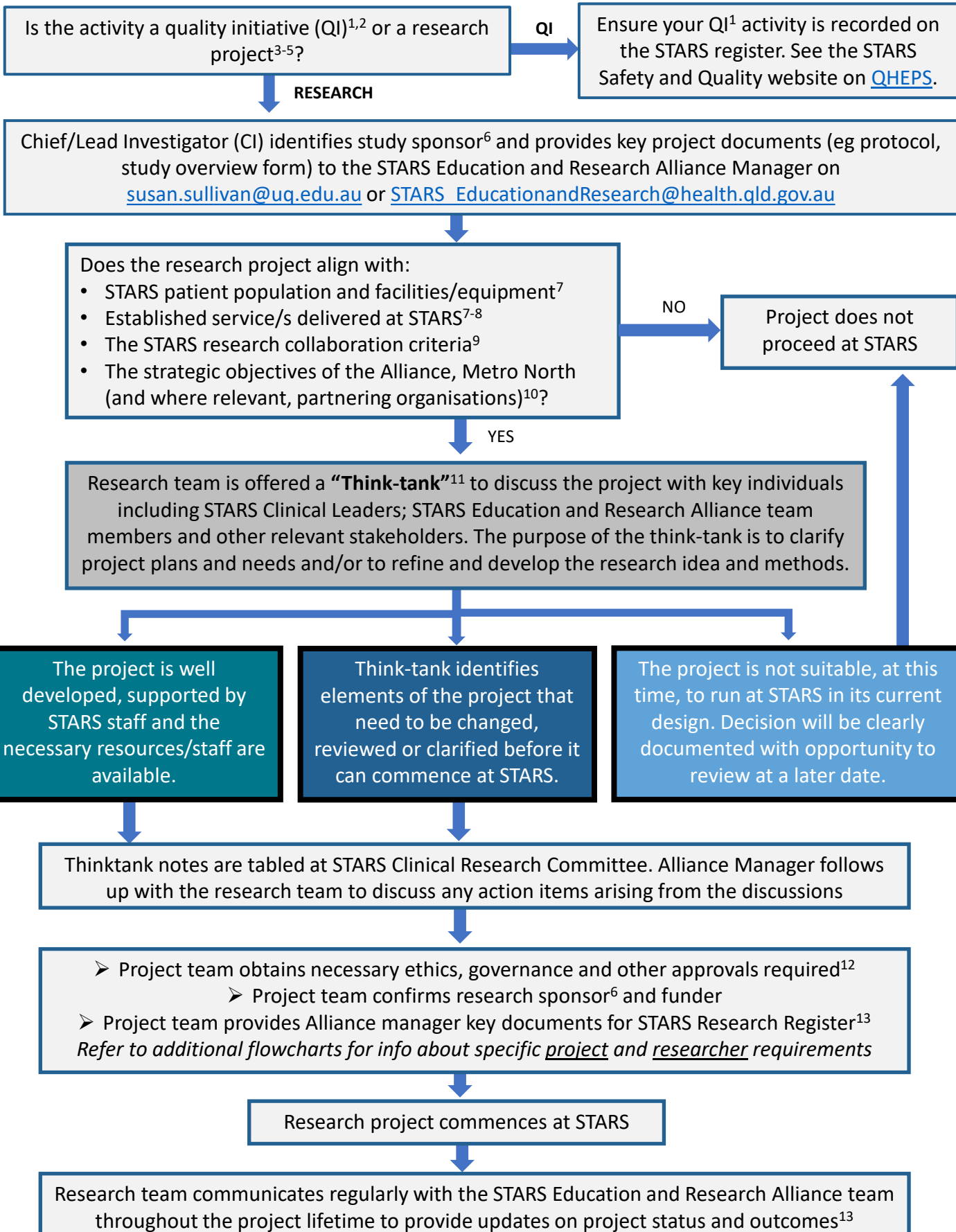


Research Processes at STARS Flowchart: Overview



Research Processes at STARS Flowchart: Project Requirements

Does the project involve Metro North (MN) patients (or their data/tissues), Metro North staff¹⁴, or collect data in a hospital or health service facility?

YES

NO

You will need human research ethics committee (HREC¹⁵⁻¹⁶) approval from an NMA-certified HREC¹⁶⁻¹⁷ and site-specific assessment (SSA¹⁸) approval, both via the ERM system¹⁹.

NB: if you have ethics and governance approval for another MN facility (eg SSA approved for RBWH), then you can complete a post-authorization notification to add STARS as a site.

Institutional (eg UQ) HREC²⁰ approval required. Research must be solely conducted by non-MN researchers only on Level 1 or 7 of STARS on participants/data/tissues that are not associated with a hospital or health service.

“STARS-led” or “STARS-collaborating” project¹³

STARS “Facility Only” project¹³

Do any of the following apply to the project?

- UQ is the sponsor or lead investigator is from UQ
- UQ students are undertaking research for their degree;
- UQ is a research site (recruitment, data collection etc)

YES

UQ HREC ratification required²¹

NO

Does the project involve multiple organisations/institutions or the commitment of resources from multiple parties?
Eg data, specimens, equipment, finances, staff in-kind time

Legal agreement required²²

YES

NO

Do you need to access confidential, identifiable, or potentially re-identifiable patient data²³ held by a hospital *without the prior consent* of the participant?

YES

You will need an approval under the Public Health Act 2005 (QLD) also called “PHA approval”²⁴

NO

Is the project a clinical trial²⁵?

YES

NO

Register trial with ANZCTR²⁶ and ensure all researchers have current GCP accreditation²⁷

Insurance & indemnity²⁸. Is UQ the study sponsor?

YES

UQ Insurance²⁹ covers the liability of almost everyone associated with human research studies.

NO

- Check that research sponsor (eg MN or other HHS) has appropriate insurance for the study²⁸.
- Ensure all individuals have appropriate insurance and indemnity to cover their role in project²⁸⁻²⁹

Does the clinical trial involve pregnant women, patients aged 2 years and below, or overseas trials sites?

YES

NO

Complete UQ Insurance **declaration**²⁹

Complete UQ Insurance **notification**²⁹

Proceed to researcher requirements flowchart

Research Processes at STARS Flowchart: Researcher Requirements

In what capacity are you undertaking this research project³⁰?

EMPLOYEE³¹

OTHER – “External researcher”³²

Examples:

- Metro North (MN) or QH employee
- Conjoint employee (MN as lead employer)
- Conjoint employee³³ (MN as affiliate employer AND legal agreement meets minimum requirements of MN External Researcher Policy 006903)³⁴

Examples:

- Unpaid appointment with a university or research institute
- Employee of University or research institute
- Conjoint employee (Uni as lead employer)³³
- Student undertaking activity not covered under the QH Student Placement Deed

YES

Are you credentialed³⁵ at STARS for the direct clinical practice activities outlined in the research project?

NO

YES

NO

Credentialing process for STARS. Refer to profession-specific guidelines³⁵

Refer to processes outlined in the Metro North External Researcher Policy³⁴ 006903, associated guideline and access form

EMPLOYEE

EXTERNAL RESEARCHER

ID badge and access card⁴⁰

Based on the defined activities of the individual researcher, determine the requirements for:

- Criminal history check³⁶
- Vaccine Preventable Disease (VPD) evidence³⁷
- Insurance and indemnity²⁸⁻²⁹
- Blue card³⁸ if working with children <18yr
- Mask fit details³⁹

Proceed once External Researcher Access Form is fully approved.

Do you require access to QLD Health ICT⁴¹ services (eg ieMR⁴²)?

YES

NO

- Determine the requirement for credentialing³⁵
- Novell (QH) account⁴³
- ieMR training⁴⁴
- ieMR access provisioning⁴⁵

- Mandatory training⁴⁶ (minimum):**
- QH GEI & First response
 - Mandatory training modules required by employer

Risk Assessments⁴⁷

- Formal, written risk assessments must be approved in UQSafe-Risk (or relevant database of collaborating institution) to cover all activities that occur as part of this research project
- All researchers aware of risk assessment/s relevant to project

Research may commence at STARS once the necessary project and researcher approvals are obtained