RESEARCH GOVERNANCE

NEWSLETTER No 030

May 2024

DoH LOW RISK RESEARCH ETHICS NOW ACCEPTING APPLICATIONS!

The DoH Low Risk Human Research Ethics Committee is now accepting lower risk research ethics applications.

Applications may be submitted via REGIS, however researchers and investigators wishing to submit an ethics application are encouraged to contact the Research Ethics Office at research.ethics@health.tas.gov.au for information and guidance prior to submission.

Dates of committee meetings and deadlines for submission of ethics applications can be viewed in the appendix below.

SUBMIT YOUR QUESTIONS FOR UPCOMING NCTGF WEBINARS

The Australian Commission for Safety and Quality in Health Care (ASQHC) is preparing to host webinars on the implementation of the National Clinical Trials Governance Framework (NCTGF) in June and/or July.

These webinars will aim to provide up to date information, insights and advice for health service organisations preparing for the process of assessment against the NCTGF, and will feature **case studies** from organisations that have already undergone accreditation.

The ASQHC is now inviting the **submission of questions** to be addressed during the webinars. Individuals are encouraged to submit questions by completing this form.

Dates and times of the webinars are to be confirmed and registrations have not yet commenced.

TASMANIAN ATP TEAM CHANGES

The REGU is sad to announce the resignation of Teletrial Coordinator Paula Chen. Over the past year, Paula has passionately promoted the adoption and establishment of the Australian Teletrial Program in Tasmania.

Fortunately, the program will continue, with Tasneem Rizvi remaining in her role as Teletrial Coordinator. Tasneem and will now be the primary point of contact for ATP related enquiries.

MIGRATING PAPER-BASED PROJECTS ONTO REGIS

THS/DoH research projects that were approved through the paper-based system prior to the Research Ethics and Governance Information System (REGIS) can now be migrated onto <u>REGIS!</u>

It is important to note that the process of migrating a project onto REGIS requires input from both researchers and the REGIS team before the project is migrated.

However, once the project is migrated, it will be automatically approved and ready for any future amendments to be made via REGIS.

The REGU strongly recommends that research projects that are to remain open and active for more than 12 months are migrated onto REGIS. If you are planning to migrate your paper-based projects to REGIS, please contact us at <u>tasregis.enquiries@health.tas.gov.au</u> for guidance and further information.

GOOD CLINICAL PRACTICE (GCP) TRAINING

It is **mandatory** that researchers associated with research projects conducted within the health service hold a current GCP Certificate. Clinical trials of medicines and biologicals regulated under the CTN or CTA schemes are subject to the Therapeutic Goods Administration (TGA) Good Clinical Practice (GCP) Inspection Program. Evidence of GCP is required to be submitted as part of a research governance application.

GCP training can be accessed free of charge through the <u>Australian Clinical Trials Education Centre</u> (A-CTEC). The training takes approximately 2.5 hours to complete. DoH/THS staff <u>must</u> upload completion certificates to <u>Tasmanian Health Education Online (THEO)</u> to be recorded as completed.

A-CTEC COURSES

Reminder that all Tasmanian researchers and investigators have access to the <u>Australian Clinical Trials Education Centre</u> (A-CTEC) free of charge. The A-CTEC has a number of interesting and educational courses and sessions available. Upcoming courses and workshops include:

Tasmanian

Government

Research Governance Newsletter

- Research Integrity & The Code. Developed through collaboration between Peter MacCallum Cancer Centre (PMCC), Melbourne Children's Research Institute (MCRI), and Australian Clinical Trials Education Centre (A-CTEC), this course is designed to assist in conducting research with integrity and complying with the Code principles.
- Investigator Site File Workshops. Registration for these workshops are now open and places are limited, so be quick!

Make sure to subscribe to the A-CTEC newsletter to be notified of new courses and upcoming webinars and workshops.

REGIS TRAINING FOR RESEARCHERS

Registrations are now open for REGIS researcher training sessions. Sessions are scheduled for:

- July 2nd, 3rd and 4th
- September 10th, 11th and 12th

Click here to register for a REGIS training session. Please note that the REGIS website also contains quick reference guides and FAQs. For Tasmania-specific REGIS support please email tasregis.enquiries@health.tas.gov.au

RGO TIP OF THE MONTH

To reduce waiting times and speed up your application, please review the **mandatory documents** list on the **REGU** intranet and ensure that your submission is complete before submitting it in REGIS.

If you are an external applicant and are unable to access the intranet, please reach out to your site PI for assistance.

REGU CONTACT INFORMATION

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Intranet:	Research Ethics and Governance Unit (REGU) Tasmanian Department of Health Intranet		
Website	https://www.health.tas.gov.au/research		
	research.governance@health.tas.gov.au		
	Research Governance consultations		
Research	will be in 30-minute intervals at the		
Governance Office	following times:		
	• Tuesdays 7.00am – 9.00am		
	Thursdays 8.00am -10.00am		
	Thursdays 2.00pm – 4.00pm		
	research.ethics@health.tas.gov.au		
Research Ethics	Consultations will be in 30-minute		
Office	intervals at the following times:		
	 Tuesdays 8.00am – 10.00am 		
	Thursdays 1.00pm – 3.00pm		
REGIS Support	tasregis.enquiries@health.tas.gov.au		
	As required		
Australian	ATP-TAS@health.tas.gov.au		
Teletrial Program (ATP) Regional	As required		
Clinical Trial			
Coordinating			
Centre (RCCC)			

Research Governance Newsletter

APPENDIX

Ethics Meeting Dates and Deadlines-2024

Submission	First Review	Committee	Ethics Committee Meeting
May 15	May 17-21	А	May 27
May 30	June 1-5	В	June 11
June 12	June 14-18	A	June 24
June 27	June 29-3 July	В	July 9
July 10	July 12-16	А	July 22
July 25	July 27-31	В	August 6
August 7	August 9-13	A	August 19
August 22	August 24-28	В	September 3
September 4	September 6-10	А	September 16
September 19	September 21-25	В	October 1
October 2	October 4-8	А	October 14
October 17	October 19-23	В	October 29
October 30	November 2-6	А	November 11
November 14	November 16-20	В	November 26
November 27	Nov 29-Dec 3	А	December 9
Dec/Jan dates tbc			W.