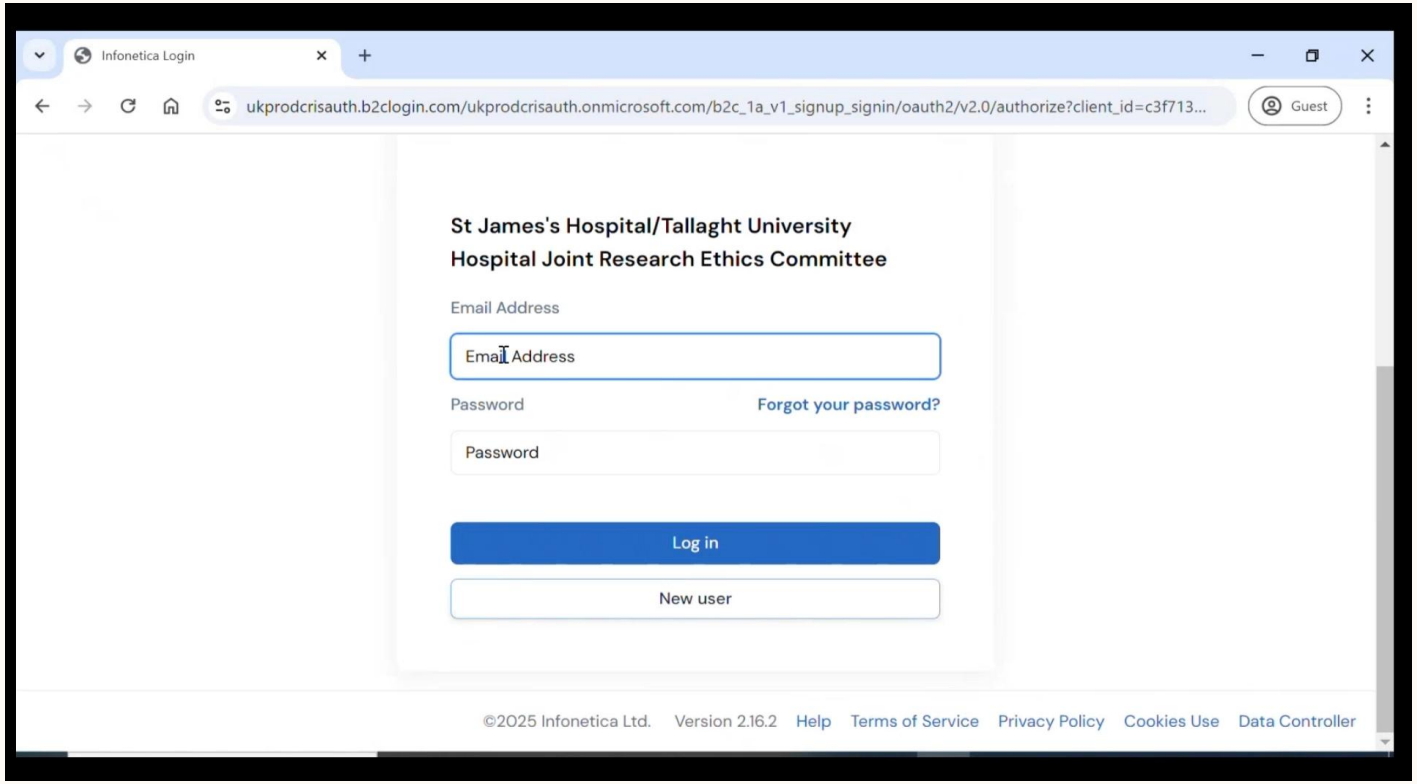
CREATING A PATHWAY 1 APPLICATION (JREC AND R&I APPLICATION)

1. Log in to your Infonetica account
2. Select ‘Create Project’ from the Action Pane
3. Select ‘SJH/TUH Research Registration and JREC Form’
4. Create and complete your JREC form
5. Create your R&I sub-form



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PATHWAY 2

Pathway 2 is for applications where **external ethics can be accepted.**

- **Low risk** studies where the R&I office can accept university or institutional ethics
- **High risk** studies where external ethics such as NREC and CTIS are required

Pathway two allows applicants to bypass the JREC form and enables applicants to upload their letter of external ethical approval.

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PATHWAY 2: RESEARCH TYPES

High Risk
Requires NREC / CTIS

Clinical Trial

Medical Device Trial – Subject to medical device regulations

Low risk
University/ Institutional accepted

Staff study

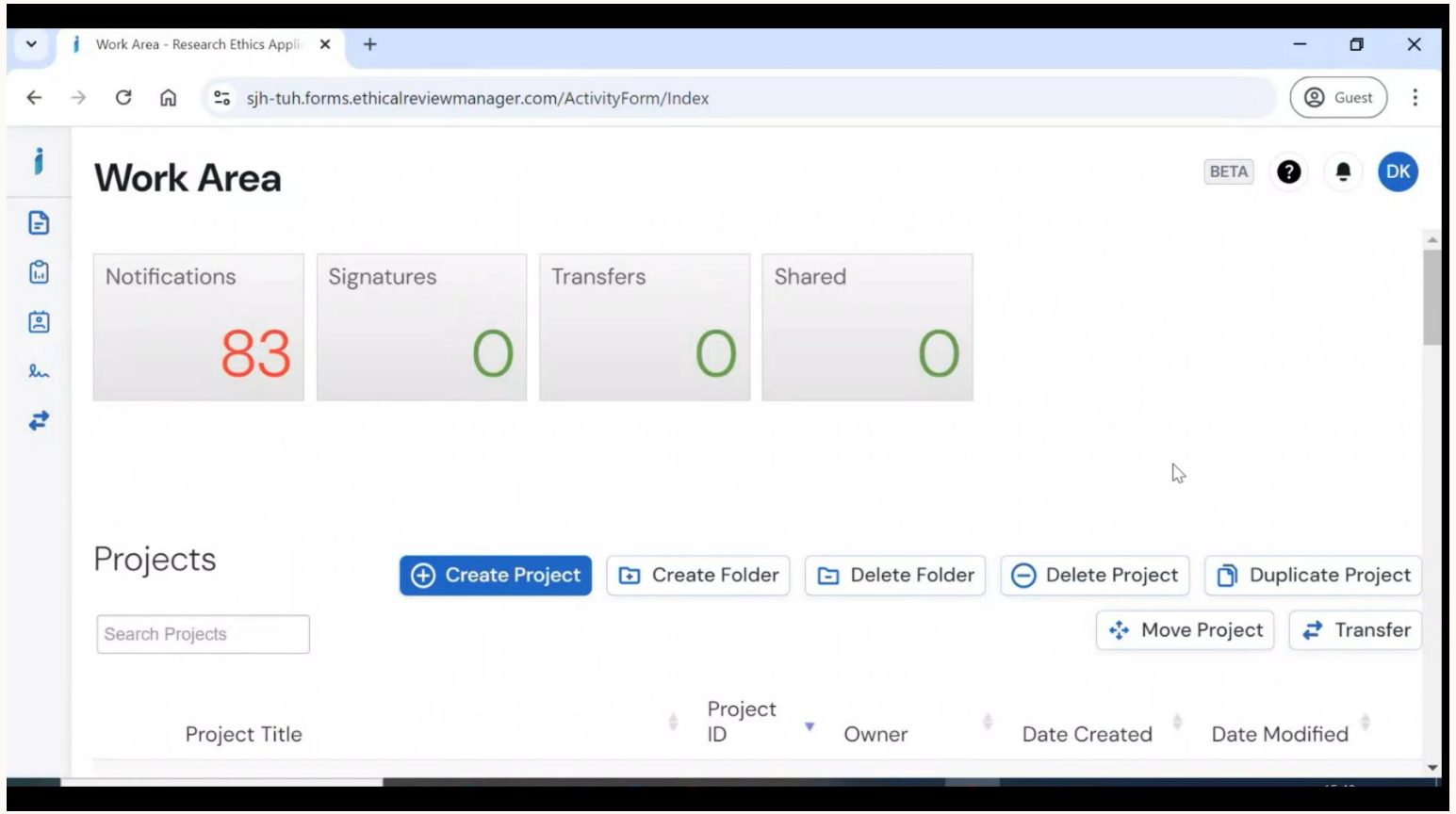
SJH as a site of advertisement only

Multi-site ionising radiation trial – where the first site has ethical approval in place

Case study - less than 5 patients (ethics not required)

CREATING A PATHWAY 2 APPLICATION (UPLOAD EXTERNAL ETHICS)

1. Log in to your Infonetica account
2. Select ‘Create Project’ from the Action Pane
3. Select ‘Pathway 2 Case Studies <5 patents, Staff Studies & regulated clinical & Medical device Trials’’
4. Complete your R&I form



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CREATING AND COMPLETING YOUR R&I APPLICATION

Pathway 1 Application Sections

Pathway 2 Application Sections

Successfully Submitting your R&I Application: 3 steps

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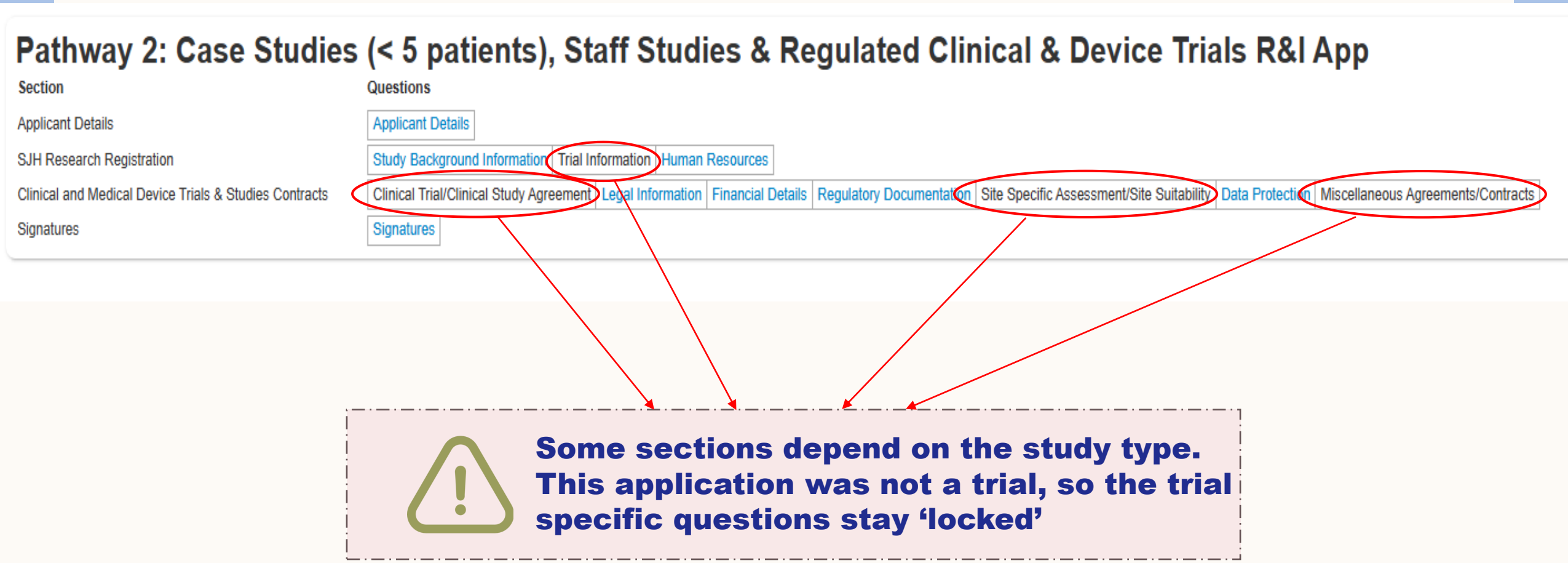
APPLICATION SECTIONS: PATHWAY 1

Pathway 1: SJH R&I Application Form Clinical Research

Section	Questions
Background	Applicant Details | General Information
SJH Research and Innovation Application Form	Study Background Information | SJH R&I Questions | Human Resources Details
SJH Mandatory Training	SJH Mandatory Training
Data Protection Impact Assessment (DPIA)	Explanation of terms used in DPIA | Data Protection Impact Assessment (DPIA)
Legal Information	Legal Information
Financial Details	Financial Details
Document Upload	Document Upload
Signatures	Sign off | Signatures

APPLICATION SECTIONS: PATHWAY 2



Some sections depend on the study type. This application was not a trial, so the trial specific questions stay 'locked'

SUBMITTING YOUR R&I APPLICATION

Once you have completed all questions in you R&I application you must submit the application for review.

There are three steps:

1. The applicant signs off using their username and password 
2. The applicant requests the PI's signature using the PI's user email 
3. The PI reviews the application and signs off with their username and password 

YOUR APPLICATION IS NOT SUBMITTED UNTIL THE PI SIGNS OFF.

THE No.1 CAUSE FOR DELAYED REVIEW AND APPROVAL IS NO PI SIGNATURE ON APPLICATION!

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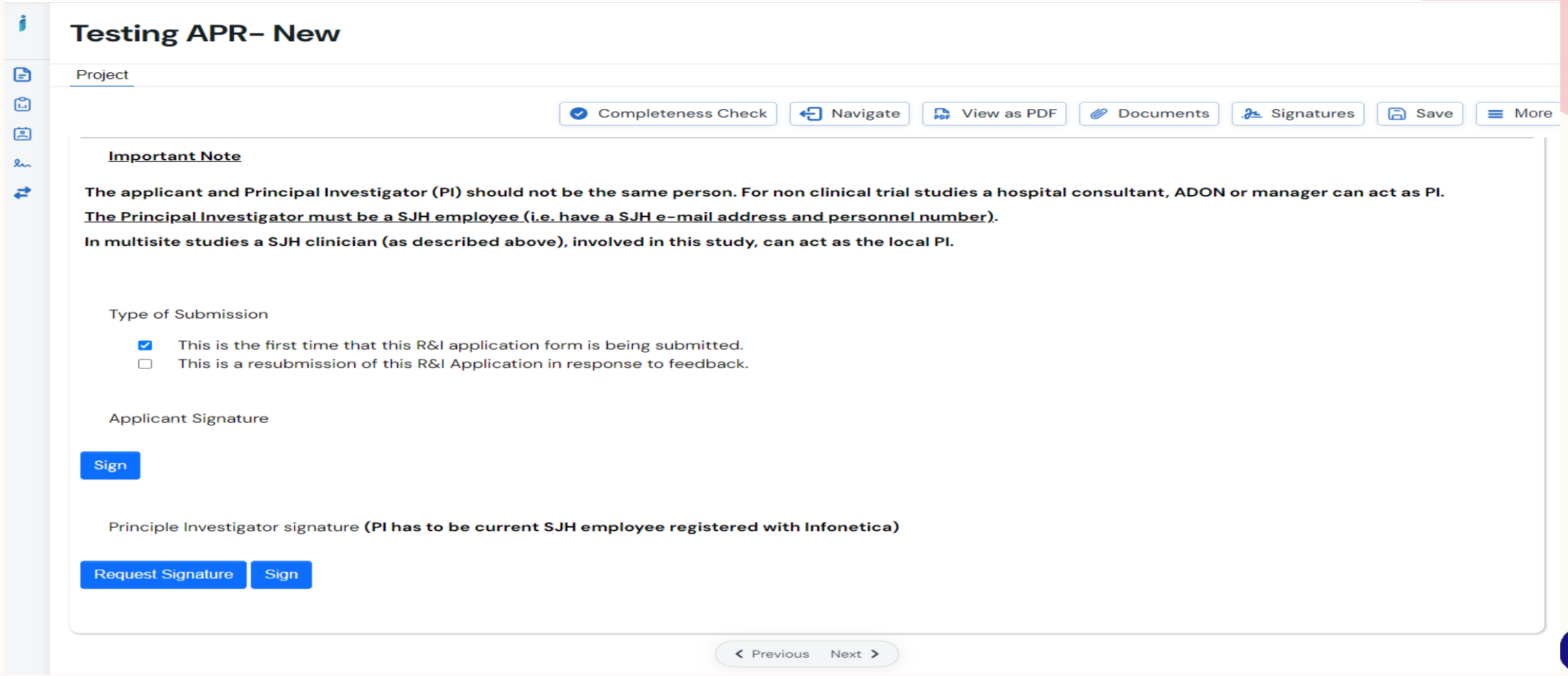
How sign off your application and request your PI's Signature



SUCCESSFUL SUBMISSION

From: donotreply@infonetica.net
Sent: Thursday 14 August 2025 09:10
To: Research & Innovation
Subject: EXTERNAL Re: Your Signature Request

CAUTION: This email originated from outside of St James's Hospital. Do not click links or open attachments unless you recognise the sender and know the content is safe.

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

Dear MsKeane

Your signature request has been accepted by Mr CRF SJH TCD.

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

Link to Infonetica: https://sjh-tuh.forms.ethicalreviewmanager.com/Account/Login

If you do not receive this email, your application is **NOT** submitted!

Your PI **must accept the signature request and sign off** to ensure full submission

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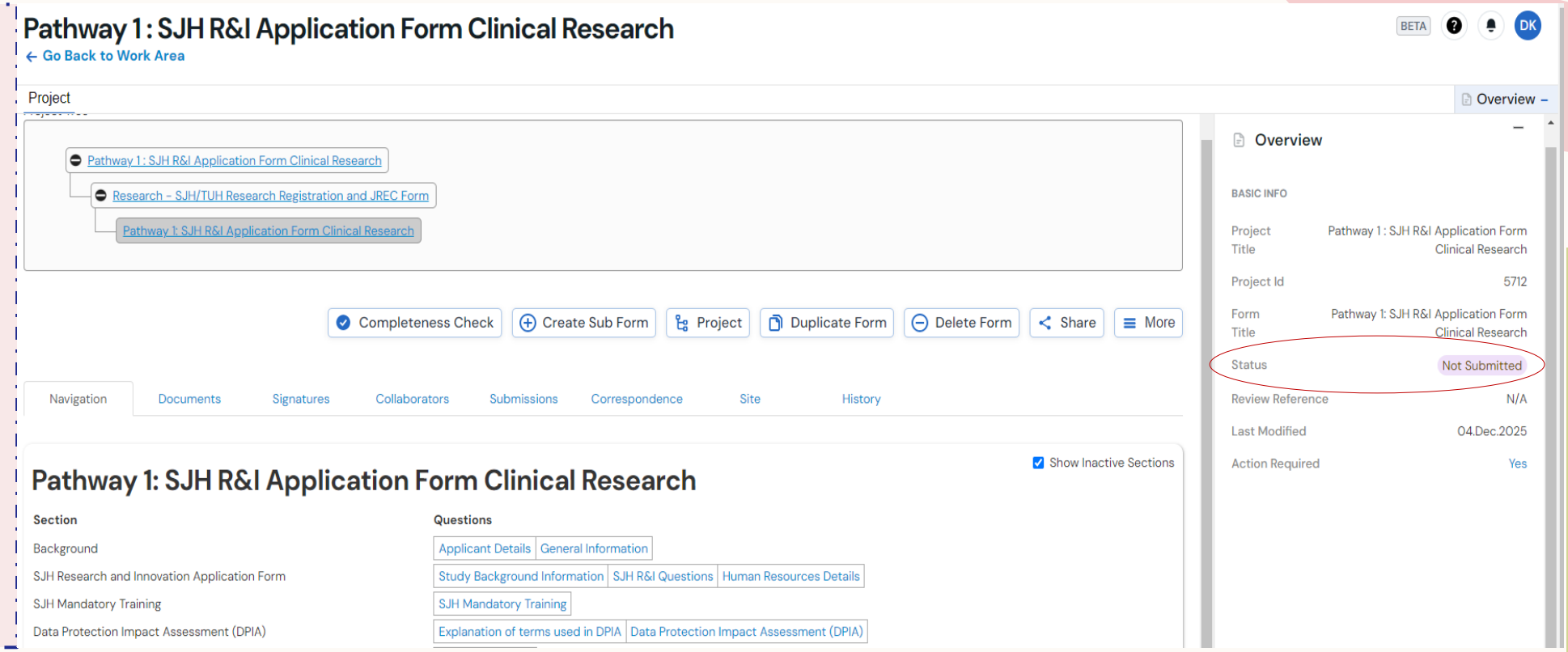
CHECK YOUR APPLICATION STATUS AT ANYTIME!

- Check if your application is fully submitted
- Helps you stay updated on your application's process
- Know when your application has been returned with queries/ comments



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AFTER SUBMISSION

Review Process

Responding to Reviewer Comments on your Application Form

Responding to Comments on Supporting Documents

R&I Approval Letter

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R&I APPLICATION REVIEW PROCESS

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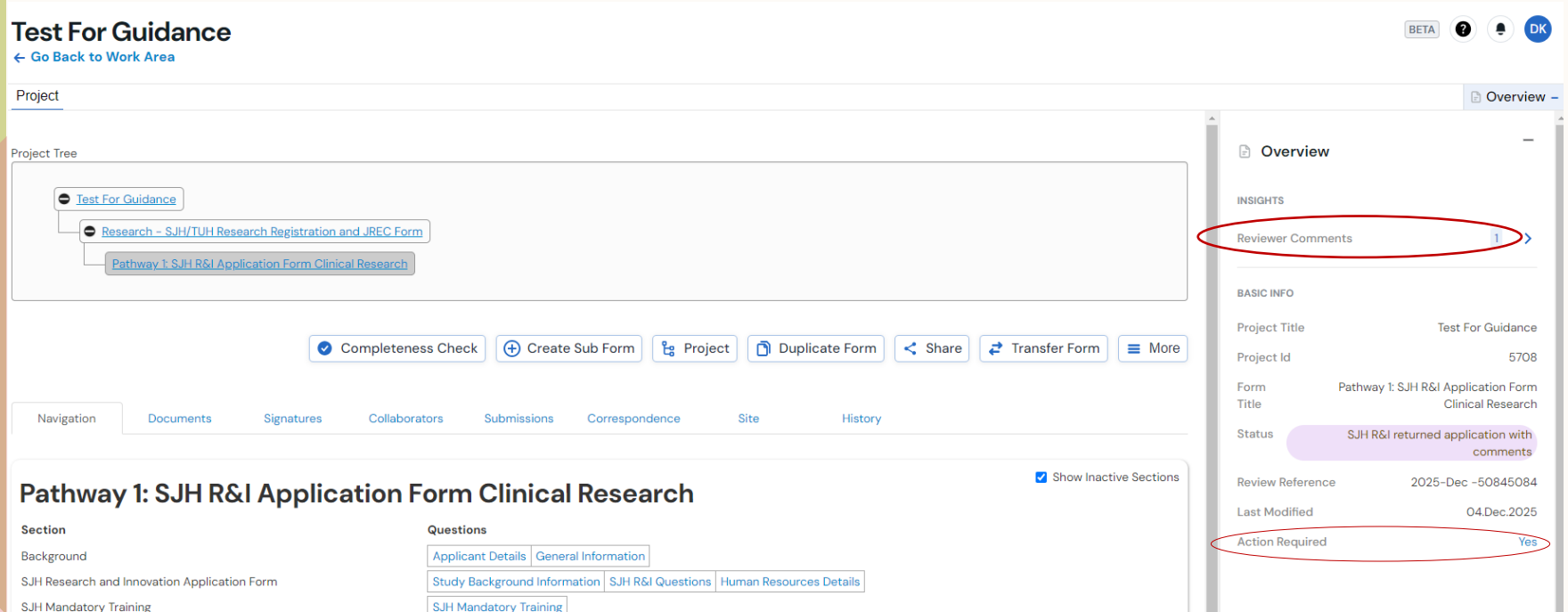
ADDRESSING COMMENTS/ FEEDBACK

When a form is returned with comments, the status will change to indicate information is required.

‘Action Required’ will state **yes** as you are required to address comments.

To view the reviewer comments, click ‘reviewer comments’ in the action pane. Clicking on the individual comments will bring you directly to their location within the form

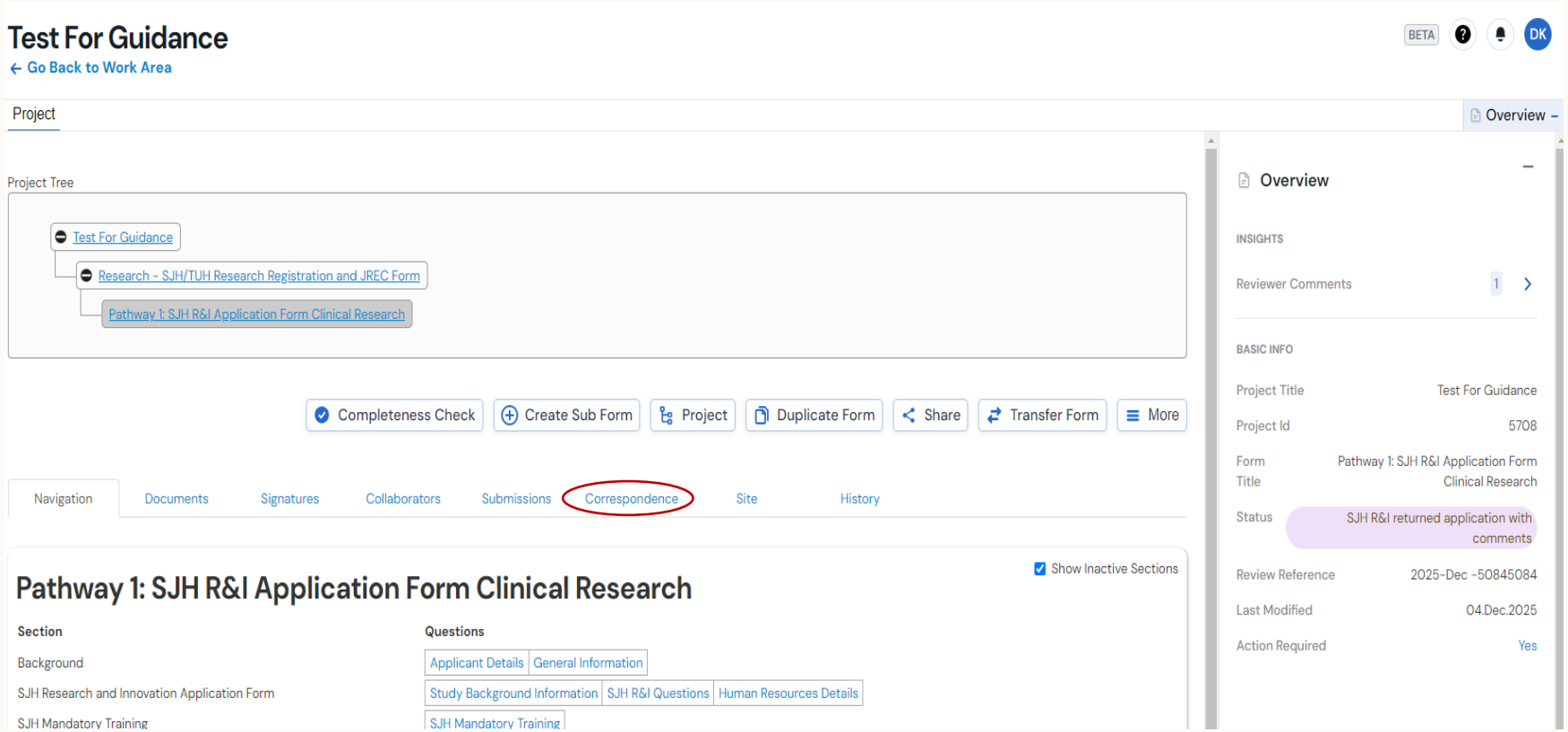


COMMENTS ON SUPPORTING DOCUMENTS

Supporting documents are also reviewed and may be returned with feedback.

Documents are returned with comments via correspondence

The applicant must download the document, address the comments and re-upload the document as a correspondence



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EXAMPLE: LETTER OF R&I APPROVAL

You do not have permission to proceed until you have received this letter of R&I approval

This is the only accepted proof of approval.

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Project ID: [Project Id]

[Applicant Title] [Applicant Last Name],

[Applicant Organisation]

[Lead Principle Investigator (Multisite) Title], [Lead Principle Investigator (Multisite) First Name], [Lead Principle Investigator (Multisite) Last Name], [Lead Principle Investigator (Multisite) Organisation]

[Lead Co-Investigators (Multi-site) Title], [Lead Co-Investigators (Multi-site) First Name], [Lead Co-Investigators (Multi-site) Last Name], [Lead Co-Investigators (Multi-site) Organisation]

[Principle Investigator Title], [Principle Investigator First Name], [Principle Investigator Last Name], [Principle Investigator Organisation]

Approval Date: [Todays Date (Long)]

Submission Number: [Submission Number]

Submission Title: [Project Title]
Submission Date: [Submission Date]

Dear [Applicant Title] [Applicant Last Name],

I wish to inform you that your study has received **FULL APPROVAL** from the St. James's Hospital Research & Innovation Office. Your study can now proceed.

Any final comments submitted by reviewers will be shown below.

Title	Comment
Title	Comment
Title	Comment

The following documents were reviewed and approved:

Document Type	File Name	Date	Version
Document Type	Title	16.May.2001	Version
Document Type	Title	16.May.2001	Version

Yours sincerely,

SJH R&I Office

KEY TIPS

- **Reminder**:
  - Pathway 1 – JREC + R&I application
  - Pathway 2 – External ethical upload within R&I application
- When checking the status of your application or addressing comments, ensure that you have selected the **R&I application branch** of your project tree
- **Data Sharing Agreement, Participant Information Leaflets and Informed Consent Form templates** are available on Infonetica – click ‘help’ on the top bar and select ‘templates’ from the drop down
- We will accept **DPIAs on sponsor templates** – you can upload these directly to the application
- You can submit your application while your ethics is still pending!

DPIA FAQS

What counts as Personal Data in hospital-based health research?

Personal Data includes any information relating to an identified or identifiable living person—such as patient names, DOB and contact details. If a patient can be identified directly or indirectly, the data is considered Personal Data.

What is Special Category Personal Data, and why is it important in hospitals?

Special Category Personal Data (also called sensitive data) includes health data, genetic and biometric data, and information revealing racial or ethnic origin, religious beliefs, or sexual orientation. The Hospital routinely process this type of data, which requires extra protection under GDPR.

Who is the Data Controller in hospital research?

The Data Controller is the organization (often, but not always, the hospital) that determines why and how Personal Data is processed. In research, the hospital is usually the Controller for data collected for the direct care of the patient, while the research sponsor (e.g., university or pharma company) may be the Controller for research data. Sometimes, both act as Separate Controllers for the same data but for different purposes.

Data handler or Data Processor?

Data handlers on a hospital research team are staff working under the hospital's control, following its policies as part of its role as Data Controller. A Data Processor is an external organisation/individual contracted by the hospital to process data on its behalf under a formal Data Processing Agreement.

What is pseudonymised data, and how should it be handled?

Pseudonymised data replaces identifying fields with a code. If the hospital holds the key, it is still Personal Data under GDPR. If shared without the key and with safeguards (e.g. Sharing Agreement), it may be considered anonymous by the recipient, but this interpretation varies—always check with the DPO before sharing

DPIA FAQS

What is anonymised data?

Anonymised data is information that has been altered so individuals cannot be identified, directly or indirectly, by any means. Once data is fully anonymised, it falls outside the scope of GDPR and Health Research Regulations.

Pseudonymised data held by the hospital cannot be considered anonymous because the hospital retains the key that can re-identify individuals.

In projects with small sample sizes, anonymisation may be harder to achieve because unique characteristics can still allow identification. Publishing anonymised datasets online increases the risk of re-identification when combined with other publicly available data. Researchers must assess and detail these risks in the DPIA before sharing data.

Do I need explicit consent from participants?

Yes, explicit consent is the default safeguard under the HRRs, in addition to GDPR Article 6(1)(e) and Article 9(2)(j) legal bases.

Can I conduct a retrospective chart review without explicit consent?

Retrospective chart reviews can be conducted, often without explicit consent, provided the research is low-risk and approved by an ethics committee. Access to patient data is restricted to authorized personnel, and the data must be handled with the highest privacy standards, with any published results being anonymized.

Only authorised individuals, such as a healthcare practitioner, a supervised student, a SJH employee who has routine access, or an 'Authorised Person' appointed by SJH, can access the data. Personal data accessed for a retrospective chart review cannot be shared with third parties unless it is fully anonymized. Any published results must not identify individuals.

DPIA FAQS

What if obtaining consent isn't feasible?

If obtaining consent is impractical and public interest justifies it, researchers can apply to the Health Research Consent Declaration Committee for a consent declaration.

What rights do patients (Data Subjects) have regarding their data in hospital research?

Patients have the right to be informed, access their data, request corrections, object to processing, restrict processing, request erasure (only in certain circumstances), and data portability. These rights must be clearly communicated, usually via a participant information leaflet or privacy notice

What are the main responsibilities of hospital-based researchers regarding data protection?

These would include:

- Seek ethics approval and complete a DPIA (if acting as a Controller) on Infonetica.
- Ensure a signed Data Processing/Sharing Agreements are in place before processing personal data for commences.
- Follow the hospital’s data protection policies.
- Undertake data protection training.
- Use secure, approved systems for storing and transmitting data.
- Notify the Data Protection Officer of any data breaches.

UPCOMING EVENTS & TRAINING

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Ethics Support Clinics

These clinics help researchers navigate the ethics application process and ask questions specific to their projects.

Thursday, 26 February, 10:00–12:00

Tuesday, 28 April, 11:00–13:00

To register, please complete this form

Ethics Clinic – Fill out form

Space is limited and sessions operate on a first-come basis.

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Statistics Support Clinics

These clinics help researchers in the study design and data analysis for research projects.

Thursday 12 March, 15:00–17:00
Monday 23 March, 10:00–12:00
Wednesday 15 April, 12:00–14:00
Friday 1 May, 08:00–10:00

To register, please complete this form

Research Statistics Clinic–Fill out form

Space is limited and sessions operate on a first-come basis.

Health Research Board
TMRN
Trials Methodology Research Network

Statistical Power and Sample Size in Clinical Trials and Statistics Clinic

€20 - €200
Fri, Mar 6, 2026 · 10 am
Get tickets

By Trinity College Dublin and the HRB-TMRN · Follow

St James Hospital · Dublin 8, Dublin
Friday, Mar 6, 2026 from 10 am to 4 pm

Overview

This Study Day is tailored for everyone involved in clinical trial design, conduct and analysis.

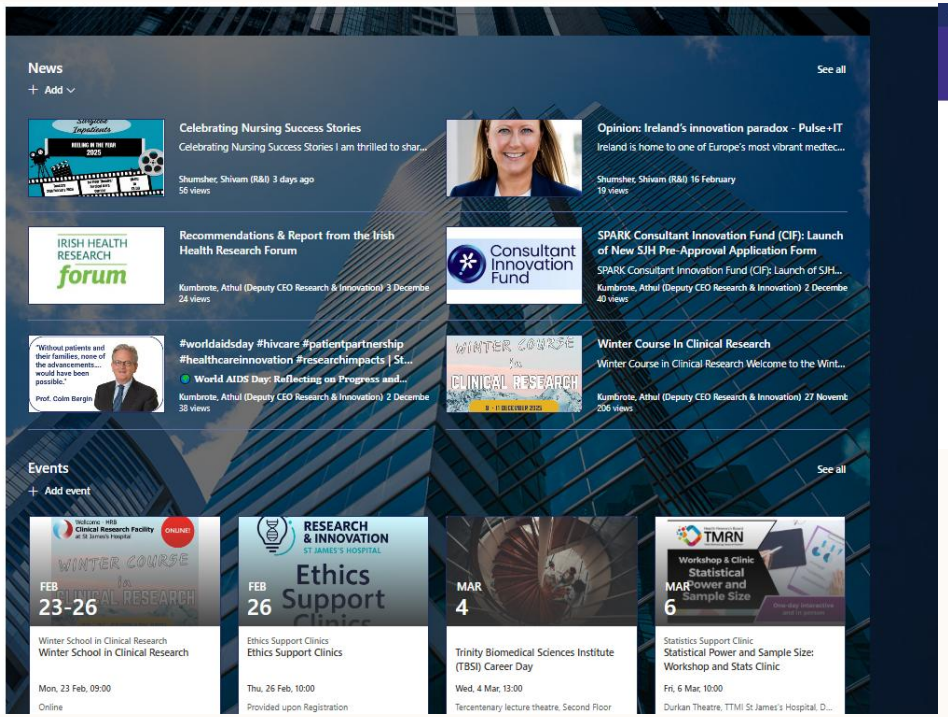
TRANSLATIONAL MEDICINE Conference 2026

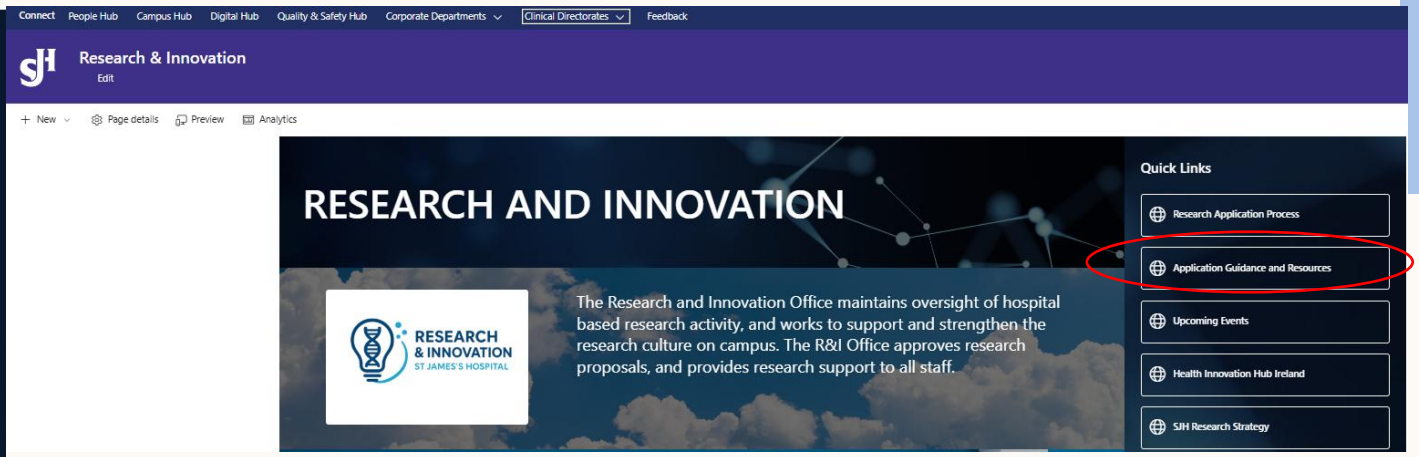
Free
Fri, Mar 27 · 9 am
Reserve a spot

Trinity Translational Medicine Institute · Dublin, Dublin
Friday, Mar 27 from 9 am to 5 pm

UPCOMING EVENTS & TRAINING

UPCOMING EVENTS & TRAINING





USEFUL LINKS

- Link to apporved projects on R&I page
- Link to publications on R&I page
- Link to funding information on R&I page
- Good Clinical Practice (GCP) Training
- R&I Application Guidance Manual
- R&I Application Guidance Videos

THANK YOU!
QUESTIONS?

research@stjames.ie

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