



Transitioning to REGIS - where do I apply?

Prior to 1st March 2019

If you are submitting a new Ethics application to an ACT or NSW Health HREC, you should register your project and complete the application via REGIS. Note: this applies to any new application regardless of whether it is Low or Negligible Risk (LNR) or greater than LNR; or whether it is a clinical trial or other type of study. Related SSAs for NSW Health sites will be generated in REGIS.

If your Ethics application is being reviewed or has been approved by an ACT or NSW Health HREC and the application was created via Online Forms, all related NSW Health site SSA's need to be generated through the Online Forms portal.

If your Ethics application is being reviewed or has been approved by any other NMA jurisdiction (QLD, SA, VIC, WA) you should register the study and generate related site applications for NSW Health sites in REGIS. See quick reference guide: National Mutual Acceptance (NMA) in REGIS and Project Registration.

From 1st March 2019

If your Ethics application is being reviewed by an ACT or NSW Health HREC and the application was submitted through Online Forms, you must ensure any related site governance application is generated via Online Forms and submitted to the relevant Research Office prior to 1 April 2019. If this does not occur, any additional site governance applications will be unable to be generated until the ethics application has been approved and migrated into REGIS.

If your Ethics application has been approved by an ACT or NSW Health HREC and the application was submitted through Online Forms the application will be migrated into REGIS and site applications for any approved site can be created in REGIS utilising the 'amendment - add new site process' (see QRG: Ethics Amendment - Completing and Submitting). NOTE: utilising the amendment process in this instance is only to enable generation of the SSA for an already approved site - the research office will 'force' the amendment to be accepted in REGIS without review by the HREC allowing the SSA to be generated.

Please confirm this approach with your Research Office prior to submitting the amendment to avoid unnecessary effort or re-work.

From 1 April 2019

All new Ethics applications to an ACT or NSW Health HREC and SSA for NSW Health sites *must* be submitted via REGIS.

SSAs for sites related to ethics applications under review or approved by any other NMA jurisdiction (QLD, SA, VIC, WA) *must* be submitted via REGIS

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¹ Data migration will be a gradual process occurring throughout March and into April 2019. Please check with your CPI if they have confirmed that the project is visible to them in REGIS after receiving notification of transfer before attempting to create an SSA.