Research Education and Training Program

Western Australian Health Translation Network

The RETP, WAHTN presents the following workshop opportunity

Title: ICH Good Clinical Practice (GCP) E6 (R2) and regulatory requirements for Clinical Trials

Workshop Format: "Flipped" = Face-to-face (3hrs) + some online component (30 min).

Day & Date: Wednesday, February 20 **Time**: 09:00-12:00

Location: Curtin University, Room TBC

Cost: $200 per person (*please note that some institutions are hosting and funding this w/shop for their staff).

Facilitator: Tanya Symons (Director, T Symons Associates PTY LTD)
Tanya has established her consultancy in Australia, working for both Commonwealth and State governments. She is using her knowledge of international best practice to influence the streamlining and standardisation of research-related processes in Australia and authored the 2016 Safety Monitoring and Reporting Guidelines and its three supporting guidelines for the NHMRC. She is the GCP training provider for numerous organisations across Australia.

Course topic overview: Participants will learn about:
The origins of GCP; Good Clinical Practice and the Regulatory Framework; The Conditions and Principles of GCP; Sponsor and Investigator Activities; Safety Reporting in Research; Informed Consent and Study Records, Reporting and Archiving.

Who should attend? Anyone conducting human research. The session is primarily designed for those working on drug or medical device trials; either managing their own investigator-led trials or collaborating on externally sponsored multi-centre clinical trials. Investigators working on other interventional trials will also gain useful insights into the quality systems that apply.

REGISTER your interest now here