REGIS PROJECT Migration Instructions

Contents

1. Introduction

Note: If you wish to migrate a multi-centre study into REGIS which has both a lead HREC and local UTAS HREC approval, you will need to transfer it to the lead NMA-certified HREC prior to migration. Contact the DoH Research Governance Office first if this is the case!

Once the project is migrated onto REGIS, it will be auto-approved and ready for you to submit future amendments via REGIS. To migrate a project onto REGIS, there are two scenarios to consider:

- **Scenario 1 -** Involves studies that are connected to NSW or ACT (i.e., The project exists in REGIS).
- **Scenario 2 -** Involves studies that are not connected to NSW or ACT (i.e., The project does not exist in REGIS).

2. Instructions for scenario 1 - Studies that are connected to NSW or ACT (i.e., The project exists in REGIS).

If your study has a site or has a lead HREC in NSW or ACT, there is a high chance that it is already registered in REGIS. This means that you don't need to register your project in REGIS to get a project ID (PID), which would look like 2023/PID00036. Instead, you can simply reach out to the Coordinating Principal Investigator (CPI) or the lead site to obtain the project ID (PID). Once you have this, there are a few necessary steps that you need to follow:

Step 1: The THS researcher/study coordinator should send an email to regis@health.nsw.gov.au with the current project registration ID (PID), for example, 2023/PID00036, (or HREC number or project title) and Cc: tasregis.enquiries@health.tas.gov.au (please mention in the email that you want to migrate a project onto REGIS and require access to edit and submit).

Step 2: Prepare a folder with zip files containing study documents. The list provided below is for reference purposes. Please gather as many study documents from the list as possible, as well as any other relevant documents, ready to upload at step 4 below.

- Full set of currently approved ethics and site documents
- Original SSA form
- Current Site-specific documents, i.e., site-specific PICFs
- Current insurance certificate (if relevant)
- CTN (if relevant)
- GCP and CV of investigators
- Radiation safety letter if relevant
- Current master documents approved by ethics (e.g., master PICF, questionnaires, surveys etc.)
- Original and subsequent ethics approval and ethics-approved documents (in a zip file)
- Original and subsequent governance approvals (site authorisation letters and original Site-specific application form)
- Original CTRA and subsequent CTRA amendments
- Original and subsequent indemnity (if relevant)
- Original financial analysis and any updates

Step 3: The NSW REGIS team will initiate the transfer and provide the THS researcher/study coordinator with edit and submit access. Once logged in, select the PID and then the THS researcher/study coordinator can see the **"Transfer site to REGIS"** option.

Do not commence the transfer until you have compiled the project documents in a zip file see step 2.

Step 4: Click on the "**Transfer site to REGIS"** option and fill out the two-page form in one sitting (you cannot save progress), attach the necessary documents (see step 2), and submit. Please watch a walk-through YouTube video to understand the process.
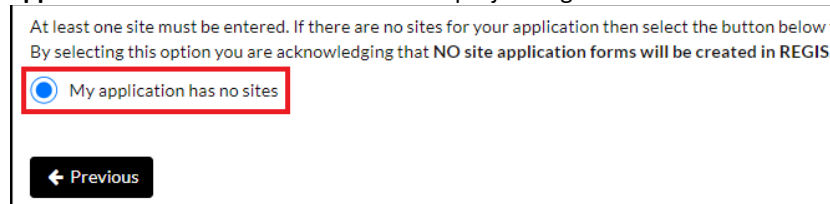
Once submitted, the project will be auto-approved and ready in REGIS to submit any future amendments.

3. Instructions for scenario 2 - Studies that are not connected to NSW or ACT (i.e., The project does not exist in REGIS).

Since the project is not currently in REGIS, the first step is to register a project in REGIS to generate a project ID (PID) for example, 2023/PID00036.

Here are the steps to follow:

Step 1: The THS researcher/study coordinator should register their project in REGIS and select **"My application has no sites"** in Part C of the project registration form.

This choice is because we do not want to create a new Site-Specific Assessment (SSA) in REGIS. Instead, our intention is to migrate the existing approved site. This step will generate a Project ID (PID) for the project.

Step 2: The THS researcher/study coordinator should send an email to regis@health.nsw.gov.au with the current project registration ID (PID), for example, 2023/PID00036, and Cc: tasregis.enquiries@health.tas.gov.au (Please mention in the email that you want to migrate a project onto REGIS and require access to edit and submit.)

Step 3: Prepare a folder with a zip file containing study documents. The list provided below is for reference purposes. Please gather as many study documents from the list as possible, as well as any other relevant documents, ready to upload at step 5 below.
Necessary documents:
- Full set of currently approved ethics and site documents
- Original SSA form
- Current Site-specific documents, i.e., site-specific PICFs
- Current insurance certificate (if relevant)
- CTN (if relevant)
- GCP and CV of investigators
- Radiation safety letter if relevant
- Current master documents approved by ethics (e.g., master PICF, questionnaires, surveys etc.)
- Original and subsequent ethics approval and ethics-approved documents (in a zip file)
- Original and subsequent governance approvals (site authorisation letters and original Site-specific application form)
- Original CTRA and subsequent CTRA amendments
- Original and subsequent indemnity (if relevant)
- Original financial analysis and any updates

Step 4: The NSW REGIS team will initiate the transfer and provide the THS researcher/study coordinator with edit and submit access. Once logged in, select the PID and then the THS researcher/study coordinator can see the **"Transfer site to REGIS"** option.

Please do not commence the transfer until you have compiled the project documents in a zip file (see step 3).

Step 5: Click on the "**Transfer site to REGIS**" option and fill out the two-page form in one sitting (you cannot save progress), attach the necessary documents (see step 3), and submit the form. Please watch a walk-through YouTube video to understand the process.

Once submitted, the project will be auto-approved and ready in REGIS to submit any future amendments.