Understanding process flows in REGIS

NSW GOVERNMENT eHealth

Submission flows in REGIS

Initial submission to approval/authorisation

- Completing Project Registration
- Completing the HREA/ETH
- Completing the SSA/STE

Post approval Monitoring - Ethics is in REGIS

Completing a Notification of an amendment

- Change CPI, Change PI and Change Admin
- HREC Extension
- Add site
- General

- Submit a Progress Report/Milestone to a NSW/ACT HREC and NSW/TAS RGO
- Submit a Safety Report to a NSW/ACT HREC and NSW RGO SSI
- Safety Report Breach (under review)

Post approval Monitoring Governance - Ethics in REGIS

Submit a Site Amendment General after NSW/ACT Ethics approval

Post approval Monitoring Governance - Ethics is external to REGIS

- Completing a Site Amendment that requires an ethics approval
  - HREC Extension & Change CPI
  - General Amendment & Change PI
- Completing a Progress Report Milestone – ethics external to REGIS (under review)

Post approval Monitoring Governance - ethics not required

- Adding/Removing Site Admin contacts and submitters
- Adding/Removing Local Site investigators (under review)
- Contract Changes from a previously approved amendment
- Submit a Certificate of Currency Milestone to a NSW RGO (under review)
- Submit a Safety Report to NSW RGO when Ethics approved from another jurisdiction
  - SSI (under review)
  - Local Safety Event (under review)

NSW/TAS Specific Acknowledgement Statement

- *"This amendment notification has been provided to all NSW/TAS Health Site Research Governance Officers, all contact details have been updated, you are not required to submit any further documentation to any NSW/TAS Health Sites (listed in REGIS)."*
- *"Each authorised site in REGIS has been notified and will only contact you if they require more information. Please accept this notification on behalf of all NSW/TAS sites listed in the form."*
- In September 2020, NSW released the governance post approval functionality in REGIS with a focus on improving researcher experience and streamlining processes by using the system to reduce duplication. This will be an overall improvement for researchers and research offices.
- A number of processes are now submitted by the Lead Site to the HREC and on approval the system manages the notification to all REGIS authorised sites (PIs, Admin Contacts and RGOs). The Ethics approval email includes a NSW Specific acknowledgement statement. One action across NSW e.g Change CPI, HREC extension, Clinical Trial Safety Notifications, HREC progress reports.
- A number of processes can now completed by one Site (any authorised site) on behalf of the other authorised sites in REGIS, the notification email includes a NSW Specific acknowledgement statement. One action for NSW sites. E.g. Clinical Trial Safety Notifications, HREC approved progress reports, updated certificate of currency.

Application Flows

Project Registration (PID) → Ethics Application HREA (ETH) *click to progress to ETH flow* → Site Application (STE) *click to progress to STE flow* → Post Approval Monitoring

How does an initial application flow through REGIS?

START: **Has this Study been registered (by the lead site) in REGIS previously?**

- **No** → **Create new project**
  Status: In Progress
  see QRG Completing Project Registration
  **the project registration can not be changed or edited after submission*
  → **Submit PID**
  Status: Registered
  HREA required in REGIS?
  REGIS supports NMA. If ethics has been submitted to a lead HREC outside of NSW/ACT the option is "No".
  - **Yes** → **Progress to ETH**
    see QRG Completing Ethics Application
    → Click for **ETH Flow**
  - **No** → Are you a "Lead Site" with sites in other jurisdictions (VIC, QLD, WA, SA)?
    - **Yes** → **Lead Site registers** the study in any other online platforms See *NMA guidance*
      → **ERM**, **RGS**, **GEMS**
    - **No** → **Progress to STE/s**
      see QRG Completing Site Application
      → Click for **STE Flow**
- **Yes** → **Do not compete a PID**
  see QRG Create a new site application
- **I don't know?**
  1. Speak to the lead site and ask if this study has been registered in REGIS. No = progress, Yes = ask for them to create the STE or give you access.
  2. Start a new Project Registration, enter the Ethics ID, if this ID has been entered before a warning message will show up. Do not progress. Contact the lead site ask them to create STE or give access.

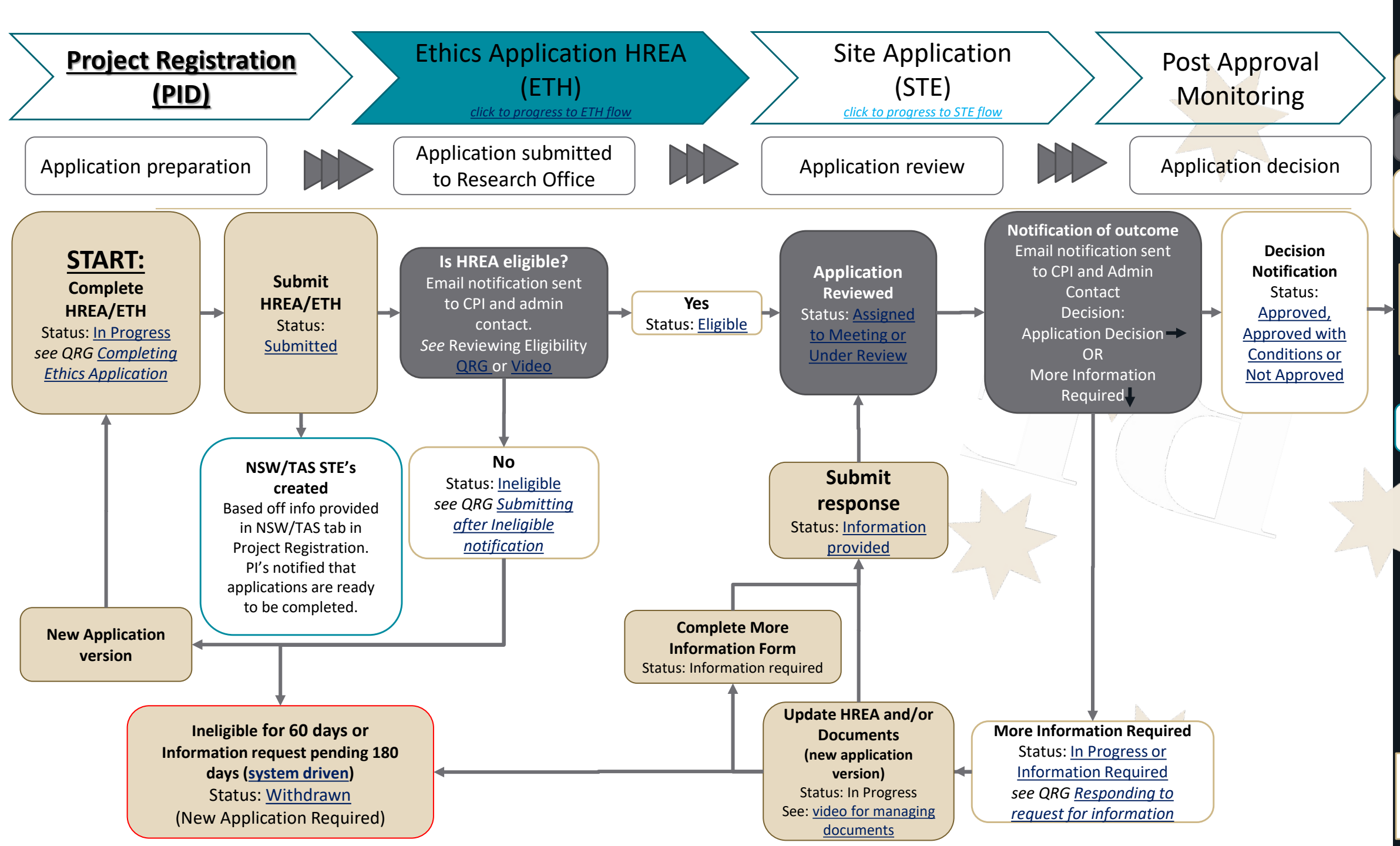
Confirmation of Registration System generated email sent to CPI, Submitter & Admin confirm PID complete and ready for next step

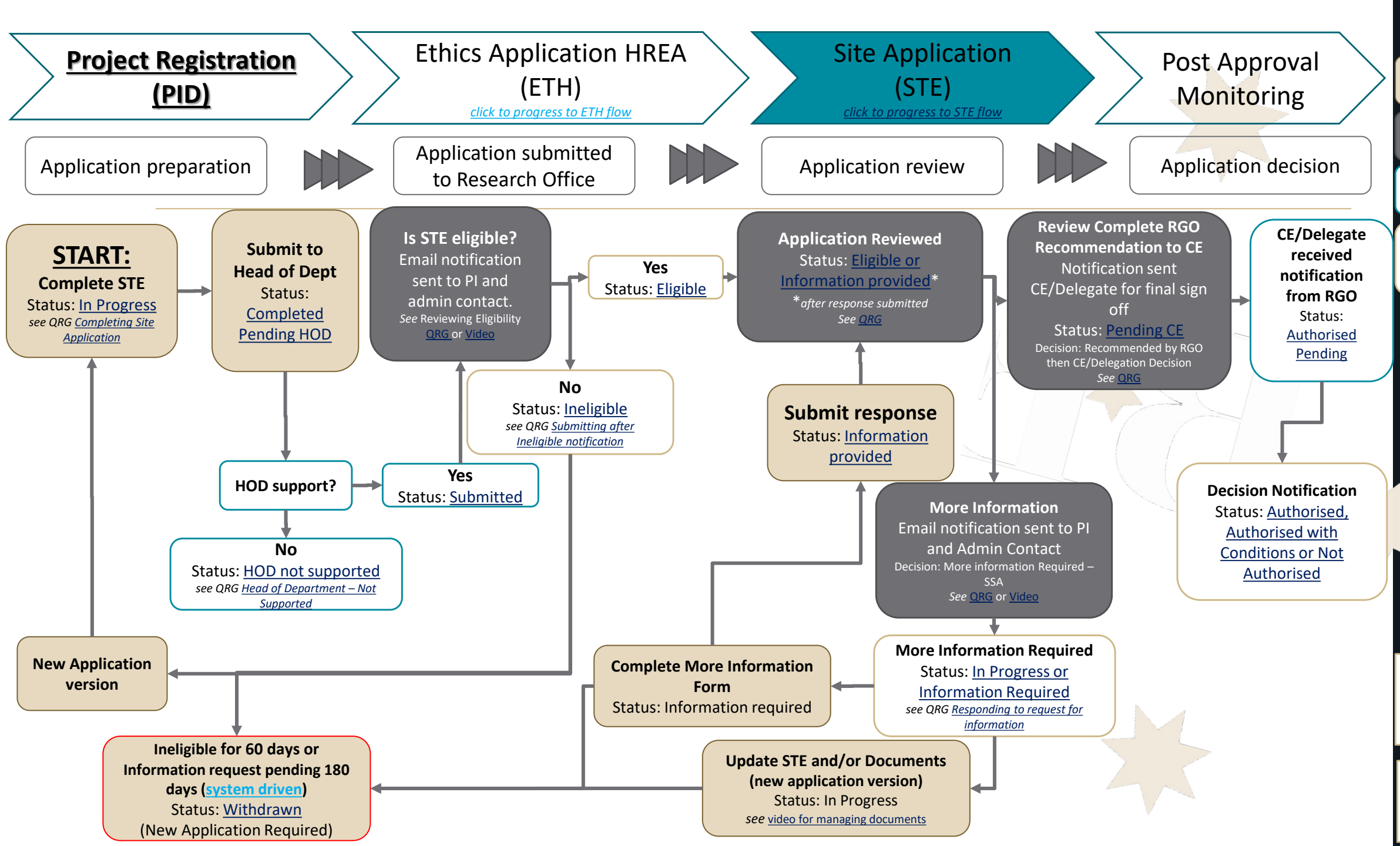
Key

- Researcher
- System automation
- Stop Point

QRG = quick reference guide

NMA = National Mutual Acceptance


Project Registration (PID)
Ethics Application HREA (ETH)
click to progress to ETH flow
Site Application (STE)
click to progress to STE flow
Post Approval Monitoring
Application preparation
Application submitted to Research Office
Application review
Application decision
START:
Complete HREA/ETH
Status: In Progress
see QRG Completing Ethics Application
Submit HREA/ETH
Status: Submitted
Is HREA eligible?
Email notification sent to CPI and admin contact.
See Reviewing Eligibility QRG or Video
Yes
Status: Eligible
Application Reviewed
Status: Assigned to Meeting or Under Review
Notification of outcome
Email notification sent to CPI and Admin Contact
Decision: Application Decision
OR
More Information Required
Decision Notification
Status: Approved, Approved with Conditions or Not Approved
NSW/TAS STE's created
Based off info provided in NSW/TAS tab in Project Registration.
PI's notified that applications are ready to be completed.
No
Status: Ineligible
see QRG Submitting after Ineligible notification
Submit response
Status: Information provided
New Application version
Complete More Information Form
Status: Information required
Ineligible for 60 days or Information request pending 180 days (system driven)
Status: Withdrawn
(New Application Required)
Update HREA and/or Documents (new application version)
Status: In Progress
See: video for managing documents
More Information Required
Status: In Progress or Information Required
see QRG Responding to request for information
Key
Researcher
Research Office
HREC Decision/ Communication
Click for STE Flow
System automation
QRG = quick reference guide
NMA = National Mutual Acceptance
CPI = Coordinating Principal Investigator
Click for PID Flow


Project Registration (PID)
Ethics Application HREA (ETH)
click to progress to ETH flow
Site Application (STE)
click to progress to STE flow
Post Approval Monitoring
Application preparation
Application submitted to Research Office
Application review
Application decision
START:
Complete STE
Status: In Progress
see QRG Completing Site Application
Submit to Head of Dept
Status: Completed Pending HOD
HOD support?
No
Status: HOD not supported
see QRG Head of Department – Not Supported
Yes
Status: Submitted
Is STE eligible?
Email notification sent to PI and admin contact.
See Reviewing Eligibility QRG or Video
Yes
Status: Eligible
No
Status: Ineligible
see QRG Submitting after Ineligible notification
Application Reviewed
Status: Eligible or Information provided*
*after response submitted
See QRG
Submit response
Status: Information provided
More Information
Email notification sent to PI and Admin Contact
Decision: More information Required – SSA
See QRG or Video
More Information Required
Status: In Progress or Information Required
see QRG Responding to request for information
Complete More Information Form
Status: Information required
Update STE and/or Documents (new application version)
Status: In Progress
see video for managing documents
Review Complete RGO Recommendation to CE
Notification sent CE/Delegate for final sign off
Status: Pending CE
Decision: Recommended by RGO then CE/Delegation Decision
See QRG
CE/Delegate received notification from RGO
Status: Authorised Pending
Decision Notification
Status: Authorised, Authorised with Conditions or Not Authorised
New Application version
Ineligible for 60 days or Information request pending 180 days (system driven)
Status: Withdrawn
(New Application Required)
Key
Researcher
Research Office
Head of Department or CE Support
RGO or CE/Delegate Decision/Communication
QRG = quick reference guide
NMA = National Mutual Acceptance
HOD = Head of Department
PI = Principal Investigator
RGO = Research Governance Officer
Click for ETH Flow
Click for PID Flow

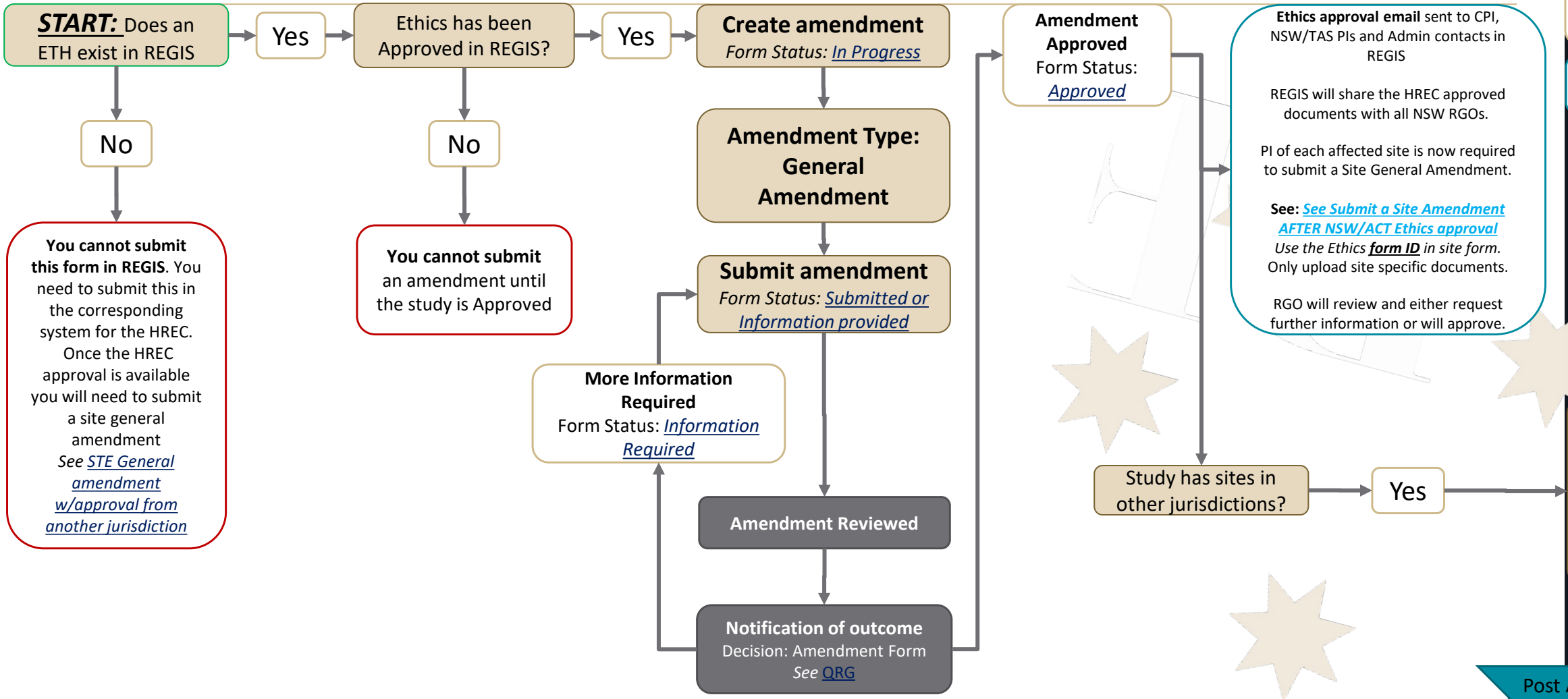
Project Flows – Ethics Post Approval

Submit a General Amendment to a NSW/ACT HREC and NSW/TAS RGO

Form Name: Notification of an amendment to a research study

Definition: are those affecting the conduct, design or methodology of a trial and includes changes to: Study Protocol, Information previously given in the HREA, Information sheet(s) and consent form/s for participants or to any other supporting documentation for the study.

Resources available: Submitting Ethics Amendment (QRG & Video), Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)

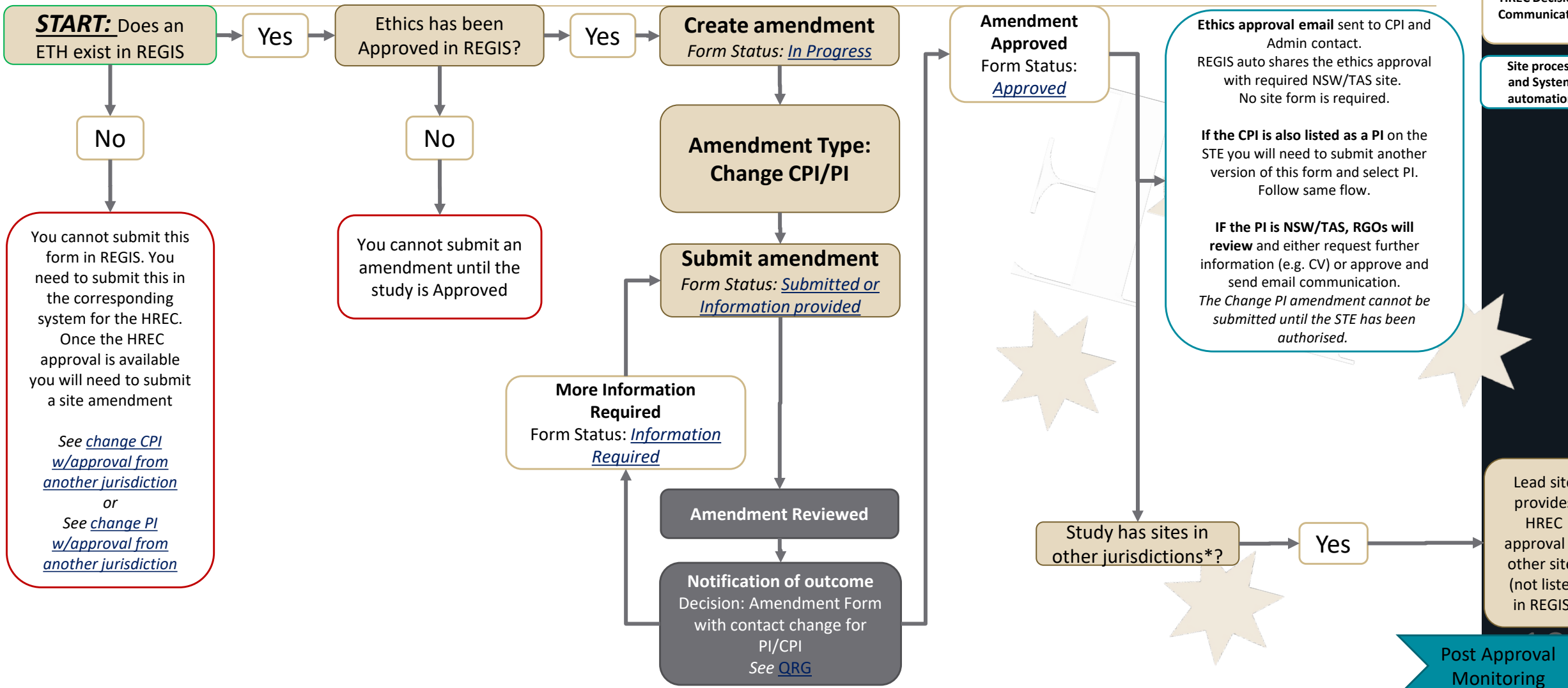


Submit a Change of CPI &/or PI Amendment to a NSW/ACT HREC and NSW RGO

Form Name: Notification of an amendment to an approved study

Definition: You are only required to notify the HREC of changes to the Coordinating Principal Investigator and/or site Principal Investigator(s). When changing the CPI it is likely that a change PI at a site will need to be submitted.

Resources available: Submitting Ethics Amendment (QRG & Video), Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)

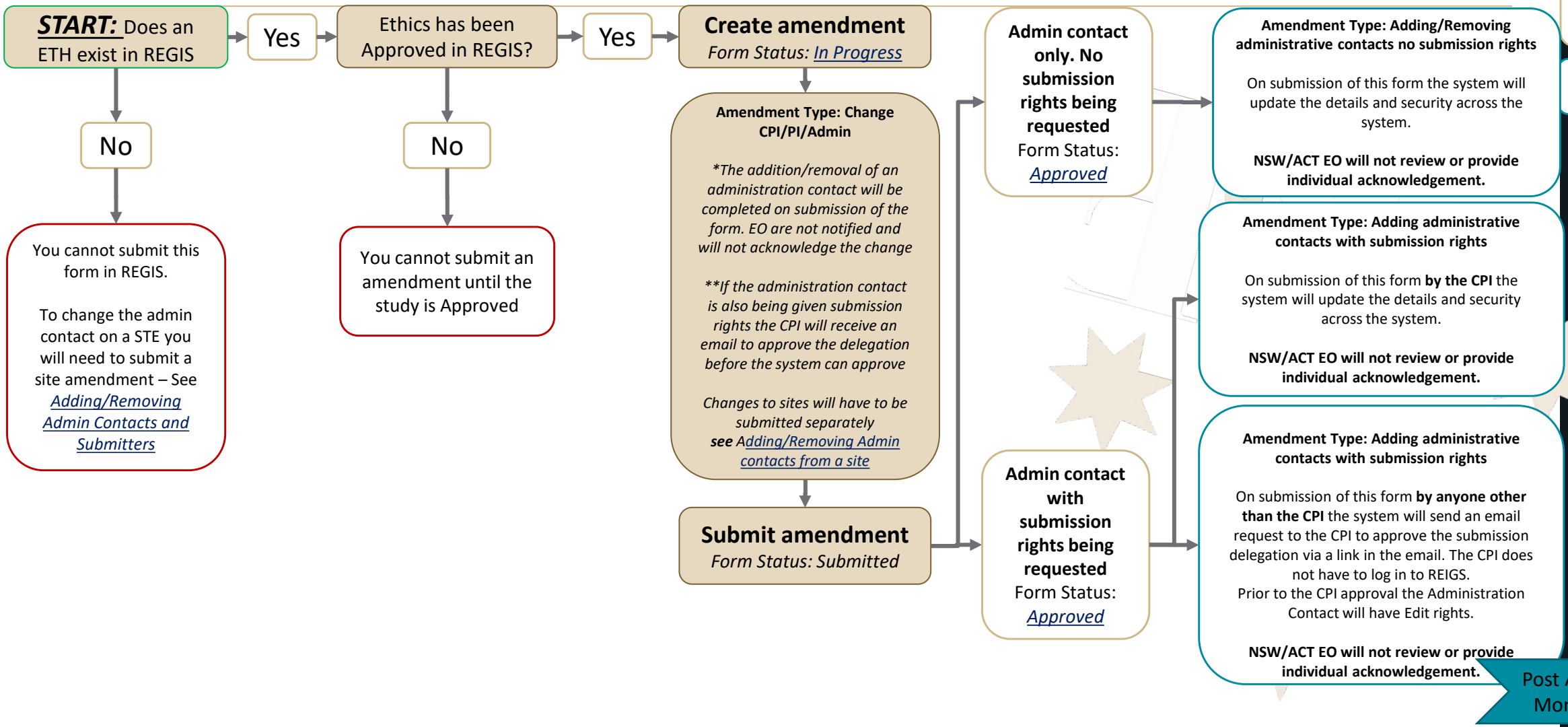


Submit an Add/Delete Admin Contact Amendment to a NSW/ACT HREC

Form Name: Notification of an amendment to an approved study

Definition: The Administration is the secondary role in REGIS to receive all system generated communications (emails). An Administration can also be delegated access roles such as Edit and Submit. This form is automated on submission and is not reviewed by a research office.

Resources available: Submitting Ethics Amendment (QRG & Video), Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

Site process and System automation

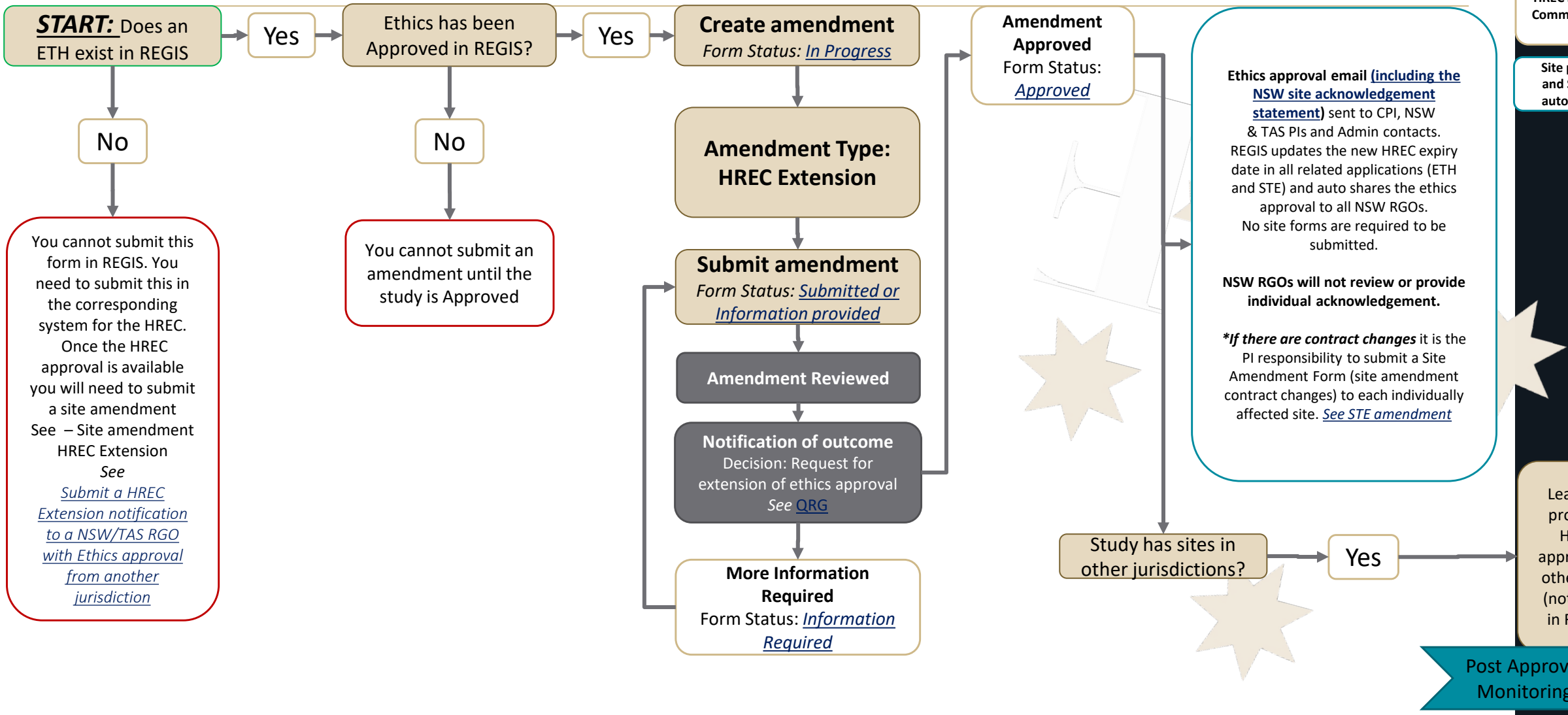
Post Approval Monitoring

Submit an Amendment to extend the HREC approval to a NSW/ACT HREC and NSW/TAS RGO

Form Name: Notification of an amendment to an approved Study

Definition: if a researcher/sponsor wishes to extend the project beyond the original period granted by the HREC. In NSW this is 5 years from the date of approval notification. Requests beyond 12 months should be discussed with the Research Office before submitting the request.

Resources available: Submitting Ethics Amendment (QRG & Video), Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)

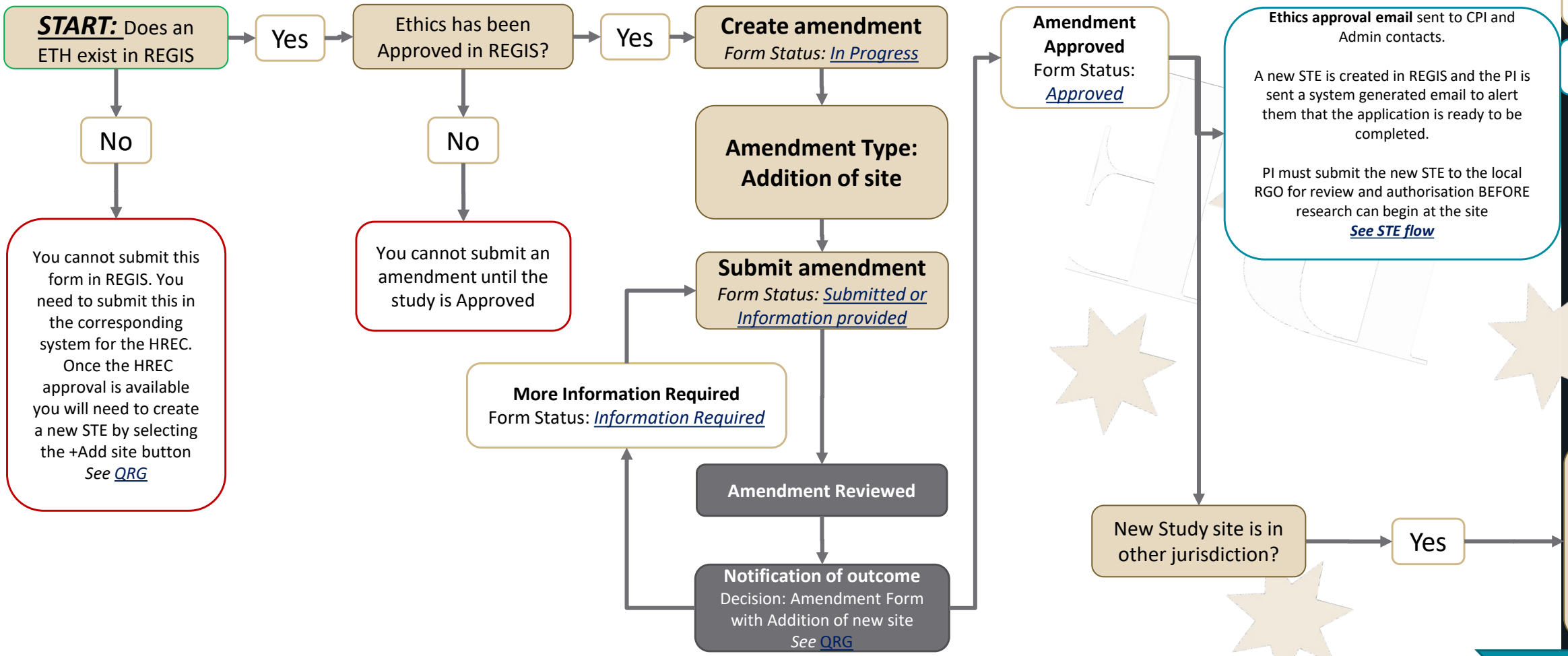


Submit an Addition of Site Amendment to a NSW/ACT HREC and NSW/TAS RGO

Form Name: Notification of an amendment to an approved study – Addition of New Site

Definition: You must update the study details of the additional site(s) and investigator(s) so that an SSA for new NSW or TAS sites to be generated and all new site investigators are notified. If the site being added is outside of NSW/TAS (e.g. VIC, QLD, SA, WA) the site application will need to be submitted through another application portal.

Resources available: Submitting Ethics Amendment (QRG & Video), Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

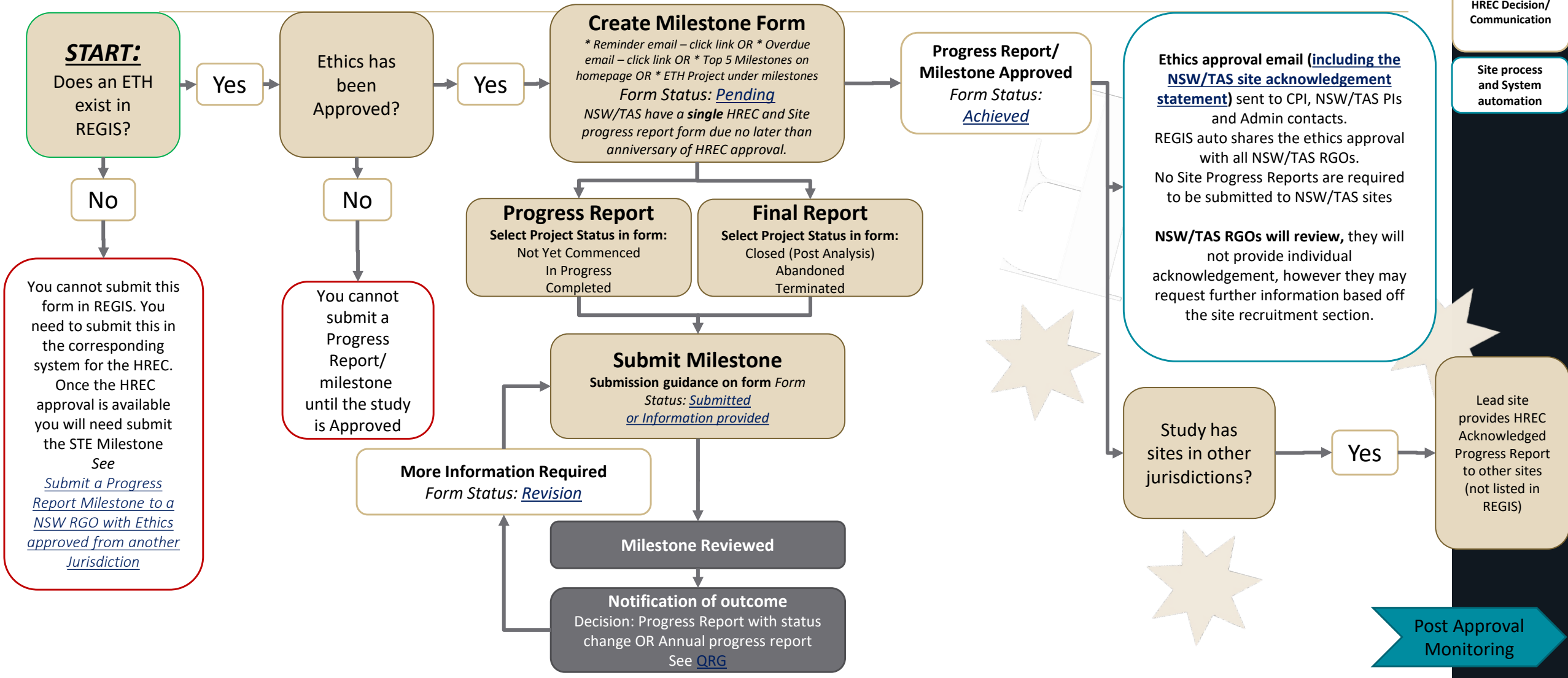
Site process and System automation

Submit a Progress/Final Report to a NSW/ACT HREC and NSW RGO

Milestone name: Progress Report

Definition: Progress Reports are a standard condition of HREC (Ethics) approval. At a minimum an annual progress report is submitted for review by the approving HREC. NSW/TAS have streamlined annual reporting where the Researcher is only required to fill out a single annual report form. In REGIS progress and final reports are processed through Milestones.

Resources available: Submitting a Progress/Final Report (QRG & Video), and Submission Guideline (coming soon)

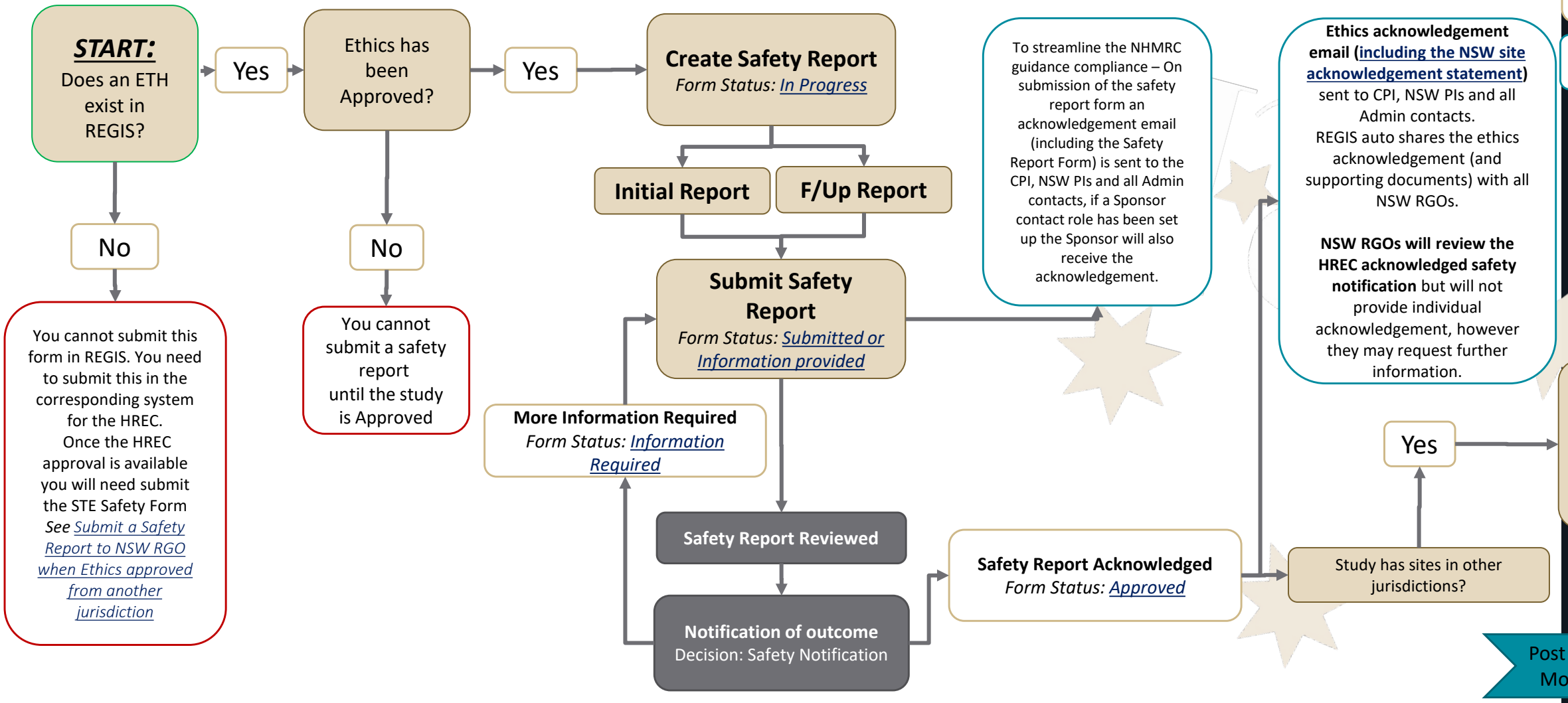


Submit a Safety Report to a NSW/ACT HREC and NSW RGO

Form Name: Significant Safety Issue

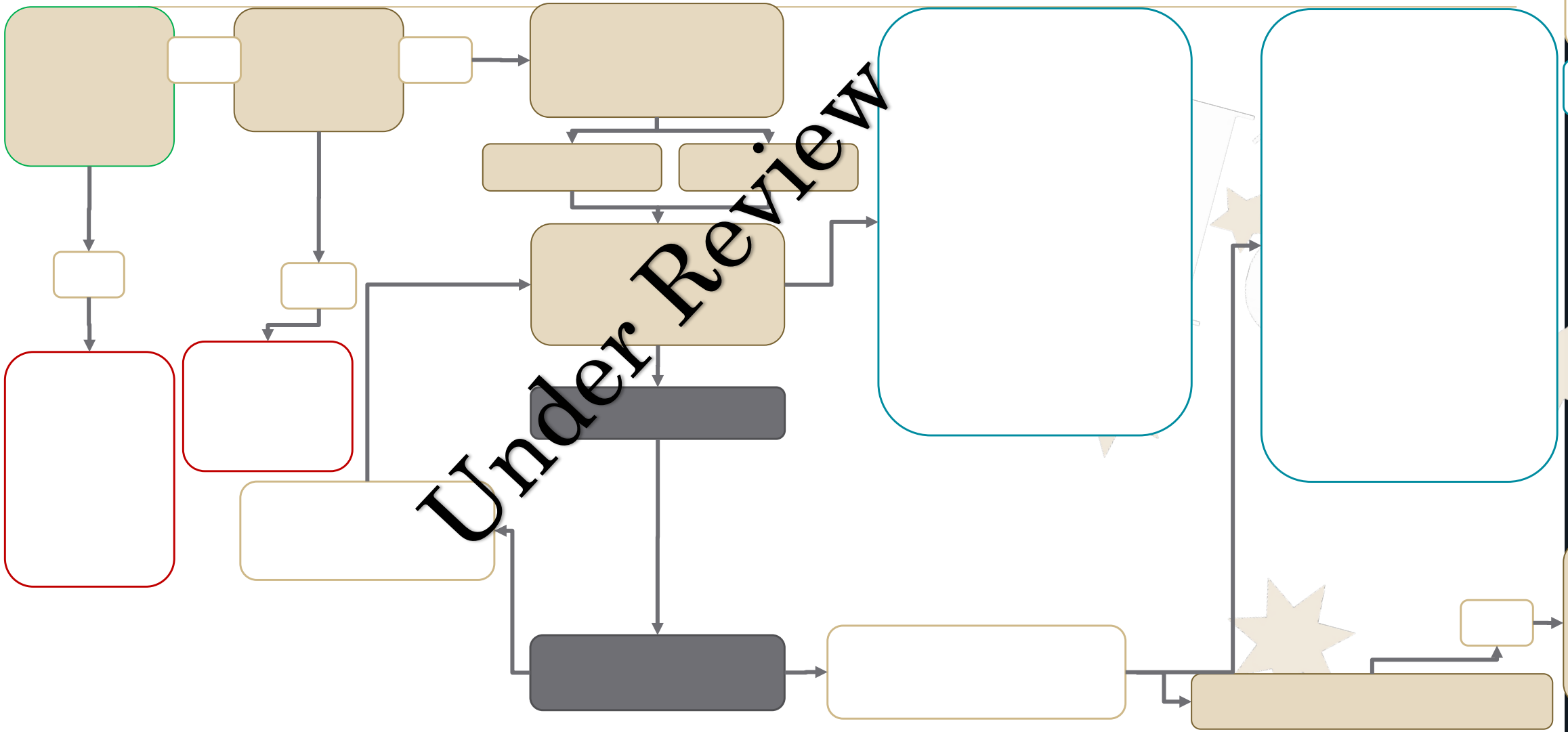
Definition: A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Resources available: Clinical Trial Safety Notification (QRG & Video), and Submission Guideline (coming soon) **Guidance:** NHMRC: Safety monitoring, NSW Health Specific Guidance



Submit a Serious Breach – need workflow action.

QRG: Walkthrough video: Guidance:



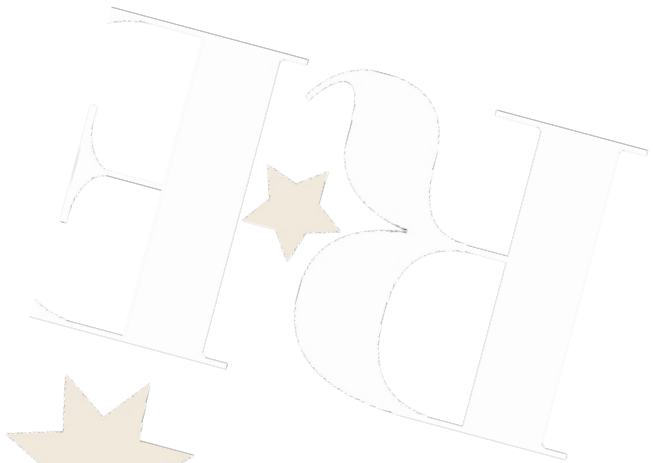
Researcher

Research Office

HREC Decision/ Communication

Site process and System automation

Project Flows – Governance (Ethics in REGIS)

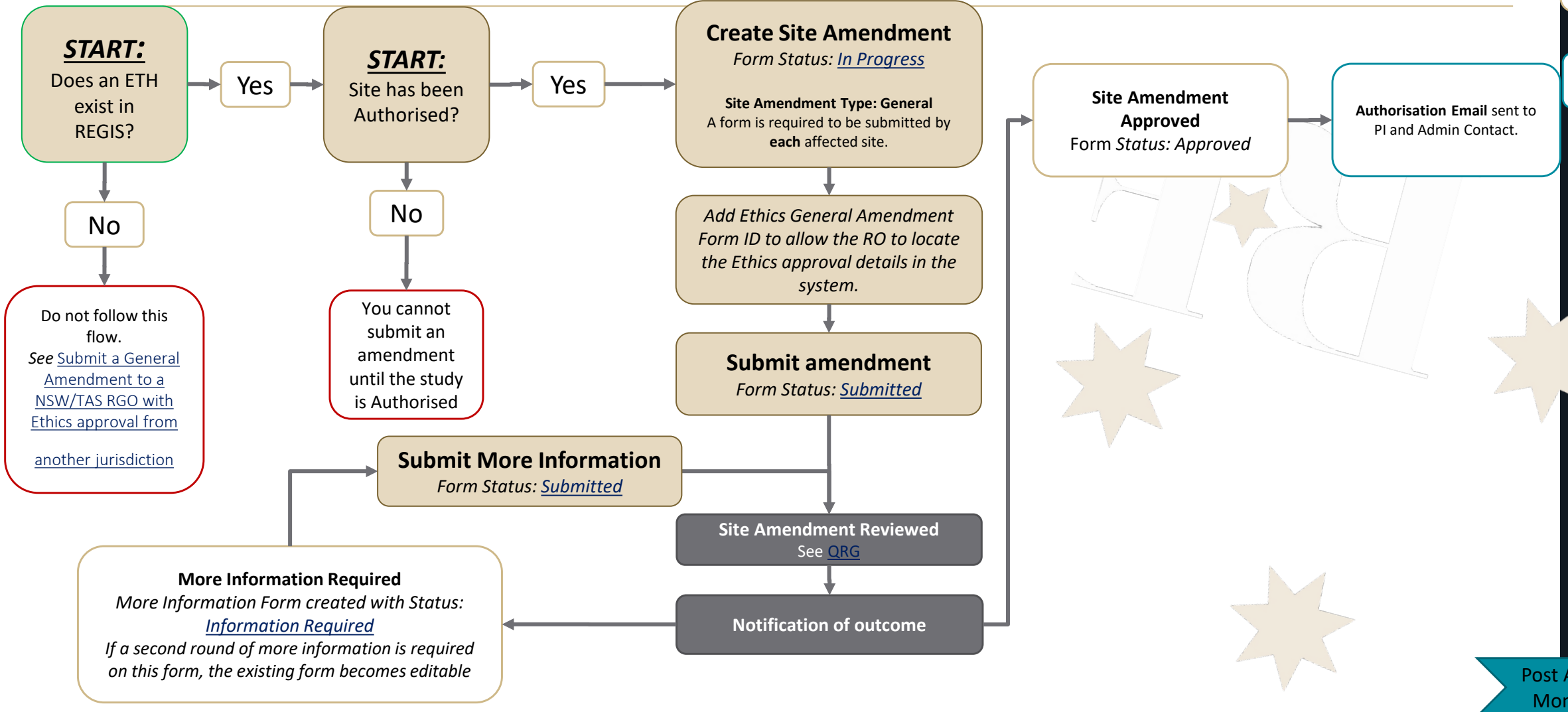


Submit a Site Amendment General AFTER NSW/ACT Ethics approval

Form Name: Site Amendment

Definition: a site general amendment are those affecting the conduct, design or methodology of a trial at the site and includes changes to: Study Protocol, Information previously given in the HREA, Information sheet(s) and consent form/s for participants or to any other site supporting documentation for the study.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), Governance Amendment - Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

System automation

Post Approval Monitoring

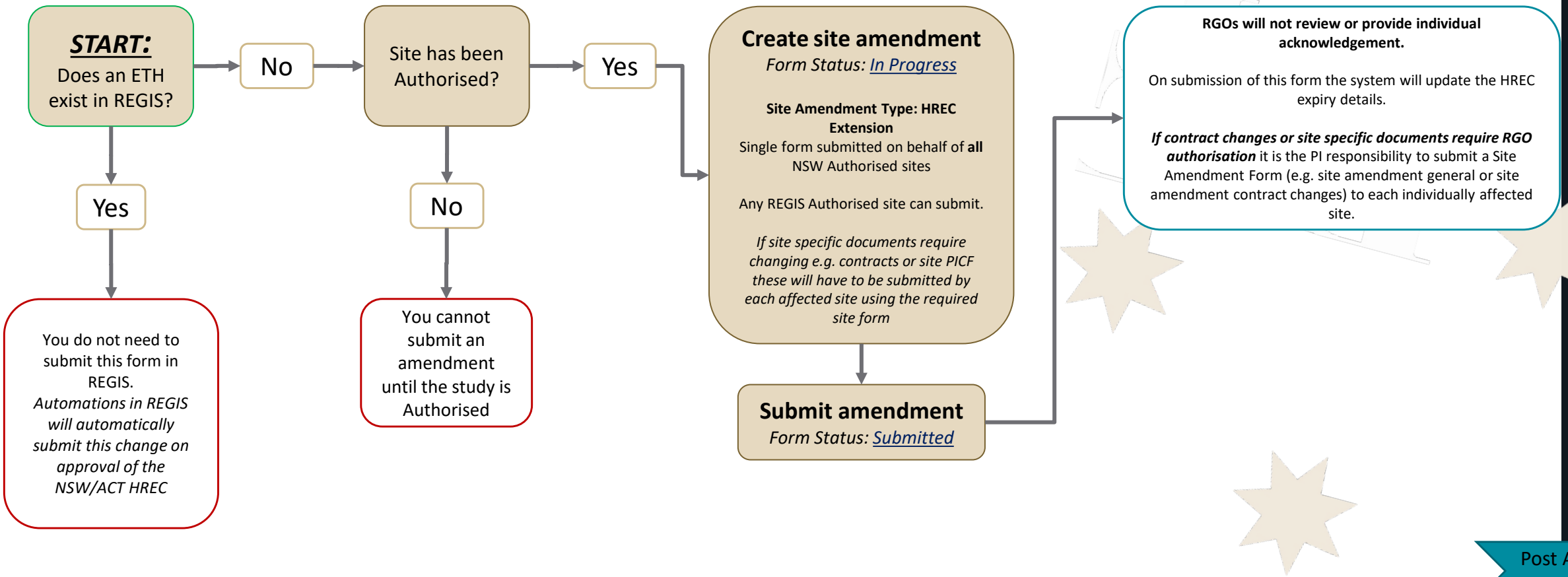
Project Flows – Governance (Ethics from another jurisdiction)

Submit a HREC Extension notification to a NSW/TAS RGO with Ethics approval from another jurisdiction (QLD, VIC, SA, WA)

Form Name: Site Amendment

Definition: Notifying the Site/RGO that approval from the HREC has been granted to extend the project beyond it's original approval period.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

System automation

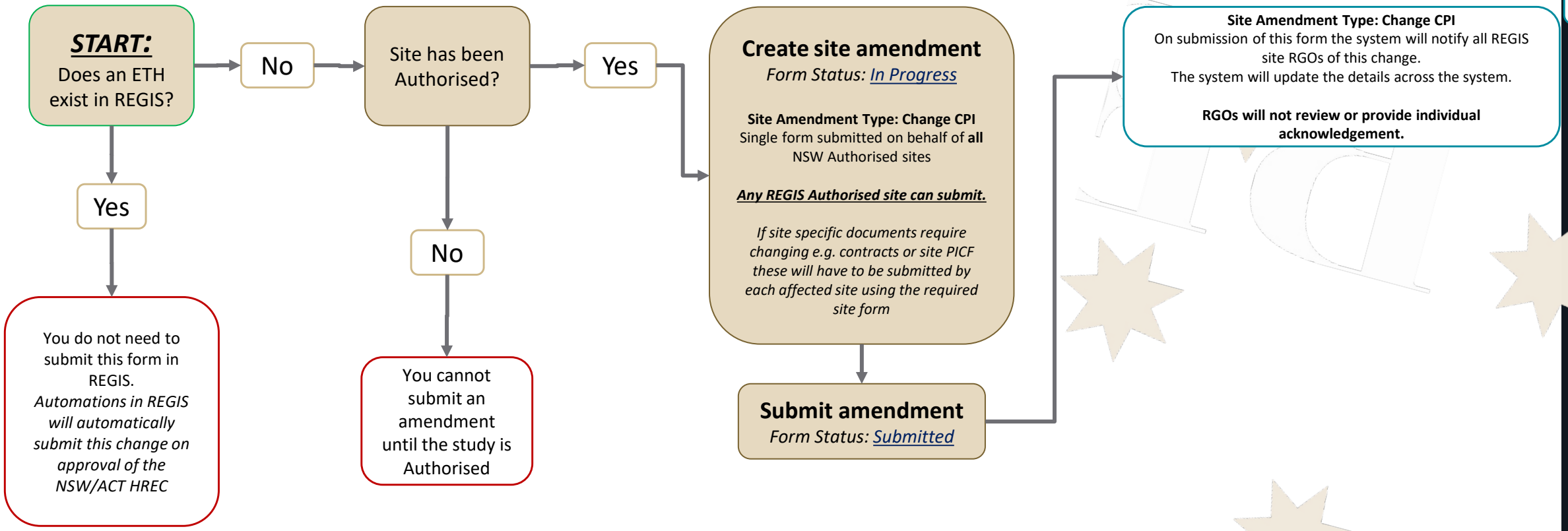
Post Approval Monitoring

Submit Change of CPI Amendment to a NSW RGO with Ethics approval from another jurisdiction (QLD, VIC, SA, WA)

Form Name: Site Amendment

Definition: Notifying the Site/RGO that approval from the HREC has been granted to change the CPI. This is a single form that is submitted to ALL NSW/TAS RGOs on submission.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

System automation

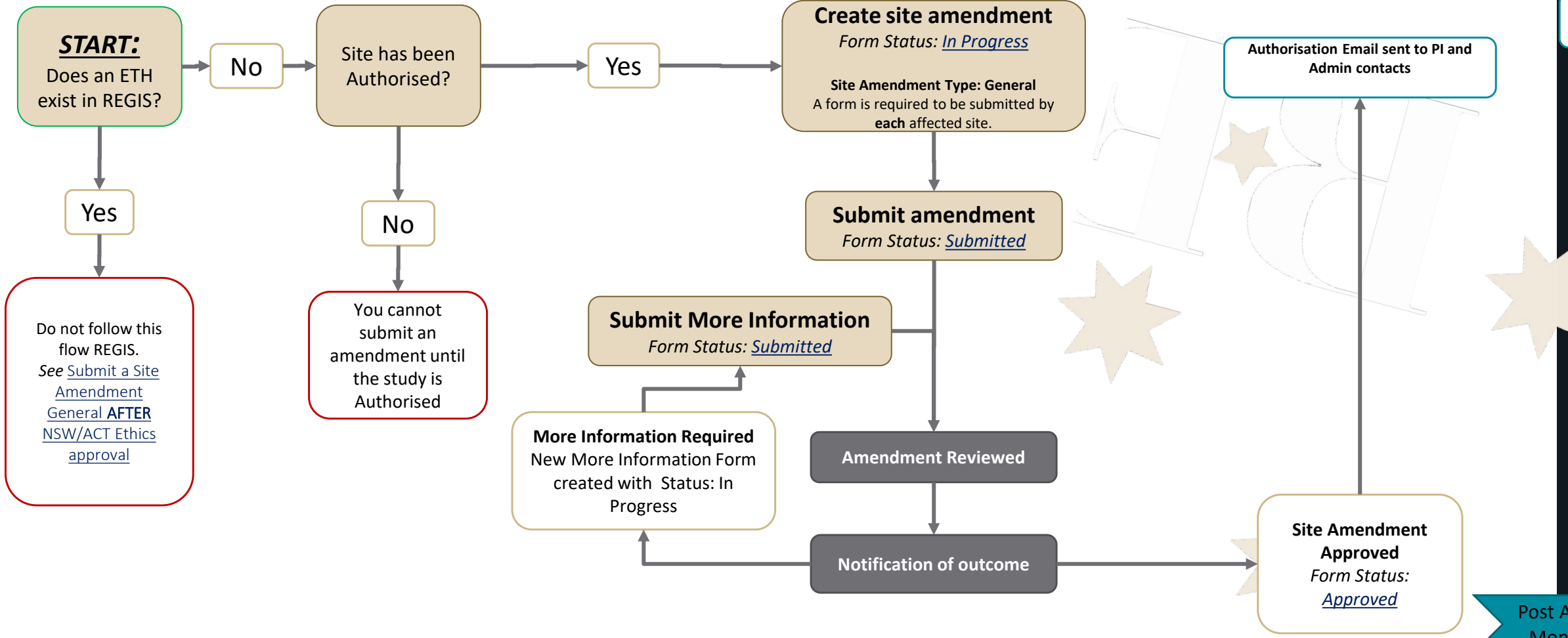
Post Approval Monitoring

Submit a General Amendment to a NSW/TAS RGO with Ethics approval from another jurisdiction (QLD, VIC, SA, WA)

Form Name: Site amendment

Definition: a site general amendment are those affecting the conduct, design or methodology of a trial at the site and includes changes to: Study Protocol, Information previously given in the HREA, Information sheet(s) and consent form/s for participants or to any other supporting documentation for the study.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), Governance Amendment - Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)

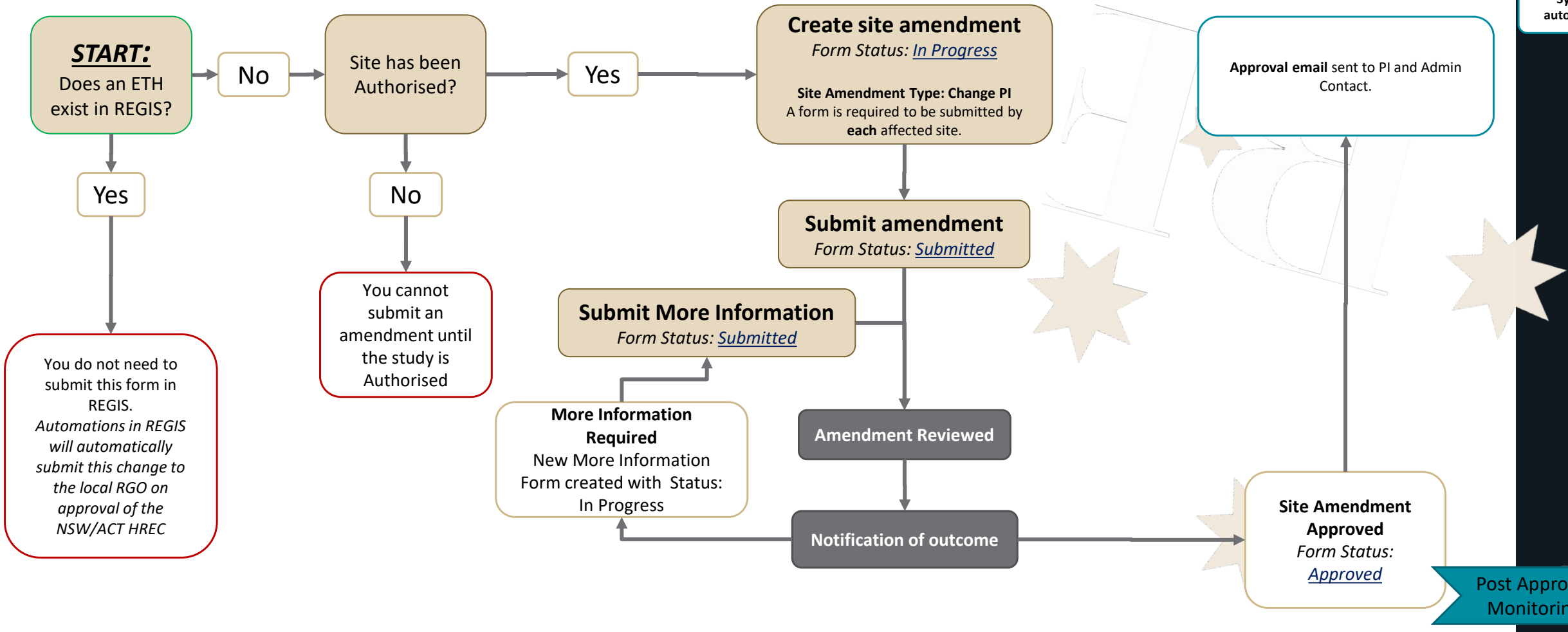


Submit a Change PI Amendment to a NSW RGO with Ethics approval from another jurisdiction (QLD, VIC, SA, WA)

Form Name: Site amendment

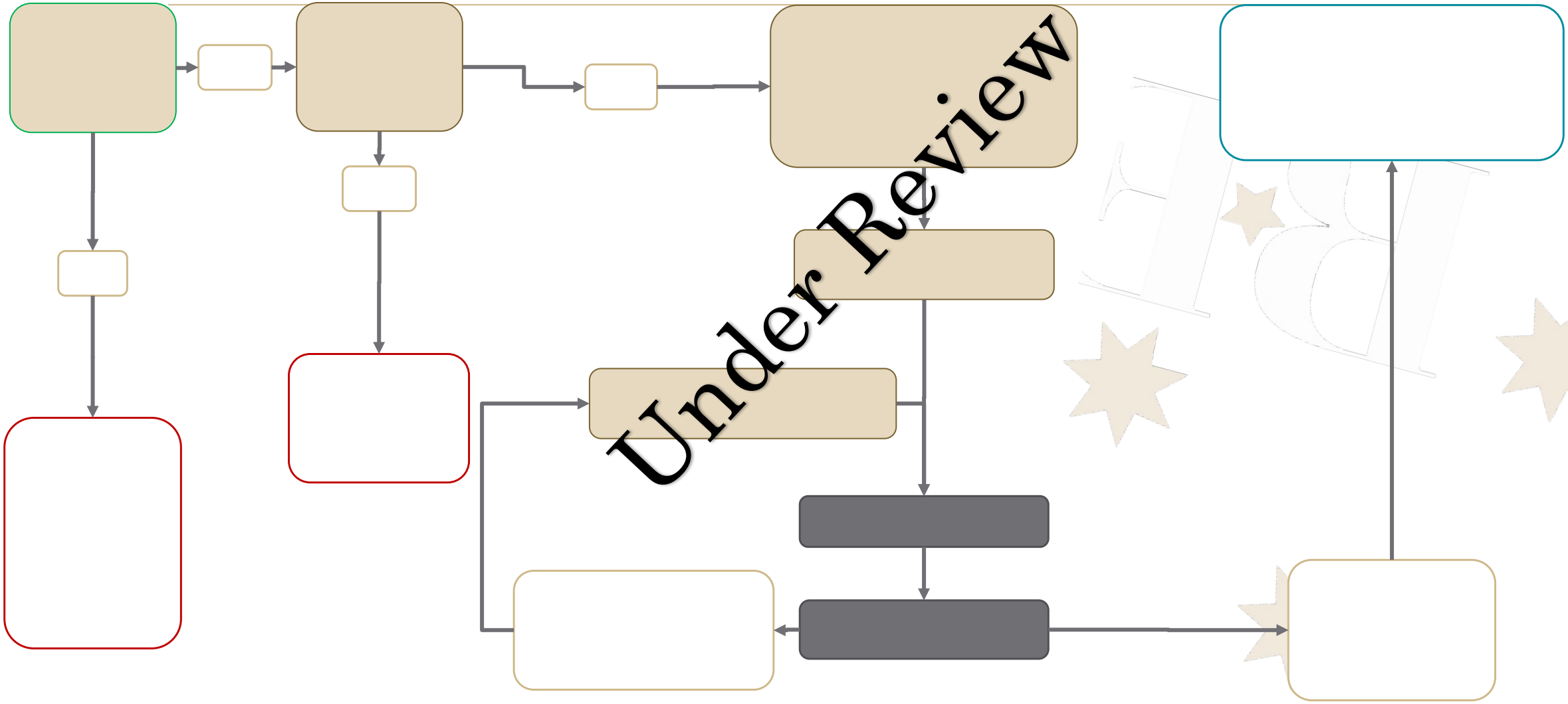
Definition: Notifying the site that the HREC have approved a change to the local PI AND providing site specific investigator requirements such as CV, evidence of GCP

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), Governance Amendment - Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)



Submit an Amendment to a NSW RGO with Ethics approval from another jurisdiction (QLD, VIC, SA, WA) Add new NSW or TAS site

QRG: Walkthrough video:



Researcher

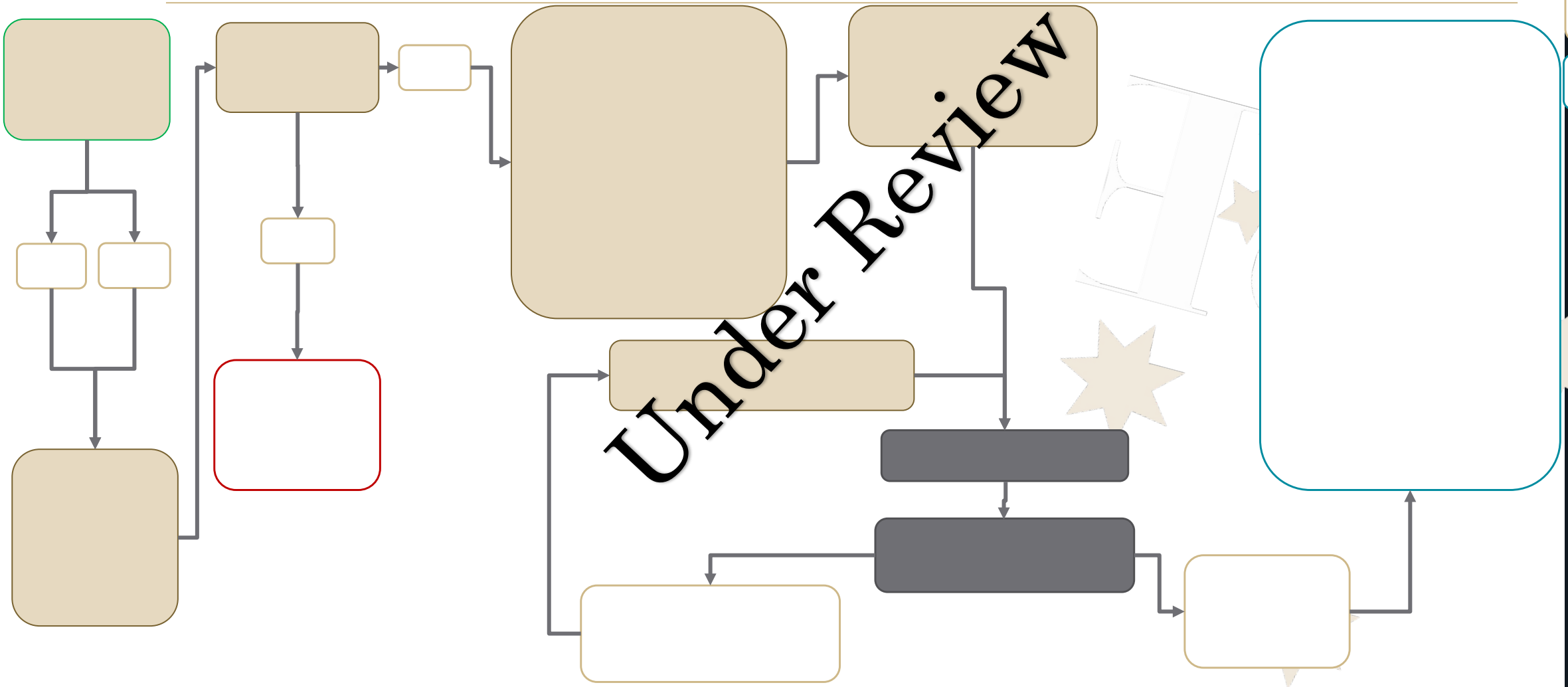
Research Office

HREC Decision/ Communication

System automation

Submit a Progress Report Milestone to a NSW RGO with Ethics approved from another Jurisdiction (QLD, VIC, SA, WA)

QRG: Walkthrough video:



Researcher

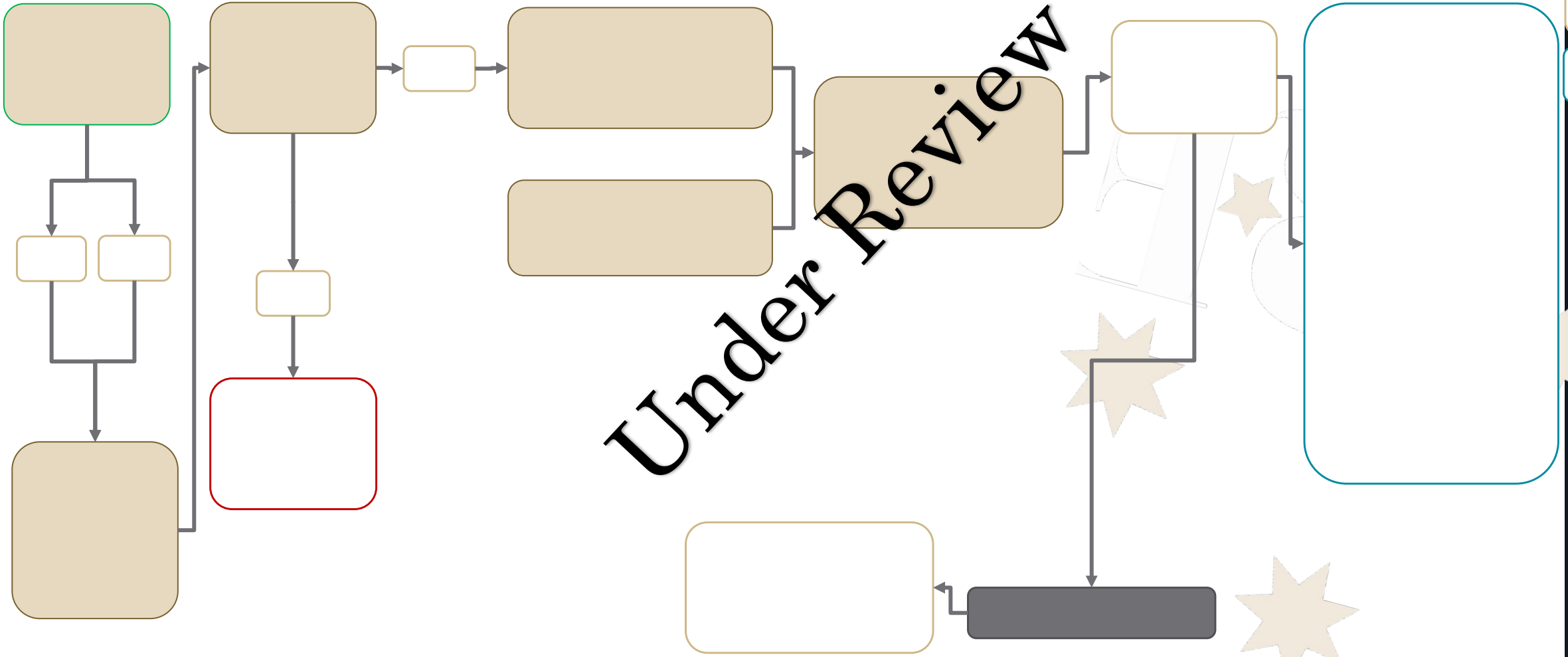
Research Office

HREC Decision/ Communication

Site process and System automation

Submit a Safety Report to NSW RGO when Ethics approved from another jurisdiction (QLD, VIC, SA, WA)

QRG: Walkthrough video:



Researcher

Research Office

HREC Decision/ Communication

Site process and System automation

Project Flows – Governance (Ethics not required)

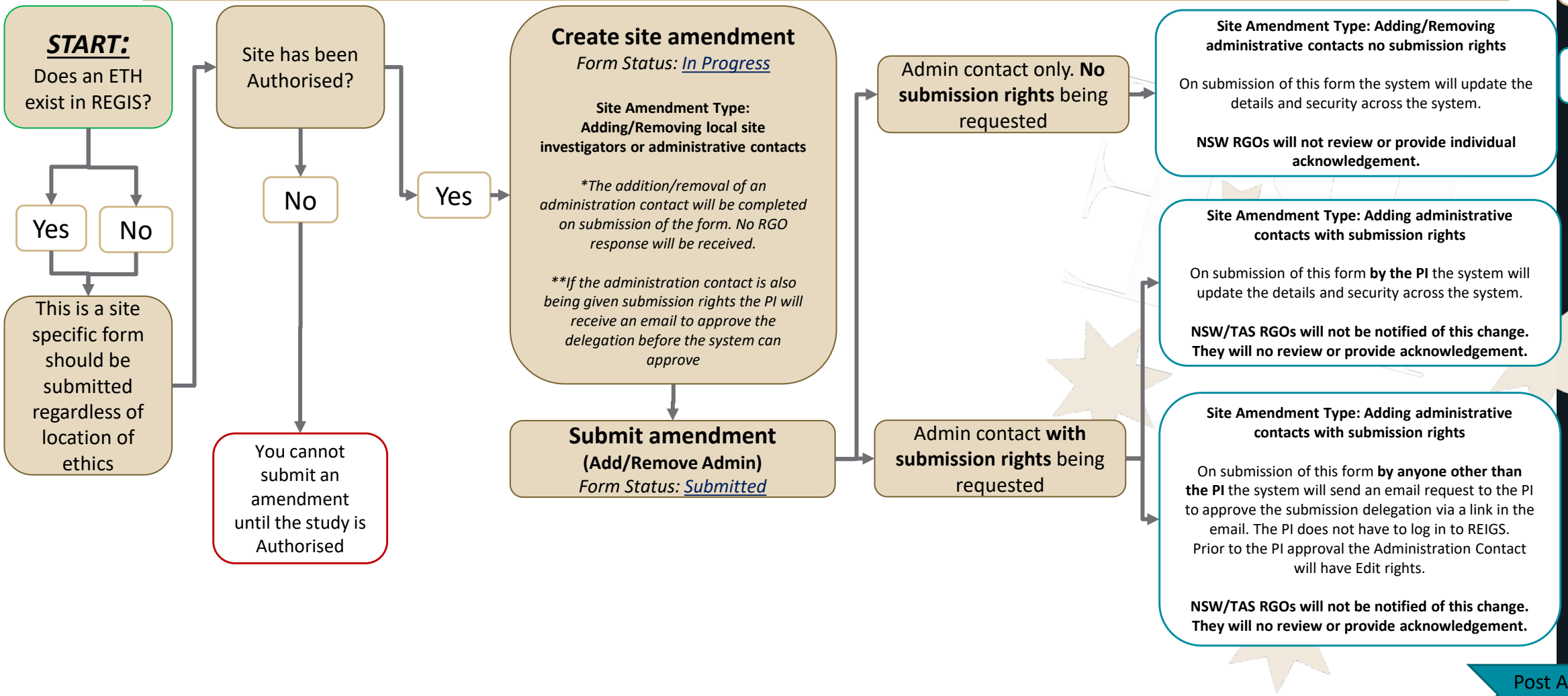
Submit an Amendment to a NSW RGO (Ethics approval not required)

Adding/Removing the Administration role and Submitter delegation authority

Form Name: Site amendment

Definition: The Administration contact is the secondary role that receives all communications. The Submitter is delegated authority from the PI to take on the administrative task of submitting forms in REGIS.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), and Submission Guideline (coming soon)



Researcher

Research Office

HREC Decision/ Communication

System automation

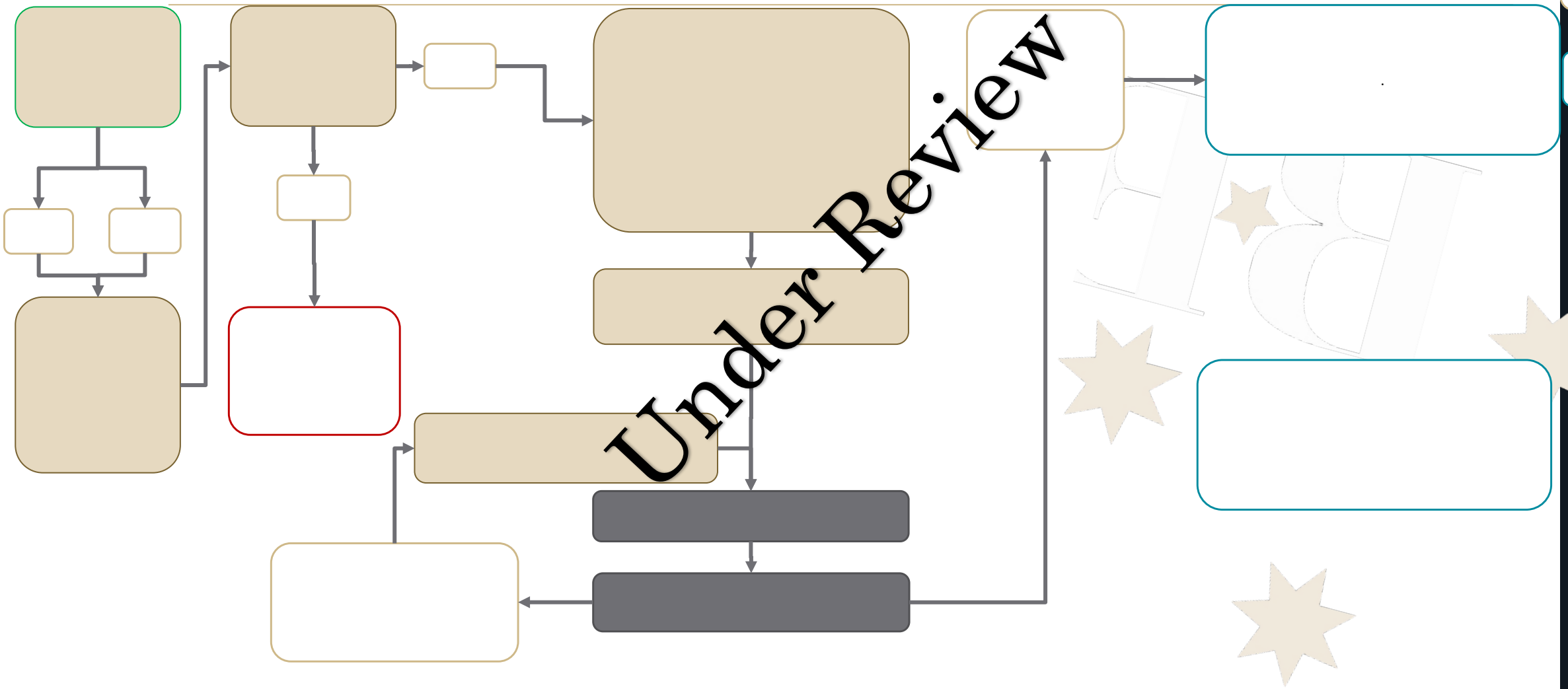
Post Approval Monitoring

Submit an Amendment to a NSW RGO (Ethics approval not required)

Adding/Removing Local Site investigators

Definition: Local site investigators include:

Resources available: (QRG & Video)



Researcher

Research Office

HREC Decision/ Communication

System automation

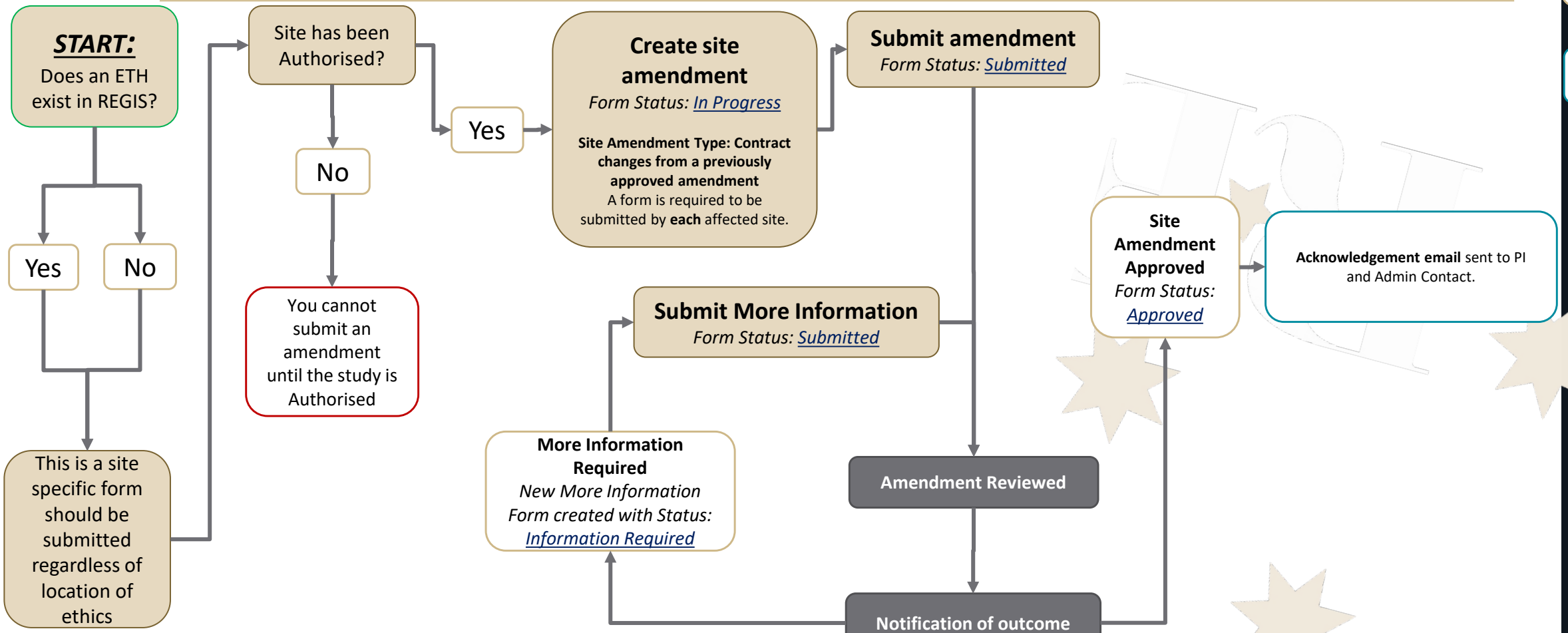
Submit an Amendment to a NSW RGO (Ethics approval not required)

Contract Changes from a previously approved amendment

Form Name : Site amendment

Definition: This flow is used when a change to an executed agreement is required either as a standalone action or after a General Amendment.

Resources available: Governance Amendment – Completing and Submitting (QRG & Video), Governance Amendment - Responding to a request for information (QRG & Video) and Submission Guideline (coming soon)



Researcher

Research Office

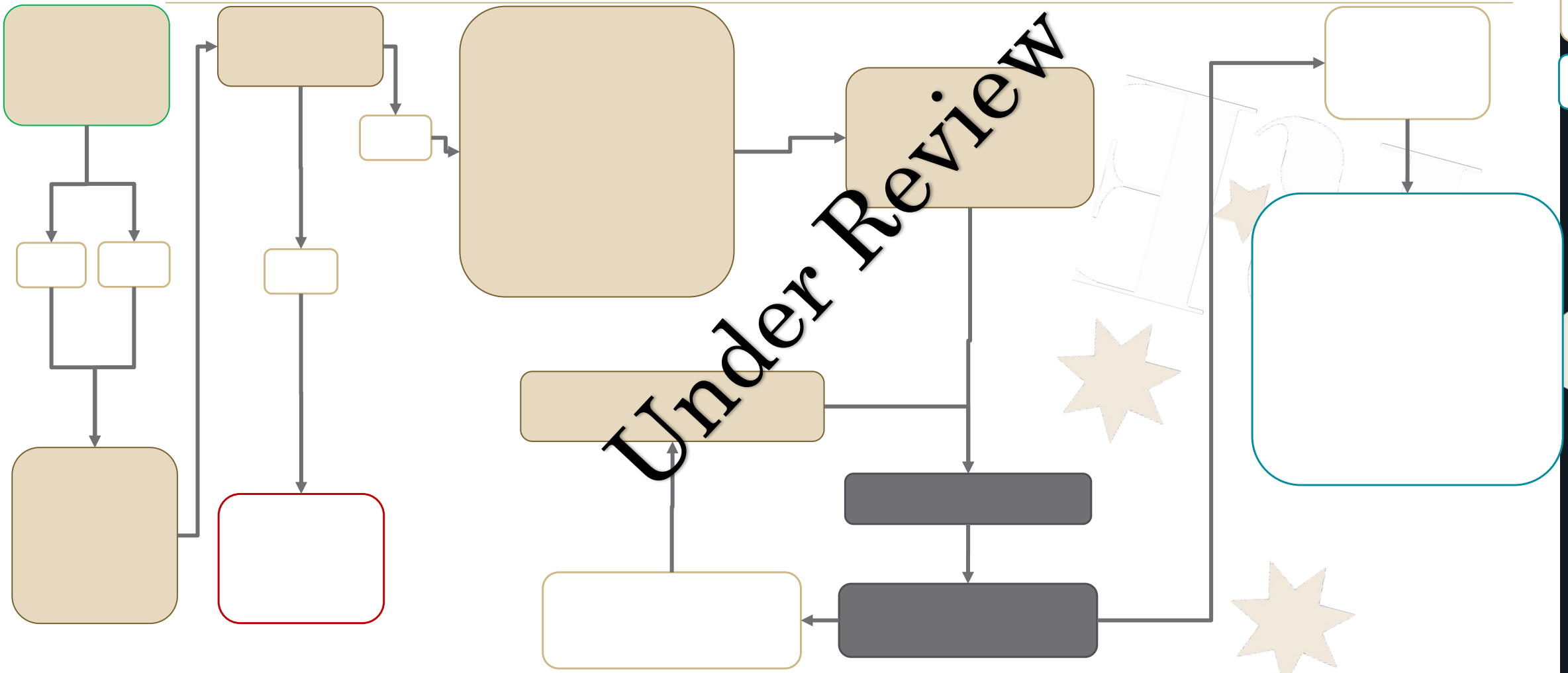
HREC Decision/ Communication

System automation

Post Approval Monitoring

Submit a Certificate of Currency Milestone to a NSW RGO (Ethics approval not required)

QRG: Walkthrough video:



Researcher

Research Office

HREC Decision/ Communication

Site process and System automation

Understanding System Driven Processes.

- Withdrawn (New Application Required)
  - The system will automatically withdraw an application that has been in the status of Ineligible for 60 days. The applicant will receive 2 reminder emails before the system withdraws the application.
  - The system will automatically withdraw an application that has had a request for information pending for 180 days.
  - A research office can communicate an expected response timeframe. If the applicant does not respond to the request in the timeframe the research office may withdraw the application .
- Suspended (Action Required by Research Team)
  - The system will automatically suspend any study that has an ethics expiry date of 12 months past.
  - (coming soon) The system will automatically suspend any study that has not submitted their annual report within 180 days of the milestone due date.