

## Research Governance Update – GCP Training

GCP policy and training opportunities

Monash Partners, of which Alfred Health is a member, has developed a [policy](#) on the training requirements for investigators undertaking research at the member institutions.

Under the policy, as a means of mitigating the risk to patients, their information and the integrity of the research, all researchers undertaking clinical trials and other interventional studies will be required to have and maintain appropriate, accredited training.

The requirement not only applies to those acting in the role of Principal Investigator but to researchers engaged as Associate Investigators and Research Co-ordinators listed in the ethics and/or site authorisation application to Alfred Health, irrespective of which institution they are from.

The minimum training required will be TransCelerate Biopharma Inc accredited, ICH E6 Good Clinical Practice course.

A list of accredited courses can be found at:

<http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/>

The commercial sponsors whose GCP courses satisfy the TransCelerate criteria can be found at: [http://www.transceleratebiopharmainc.com/wp-content/uploads/2016/04/Member-Co\\_GCP\\_Matrix\\_v15\\_4Apr16.pdf](http://www.transceleratebiopharmainc.com/wp-content/uploads/2016/04/Member-Co_GCP_Matrix_v15_4Apr16.pdf)

Researchers who have completed ICH GCP training should submit their training certificates to the Ethics & Research Governance Office.

**From 01 January 2018, any researcher listed on a new application and/or included on an ongoing application, who has not provided evidence of acceptable research training to the Alfred Health Ethics & Research Governance Office, will not be able to undertake research with an Alfred Health component until they have complied with the requirement.**

For researchers who will require GCP training, the requirement is for an Australian course to be undertaken. Monash Partners currently provides free face-to-face TransCelerate accredited ICH E6 GCP training on the campuses of AMREP and the Monash Health Translational Precinct. At this stage, the free training will be available until July 2017. All researchers with a salaried appointment at a Monash Partner Institution will be eligible for the free training. Registration and information about the initial course can be found at: <http://www.med.monash.edu.au/sphpm/shortcourses/good-clinical-practice.html>

Other Australian courses which meet the TransCelerate ICH E6 GCP Training Minimum Criteria include:

- ARCS Australia:

<http://www.arcs.com.au/events/interest-areas-committee-meetings-2>

- Peter MacCallum Cancer Centre:

<https://www.petermac.org/education/research-education/clinical-research-education>

- Murdoch Children's Research Institute:  
<https://www.mcri.edu.au/research/facilities-resources-and-training/clinical-research-development-office-crdo/crdo-workshops>)

The duration and costs associated with the required courses are outlined in the table below:

Course	Time Requirements	Cost
<b>Monash Partners</b>	Face-to-face at AMREP and MHTP Translational Research Facility (Monash Health)	
	5 Hours for initial course	Free
	2 hours for refresher	Free
<b>ARCS Australia *</b> If there is sufficient interest, Alfred Health may be able to purchase licences in bulk which will reduce the fee.	Online Licences are valid for one year from date of purchase but participants have one month to complete the course once commenced.	
	Up to 10 hours for initial course	\$269 for ARCS Members \$340 for non-ARCS members
	1 hour for refresher	Free to ARCS members
		\$89 for non-ARCS members who have previously completed a TransCelerate initial course.
<b>Peter MacCallum Cancer Centre *</b>	Face-to-face at Peter MacCallum Cancer Centre (Can also come to a Site for a minimum of 15 attendees)	
	5 hours for initial course	\$214.50
	3 hours for refresher	\$86.90
<b>Murdoch Children's Research Institute *</b>	Face-to-face	
	4 hours for initial course	\$160
	Refresher not offered.	

The above courses will need to be funded by individual researchers and/or Departments but may be covered by educational allowances or claimed as a tax deduction.

**Researchers will also be required to maintain their training by completing a TransCelerate accredited ICH GCP refresher course every three years.**

Monash Partners will offer a free face-to-face refresher course until July 2017. Researchers, who have completed a TransCelerate ICH GCP course and hold an Alfred Health salaried or appropriate honorary appointment as described previously, will be eligible to undertake the GCP refresher course. Registration and information about the refresher can be found at: <http://www.med.monash.edu.au/sphpm/shortcourses/refresher-ich-good-clinical-practice.html>

It should be noted that whilst the online NIH National Drug Abuse Treatment Clinical Trials Network (NIDA) GCP training is not a TransCelerate accredited course, **it will be deemed as an acceptable course** and researchers who have undertaken this course will be eligible to attend the free TransCelerate accredited Monash Partners ICH-GCP refresher course.