CHAPTER FOUR: GUIDANCE DOCUMENTS

Introduction

Chapter Four of the Australian ICH GCP (Including Teletrials) Standard Operating Procedures (SOP) Compendium identifies all the documents and guidelines that were consulted in the compilation of all the SOPs in this compendium. Chapter 4 also contains the links to all the guidance documents.

The following guidance documents are fundamental to each and every SOP and are termed key guidance documents:

- ICH GCP E6 (R2) (November 2016)
- National Statement on Ethical Conduct in Human Research 2007 (updated 2018)
- Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) - annotated with TGA comments (February 2018)
- TGA Australian Clinical Trial Handbook (March 2018)
- Australian Code for the Responsible Conduct of Research, 2018

Consequently, these key guidance documents are not listed in Section 5 GUIDANCE DOCUMENTS in each of the individual SOPs. Section 5 will therefore identify the guidance documents specific to that SOP but inherently include the key guidance documents.

If there are any questions in relation to any guidance document, please contact the Health Innovation, Investment and Research Office (HIIRO) on hiiro@health.qld.gov.au with the specific document in question and in which SOP/s the document is considered in the subject header for action.

Thank you for your vigilance.

Queensland Clinical Trials Coordination Unit (QCTCU)
Health Innovation Investment and Research Office (HIIRO)
Office of the Director-General (ODG)
Queensland Department of Health
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NOTE regarding TGA and NHMRC guidance documents used in this compendium

The TGA have revised and released the Australian clinical trial handbook on their website in March 2018. The Handbook has been updated to reflect current practice and consolidates information from the following previous clinical trials guidance documents to ensure that stakeholders have a single, complete source of policy information. The handbook also provides policy guidance on the clinical trials schemes administered in Australia by the TGA.

The following documents are now obsolete:

- Access to unapproved therapeutic goods – Clinical trials in Australia October 2006
- Australian Clinical Trial Handbook March 2006
- Human Research Ethics Committees and the therapeutic goods legislation June 2001

Additionally, the NHMRC have re-published their document Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Goods (May 2009), in November 2016 as Guidance on Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods following a revision of the AHEC's Position Statement which identified a need for supplementary guidance to establish a reporting framework for protocol deviations.
Consequently, the following document is now obsolete:

- Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Goods (May 2009)

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An electronic version of this document is available at: https://www.health.qld.gov.au/hiiro/html/regu/regu_home

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GUIDANCE DOCUMENTS

1. **Australian Clinical Trial handbook March 2018**
   https://www.tga.gov.au/publication/australian-clinical-trial-handbook
   https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf

2. **Australian Code for the Responsible Conduct of Research 2018**
   https://www.nhmrc.gov.au/guidelines-publications/r41

   https://www.nhmrc.gov.au/_files_nhmrc/file/publications/17628_nhmrc_-_nhmrc_the_australian_code_for_the_responsible_conduct_of_research_-_v1-1-accessiblefinal_0.pdf

3. **Australian Code for the Transportation of Dangerous Goods by Road and Rail**
   http://www.ntc.gov.au/heavy-vehicles/safety/australian-dangerous-goods-code/
   http://www.ntc.gov.au/Media/Reports/(91D53582-C568-8B4A-6C7C-E746D36C65FD).pdf

4. **Blue Card or CIOMS form:** email to adr.reports@tga.gov.au
   https://www.tga.gov.au/sites/default/files/blue-card-adverse-reaction-reporting-form-151102.pdf

5. **CaSS Pathology Queensland Dangerous Goods Manual: Manual for Shipper of Infectious Substances, GMOs GMMOs and Dry Ice (Updated with 2018 IATA 59th Edition. Small changes to Table 2.3.A and Road ADG Code 7 updated to 7.5. Mandatory from March 2018)**
   http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=29655

6. **Clinical Trials Exemption (CTX) Form and scheme**
   https://www.tga.gov.au/form/ctx-scheme-forms
   NOTE: Guidance on the application process for the Clinical Trial Exemption (CTX) scheme is currently under review.

7. **Clinical Trials Notification (CTN) Form and scheme**
   https://www.tga.gov.au/form/ctn-scheme-forms
   NOTE: Guidance on the notification process for the Clinical Trial Notification (CTN) scheme is available at Clinical trial notification form – user guide.

8. **Clinical Trials Tool Kit**
   https://www.australianclinicaltrials.gov.au/clinical-trials-toolkit

9. **COSA Australasian Tele-trial Model**
https://www.cosa.org.au/media/332325/cosa-teletrial-model-final-19sep16.pdf

10. **CTN and CTX clinical trial completion advice form**.
https://www.tga.gov.au/sites/default/files/clinical-trials-forms-completion-140701.pdf

11. **E2B reports:** Information found here https://www.tga.gov.au/e2b-reports-frequently-asked-questions and also at http://www.ich.org/home.html
NOTE: Reports are emailed to e2b.reports@tga.gov.au

12. **Guardianship and Administration Act 2000(QLD)**
https://www.legislation.qld.gov.au/view/html/inforce/current/act-2000-008
https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2000-008

13. **Guide To Good Manufacturing Practice For Medicinal Products Annexes**
https://www.tga.gov.au/sites/default/files/manuf-pics-gmp-medicines-annexes.pdf

14. **Health (Drugs and Poisons) Regulation 1996 (Qld)**
https://www.legislation.qld.gov.au/view/pdf/inforce/2014-10-01/sl-1996-0414

15. **IATA Dangerous Goods Regulations 59th Ed 2018.**
http://www.iata.org/whatwedo/cargo/dgr/Documents/dgr-59-significant-changes.pdf
http://www.iata.org/whatwedo/cargo/dgr/Documents/dgr59-addendum1-en.pdf

16. **ICH GCP E6 (R2)**
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

17. **Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) - annotated with TGA comments February 2018**
https://www.tga.gov.au/publication/note-guidance-good-clinical-practice
http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm

18. **Investigator's Brochure table of contents for an ICH GCP E6(R2) compliant Investigator's Brochure**
https://ichgcp.net/7-investigators-brochure

19. **ISO 14155:2011 Clinical Investigation of Medical Devices for Human Subjects**
www.iso.org
https://www.iso.org/obp/ui/#iso:std:iso:14155:ed-2:v1:en

20. **Manual for Shippers of Infectious Substances, GMOs GMMOs and Dry Ice**
http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=29655

21. **National Mutual Acceptance. Single Ethical Review of Multi-centre Human Research Projects.**
MONITORING AND REPORTING TABLES
https://www2.health.vic.gov.au/about/publications/policiesandguidelines/monitoring-and-reporting-tables

22. **National Participant Information and Consent Form (PICF)**
http://www.nationalpicf.com.au/

23. **National Pathology Accreditation Advisory Council (NPAAC) Requirements for the packaging and transport of pathology specimens and associated materials (Fourth Edition 2013)**
https://www.health.gov.au/internet/main/publishing.nsf/Content/4F97263708B66C49CA257BF0001E012A/$File/Reqmts%20PackagingTransport%202013.pdf

24. **NHMRC Data Safety Monitoring Boards (DSMBs) 2018**
https://www.nhmrc.gov.au/guidelines-publications/eh59
https://www.nhmrc.gov.au/_files_nhmrc/file/publications/data_safety_monitoring_boards.pdf

25. **NHMRC Guidance: Safety Monitoring And Reporting In Clinical Trials Involving Therapeutic Goods November 2016**
https://www.nhmrc.gov.au/guidelines-publications/eh59
https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

26. **NHMRC National Statement on Ethical Conduct in Human Research 2007** (updated 2018)
https://www.nhmrc.gov.au/_files_nhmrc/file/publications/national-statement-2018.pdf

27. **NHMRC Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018**
https://www.nhmrc.gov.au/guidelines-publications/eh59
https://www.nhmrc.gov.au/_files_nhmrc/file/publications/guidance_on_the_reporting_of_serious_breaches_of_gcp.pdf

28. **NHMRC Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018**
https://www.nhmrc.gov.au/guidelines-publications/eh59
https://www.nhmrc.gov.au/_files_nhmrc/file/publications/risk-based_management_and_monitoring_of_clinical_trials_0.pdf

29. **Pharmacovigilance responsibilities of medicine sponsors**.
https://www.tga.gov.au/book-page/your-regulatory-reporting-requirements

30. **Protocol table of contents for an ICH GCP E6(R2) compliant protocol (see also TransCelerate and SCRS Forms: Common Protocol Template)**
http://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments

31. **Queensland Civil and Administrative Tribunal (QCAT)**
http://www.qcat.qld.gov.au/

32. **Queensland Government Contracts Directory GovNet** Records **Storage, retrieval and destruction. Both documents are for QH internal Use only**
http://qcd.govnet.qld.gov.au/Pages/Details.aspx?SOANumber=QGCPO747-08

33. **Queensland Health Guidance "Research involving patients who are unable to give consent" 2018**
https://www.health.qld.gov.au/hiiro/html/regu/regu_home

34. **Queensland Health Guide to Informed Decision-making in Health Care (Queensland Health)**
https://www.health.qld.gov.au/__data/assets/pdf_file/0019/143074/ic-guide.pdf

35. **Queensland Health Research Ethics and Governance Health Service Directive # QH-HSD-035:2016**
https://www.health.qld.gov.au/__data/assets/pdf_file/0025/494008/qh-hsd-035.pdf

36. **Queensland Health Research Management Policy QH-POL-013:2015 (23 June 2015)**
https://www.health.qld.gov.au/__data/assets/pdf_file/0020/164162/qh-pol-013.pdf

37. **Queensland Health Research Management Standard QH-IMP-013-1:2016**
https://www.health.qld.gov.au/__data/assets/pdf_file/0035/397448/qh-imp-013-1.pdf

38. **Queensland State Archives: Health Sector (Clinical Records) Retention and Disposal Schedule**
https://www.forgov.qld.gov.au/system/files/schedules/health-sector-clinical-records-retention-and-disposal-schedule-qdan683.pdf?v=1485126228

39. **Retention of records – Queensland Health**
https://www.forgov.qld.gov.au/system/files/schedules/health-sector-clinical-records-retention-and-disposal-schedule-qdan683.pdf?v=1485126228

40. **Standardised Patient Informed Consent: See NHMRC website**
https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and

41. **Standard Operating Procedures for Research Governance Officers**
http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf

42. **Teletrial Clinical Consultation User Guide**
https://www.health.qld.gov.au/hiiro/html/regu/regu_home

43. **TGA reporting guidelines**
https://www.tga.gov.au/reporting-problems

44. **TransCelerate and SCRS Forms:**
    a. **Site Signature and Delegation of Responsibility Log_SCRS**
    http://myscrs.org/learningcampus/site-management-modules/
    b. **Curriculum Vitae Template_TransCelerate**
    http://www.transceleratebiopharmainc.com/wp-content/uploads/2018/03/CV-Template-1.pdf
    c. **Common Protocol Template_TransCelerate**
    http://www.transceleratebiopharmainc.com/assets/common-protocol-template-old/
    d. **Other Site Qualification and Training Forms**
    http://www.transceleratebiopharmainc.com/assets/site-qualification-and-training/