

Process flows in REGIS



Submission flows in REGIS



Initial submission to approval/authorisation

- [Completing Project Registration](#)
- [Completing the HREA/ETH](#)
- [Completing the SSA/STE](#)

Post approval Monitoring

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](#)

Post approval Monitoring Governance - Ethics in REGIS

[Submit a Site Amendment General after NSW/ACT Ethics approval](#)

Application Flows



Project Registration (PID)

Ethics Application HREA (ETH)

Site Application (STE)

Post Approval Monitoring

Key

Researcher

System automation

Stop Point

Click for ETH Flow

START:
Has this Study been registered

No

Create new project

Submit PID

Progress to ETH

Yes

Do not compete a PID

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

Data Transfer
Information entered into the Project Registration is auto mapped to answers in HREA and or STE.

*reduces data entry across application, ensures free text fields entered into forms per NSW Health requirements

Document Management
Protocol is mandatory to complete PR. All documents added at PR are mapped over to upload section of HREA.

Project Registration allows system to better manage document title fields.



Key

Researcher

Research Office

HREC Decision/Communication

System automation

Project Registration (PID)

Ethics Application HREA (ETH)

Site Application (STE)

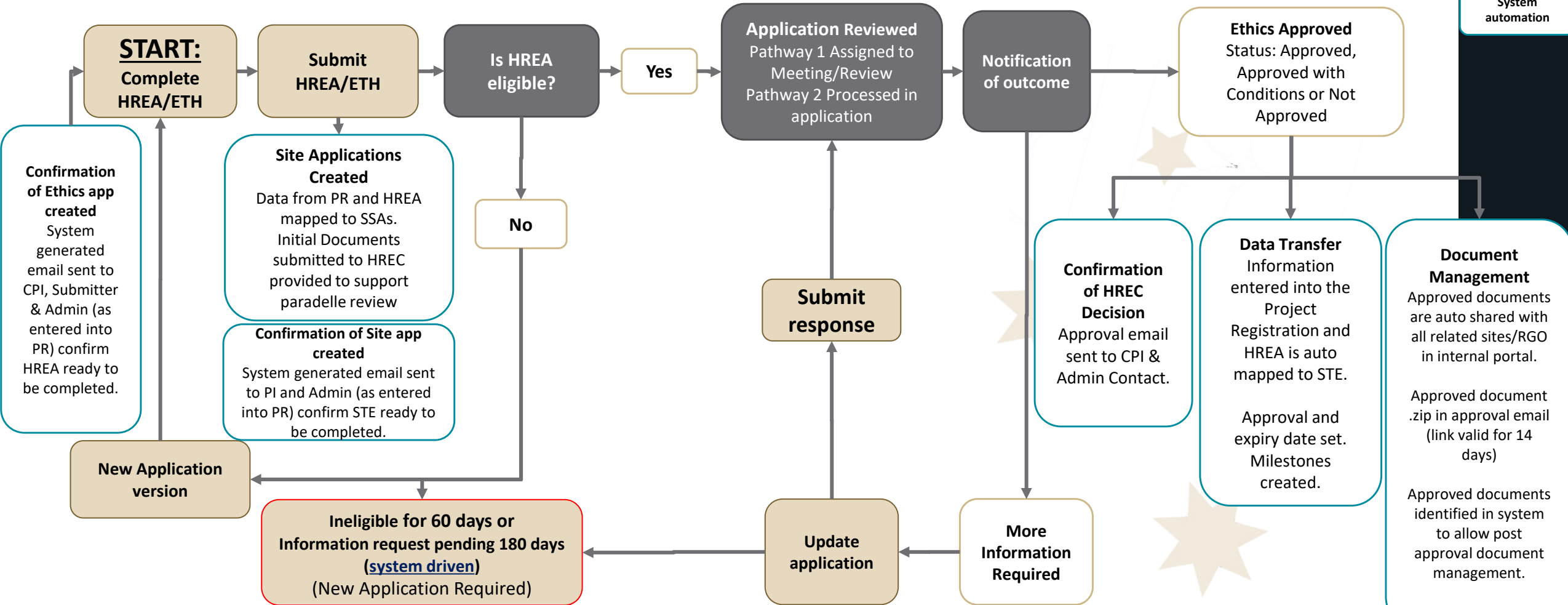
Post Approval Monitoring

Application preparation

Application submitted to Research Office

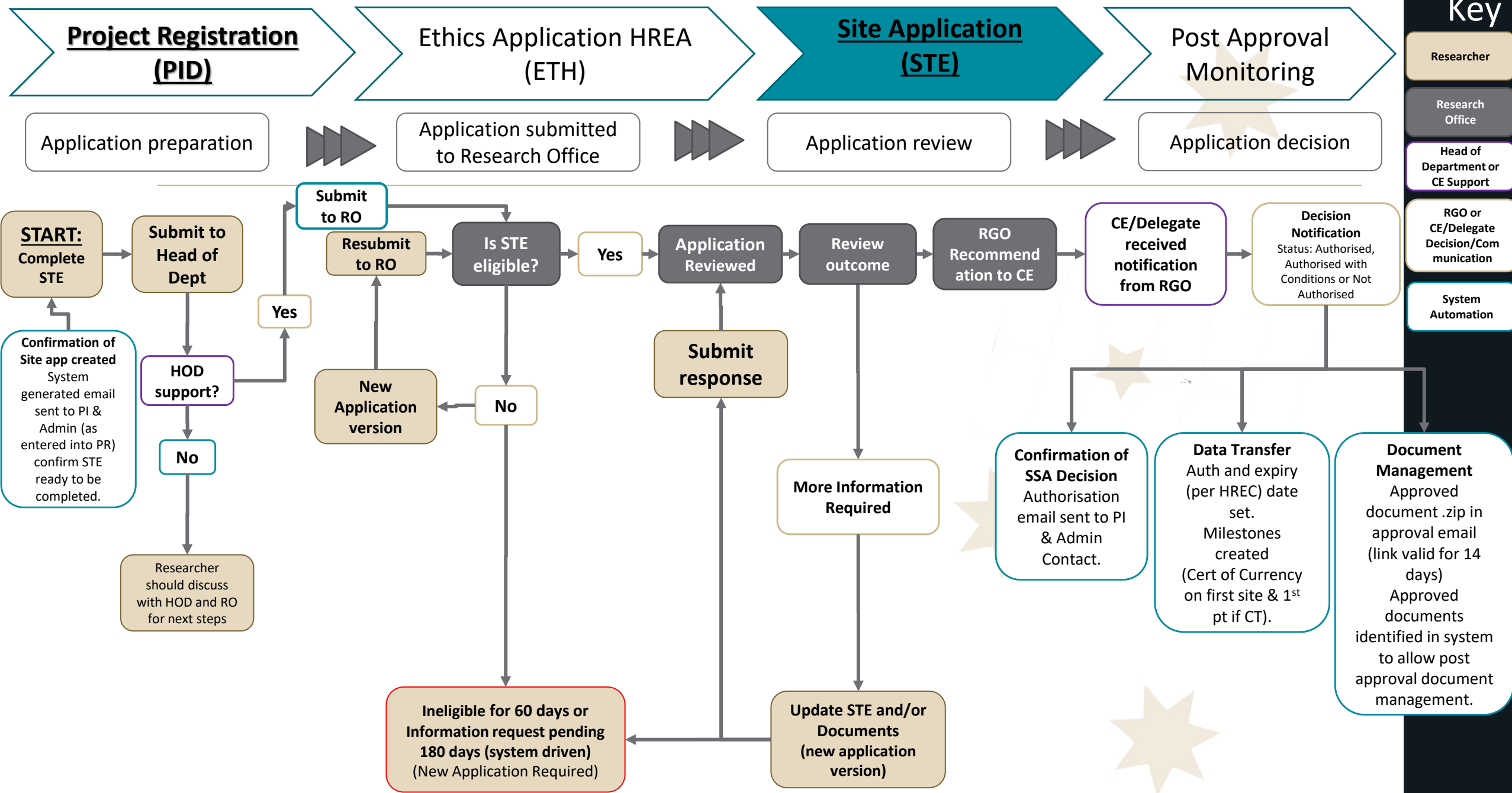
Application review

Application decision



Key

- Researcher
- Research Office
- Head of Department or CE Support
- RGO or CE/Delegate Decision/Communication
- System Automation



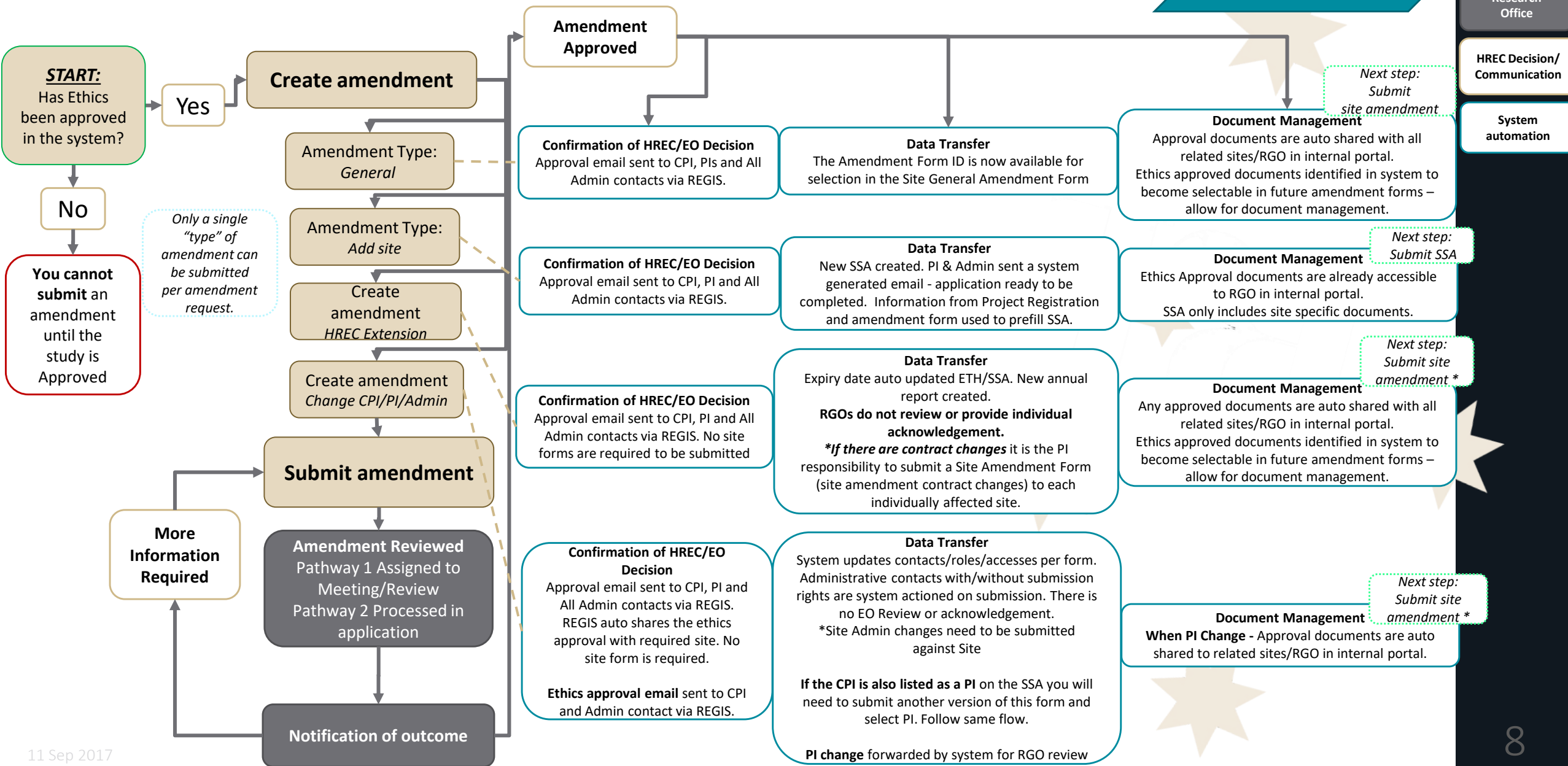
Project Flows – Ethics Post Approval

Submit an Amendment to a HREC and RGO

Form Name: Notification of an amendment to a research study



- Researcher
- Research Office
- HREC Decision/Communication
- System automation



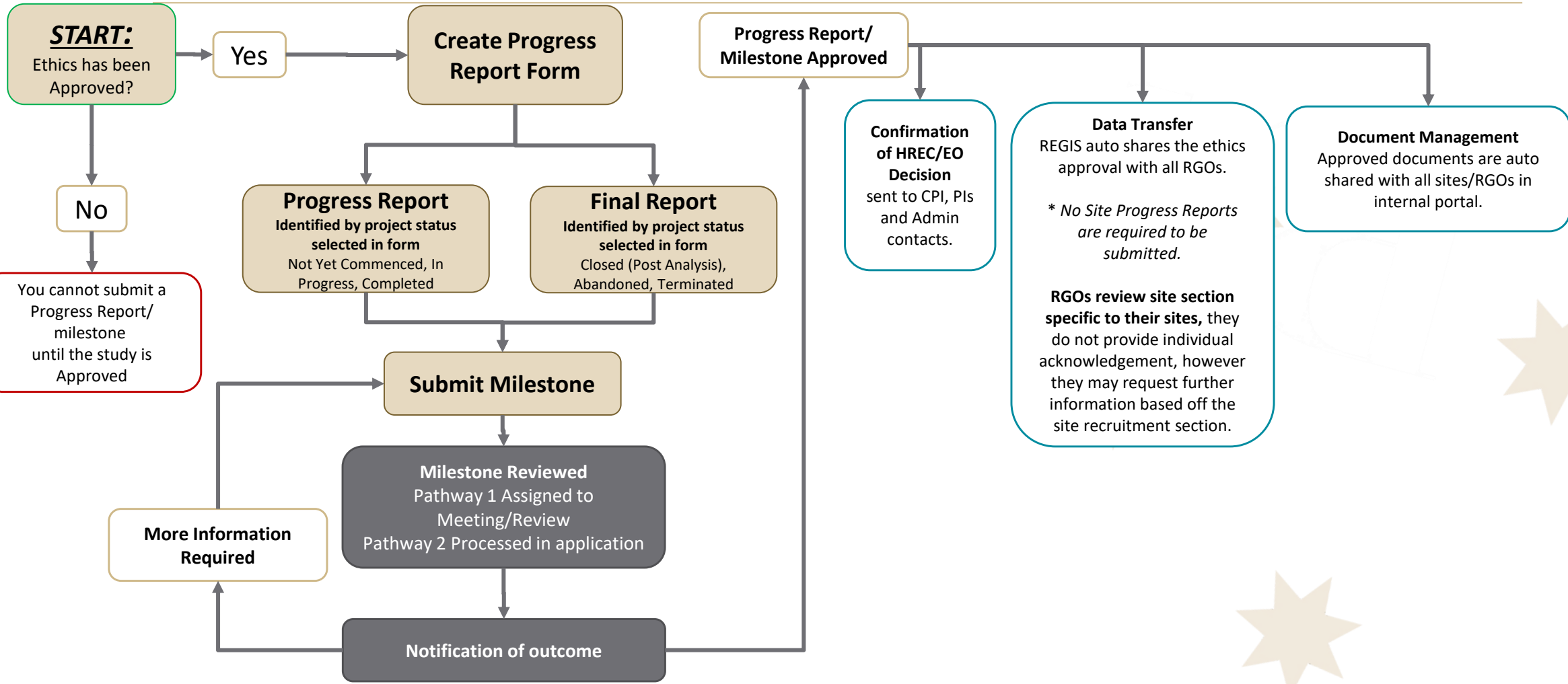
Submit a Progress/Final Report to a NSW/ACT HREC and NSW RGO

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.

- Researcher
- Research Office
- HREC Decision/Communication
- Site process and System automation



Submit a Safety Report to a HREC and RGO

Form Name: Significant Safety Issue



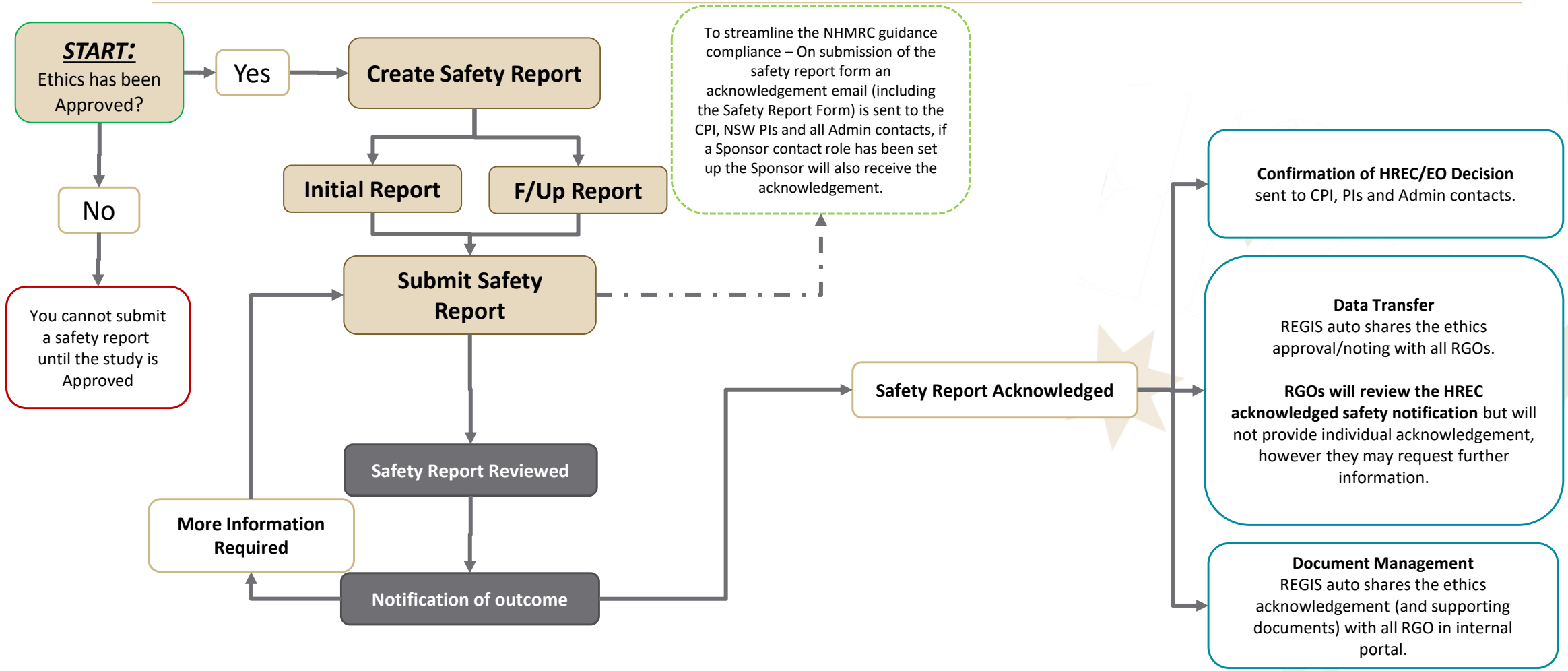
Researcher

Research Office

HREC Decision/Communication

Site process and System automation

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.



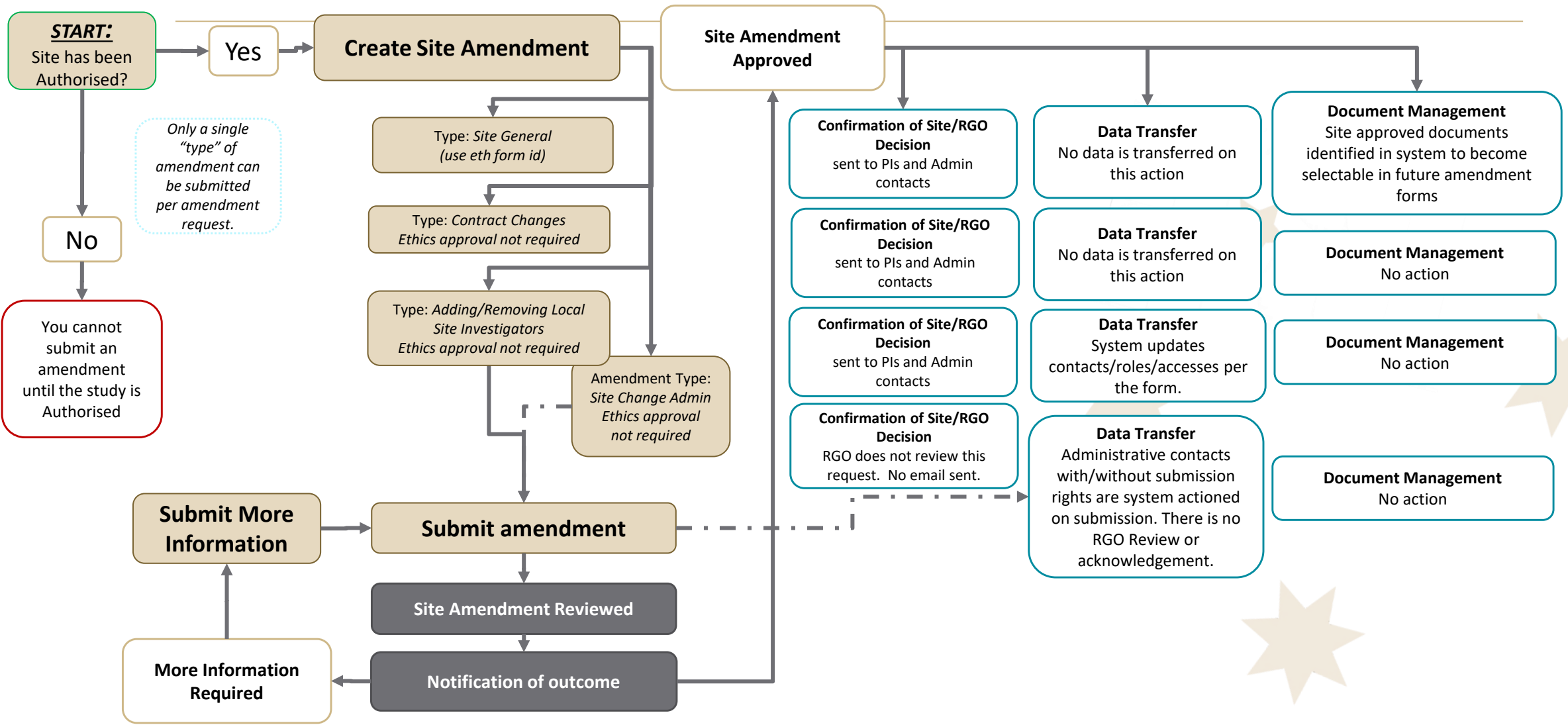
Submit a Site Amendment

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.

- Researcher
- Research Office
- RGO Decision/Communication
- System automation
- Action automated on submission



Submit a Certificate of Currency Milestone to an RGO

Researcher

Research Office

HREC Decision/
Communication

Site process
and System
automation

