

**AUSTRALIAN ICH GCP (Including Teletrials) SOP 30 Appendix 2  
Example Internal Training Record**

**Complete, sign, date, and retain the original form at the site. Provide a copy of the completed form to the sponsor representative.**

<b>Trainee Name:</b> (Printed)		<b>Trainee Role:</b> <input type="checkbox"/> Principal Investigator (PI) <input type="checkbox"/> Study Coordinator (SC) <input type="checkbox"/> Sub-investigator (Sub-I) <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (Specify role, e.g. study nurse):
<b>PI Name:</b>		
<b>Protocol:</b>		
<b>Site Number:</b> <input type="checkbox"/> Primary <input type="checkbox"/> Satellite		
<b>Training Method:</b>	Classroom face to face <input type="checkbox"/> video / teleconference <input type="checkbox"/> eLearning <input type="checkbox"/> self-directed <input type="checkbox"/> other <input type="checkbox"/> (see below)	
<b>Other description:</b>		

Protocol and Non-protocol-specific Training Topics	Trainer(s) Name & Role (Printed) if applicable.	Training method	Training Completed DDMMYYYY
Protocol Version NN DDMMYYYY			
Investigator Responsibilities Version NN DDMMYYYY			
Informed Consent Version NN DDMMYYYY			
Interactive Web Response System (IWRS)/ IVRS Version NN DDMMYYYY			
ICH GCP E6 R2 Version NN DDMMYYYY			

CRF completion Version NN DDMMMYYYY			
EDC system Version NN DDMMMYYYY			
Serious Adverse Event (SAE) Reporting Version NN DDMMMYYYY			
Safety Monitoring Plan Version NN DDMMMYYYY			
IMP handling Version NN DDMMMYYYY			
Laboratory Manual Version NN DDMMMYYYY			
Source Documentation Version NN DDMMMYYYY			
Monitoring Plan Version NN DDMMMYYYY			

By signing this certificate, I attest that I have completed all training topics listed above for my role in the trial. I agree to follow TGA, NHMRC national Statement and ICH GCP guidelines as well as instructions provided in these training topics when conducting this trial. This training was completed before performing any trial responsibilities, and trial related activities. I was given the opportunity to ask questions and received satisfactory clarification.

\_\_\_\_\_  
Signature of Trainee

\_\_\_\_\_  
Date (dd-mmm-yyyy)