REGIS Training Resources

Contents

1.   Introduction

The "How To" YouTube videos are generally four to five minutes long.
The Quick Reference Guides provide written explanations and images to assist.
It is recommended that the resources be accessed as needed, rather than viewed all at once.

2.   TAS Specific FAQs for Researchers and Applicants
- REGIS FAQs for Researchers and Applicants (Intranet)

3.   For all Users
3.1.   Establish an Account in REGIS
- Quick Reference Guide (pdf): REGIS User Account and System Symbols

3.2.   Status Definitions
- Quick Reference Guide (pdf): Status Definitions

3.3.   Update your REGIS Username and Password
- Quick Reference Guide (pdf): Updating a REGIS Username and Password

3.4.   Complete Project Registration
- YouTube Video: Completing Project Registration in REGIS - YouTube
- Quick Reference Guide (pdf): Completing Project Registration

NOTE: If **ethics** is to be created in REGIS, the **ethics** application will be generated first. Once submitted, site applications will be generated. If ethics is external to REGIS, site applications will be generated upon submission of the project registration.

o   If you have already received approval from an HREC or your application is currently under review, select "Yes" to **QA1**. (Further questions will be displayed for you to respond.)
o   If you are submitting a low-risk ethics application to the Tasmanian DoH LRR Ethics Committee, select "No" to **QA1**. (If you select "No", REGIS will create an ethics application for you to submit to the TAS DoH Health LRR, NSW or ACT HREC for ethics review.)
o   If your project is higher risk, contact the research ethics office for advice on the most appropriate HREC to submit your ethics application (UTAS HREC or an NMA HREC).

4.   ETHICS: Initial Submission

4.1.   Complete Ethics Application

- YouTube Video: [Completing an Ethics Application in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Completing an Ethics Application](#)

4.2.   Ineligible Notification – Resubmitting Application

- YouTube Video: [Resubmitting an Ineligible Application in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Submitting a new version of an application after an ineligible notification](#)

4.3.   Responding to Requests for More Information

- YouTube Video: [Responding to a Request for Further Information in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Responding to a request for information](#)

4.4.   Downloading a Copy of the Ethics Application

- YouTube Video: [Downloading your Ethics or Site Application in REGIS – YouTube](#)
- Quick Reference Guide (pdf): [Downloading a copy of your ethics application](#)

5.   ETHICS: Post-Approval

5.1.   Ethics Amendment

- YouTube Video: [Creating an Ethics Amendment in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Ethics Amendment - Completing & Submitting](#)

5.2.   Ethics Amendment – Responding to Request for Information

- YouTube Video: [Responding to Requests for Information for Ethics Amendment and Safety Notifications in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Ethics Amendment – Responding to an Information Request](#)

5.3.   Submitting Annual Progress or Final Report (milestone)

- YouTube Video: [Completing and Responding to a Request for Information for an Ethics Progress Report in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Submitting a Progress/Final Report](#)

5.4.   Clinical Trial Safety Reporting

- YouTube Video: [Creating an Ethics Safety Notification in REGIS - YouTube](#)
- Quick Reference Guide (pdf): [Submitting a Clinical Trial Safety Report](#)
  Note: For safety reports other than clinical trials, please refer to the Research Ethics and Governance (REGU) website page.

6. Site Governance: Initial Submission – Pre-Authorisation

6.1. Complete Site Application
- YouTube Video: [Completing a Site Application in REGIS](#)
- Quick Reference Guide (pdf): [Completing, Requesting HOD Support and Submitting](#)

6.2. Site Application HOD Not Supported.
- YouTube Video: [HOD Not Supported - How to resubmit your application in REGIS](#)
- Quick Reference Guide (pdf): [Head of Department – Not Supported](#)

6.3. Create a New Site Application
- YouTube Video: [Creating a New Site Application in REGIS when: Ethics is Under Review, Approved or External to REGIS](#)
- Quick Reference Guide (pdf): [Create a New Site Application](#)

6.4. Resubmitting an Ineligible Application
- YouTube Video: [Resubmitting an Ineligible Application in REGIS](#)
- Quick Reference Guide (pdf): [Submitting a new version of an application after an ineligible notification](#)

6.5. Responding to a Request for Information - Initial Application
- YouTube Video: [Responding to a Request for Further Information in REGIS](#)
- Quick Reference Guide (pdf): [Responding to a request for information](#)

6.6. Downloading a copy of your Site Application
- YouTube Video: [Downloading your Ethics or Site Application in REGIS](#)
- Quick Reference Guide (pdf): [Downloading a copy of your Site Application](#)

7. Governance: Post Approval

7.1. Creating and Submitting a Site Amendment
- YouTube Video: [Creating and Submitting a Site Amendment](#)
- Quick Reference Guide (pdf): [Site Amendment - Completing & Submitting](#)

7.2. Site Amendment – Responding to a More Information Required Request
- YouTube Video: [Responding to a request for information](#)
- Quick Reference Guide (pdf): [Site Amendment – Responding to a More Information Required Request](#)

7.3. Submitting a Governance Milestone
- YouTube Video: [Governance Milestones (External HREC Progress Report and CoC) in REGIS](#)
- Quick Reference Guide (pdf): [Submitting a Governance Milestone](#)

7.4. Clinical Trial Safety Reporting
- YouTube Video: [Creating and Submitting Site Safety Notifications](#)
- Quick Reference Guide (pdf): [Submitting a Clinical Trial Safety Report](#)

8. Additional Resources

8.1. Sharing Access to an Application/Project
- YouTube Video: [Delegating Submit Access for Approved/Authorised Studies](#)
- Quick Reference Guide (pdf): [Sharing Access to an Application/Project](#)

8.2. Approving Delegate Submitter Access Requests to Approved/Authorised Sites
- YouTube Video: [CPI/PI Approving Delegate Submit Access Request](#)
- Quick Reference Guide (pdf): [Approving Delegate Submitter Access Requests](#)

8.3. Withdrawing an Application
- YouTube Video: [Withdrawing, Deleting In Progress Version and Deleting an Application in REGIS](#)
- Quick Reference Guide (pdf): [Withdrawing an Application in REGIS](#)

8.4. FAQ – CPI/PI Delegation
- Quick Reference Guide (pdf): [FAQ – CPI/PI Delegation](#)

8.5. Chief Executive/Delegate - Authorising Governance Applications
- Quick Reference Guide (pdf): [Authorising Human Research Projects](#)

8.6. Heads of Department - Providing Declarations of Support
- YouTube Video: Providing [Head of Department (HOD) Support in REGIS](#)
- Quick Reference Guide (pdf): [Providing Declarations of Support](#)

8.7. HREC Member - Accessing Meeting Documents
- Quick Reference Guide (pdf): [Accessing Meeting Papers](#)

8.8. HREC Member - Completing the Lead Review
- Quick Reference Guide (pdf): [Reviewing an Application in REGIS](#)