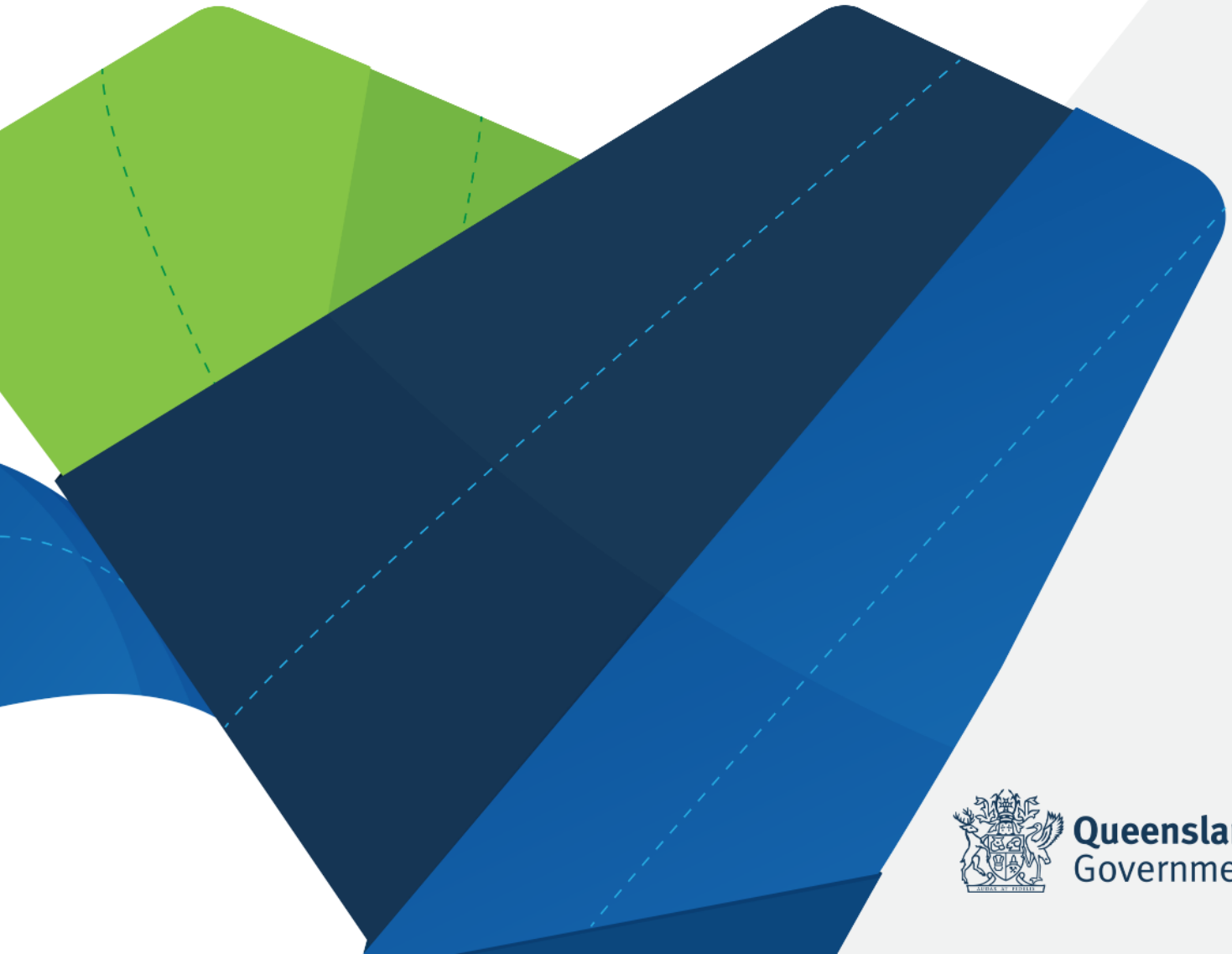
# National Standard Operating Procedures for Clinical Trials including Teletrials in Australia.

Queensland Health Specific Guidance Notes V1 August 2021



Queensland Government

# Contents

# INTRODUCTION

This guidance identifies all the documents and guidelines included in the consultation for the compilation of the National Standard Operating Procedures (SOPs) for Clinical Trials including Teletrials in Australia and provides the link to the source. This guidance document is specific to Queensland.

If there are any questions in relation to any guidance document, please contact the Queensland Clinical Trials Coordination Unit (QCTCU) at qctcu@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.

Queensland Clinical Trials Coordination Unit (QCTCU)

Health Innovation Investment and Research Office (HIIRO)

Prevention Division

Queensland Health

August 2021

***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)

**National Standard Operating Procedures for Clinical Trials including Teletrials in Australia.**

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

# GUIDANCE NOTES SPECIFIC TO EACH SOP

The following references are fundamental to each and every SOP of the National Standard Operating Procedures (SOPs) for Clinical Trials including Teletrials in Australia and are termed ***KEY REFERENCES***:

- 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)
- NHMRC Australian Code for the Responsible Conduct of Research, 2018

Consequently, these key references are not listed in ***Table 1. SOP versus REFERENCE***. The table will therefore indicate the reference/s specific to that SOP but inherently include the ***KEY REFERENCES*** listed above.

## *Table 1. SOP versus REFERENCE*

| SOP number | SOP Title | Relevant Reference/s (links are provided at the end of this document) |
|---|---|---|
| **1** | Creation, Implementation and Revision of Standard Operating Procedures | Nil extra |
| **2** | Investigator Responsibilities | Teletrials Clinical Consultation User Guide |
| **3** | Site Staff Qualifications, Training Records and Capability | Nil extra |
| **4** | Protocol and Investigational Brochure Requirements | Nil extra |
| **5** | Communication with HREC, RGO, Sponsor and Institution's Insurer | 1. NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods November 2016<br>2. NHMRC Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods 2018<br>3. NHMRC Guidance on the Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018<br>4. National Mutual Acceptance. Single Ethical Review of Multicentre Human Research Projects. MONITORING AND REPORTING TABLES |
| **6** | Site Initiation | Nil extra |
| **7** | The Study Master File | Nil extra |
| **8** | Case Report Forms and Source Documents | 1. NHMRC Australian Code for the |

| | | |
|---|---|---|
| | | Responsible Conduct of Research (Part A, Section 1)<br>2. Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1<br>3. Queensland Government Contracts Directory GovNet<br>4. Teletrials Clinical Consultation User Guide |
| **9** | Participant Informed Consent Process and Documentation | *1. Public Health Act 2005*<br>2. Queensland Health Research Ethics and Governance Health Service Directive # QH-HSD-035:2019<br>3. Queensland Health Guide to Informed Decision-making in Healthcare (2nd Edition January 2017)<br>4. Queensland Health Guidance "Research involving patients who are unable to give consent 2018"<br>5. Queensland Health Research Management Policy QH-POL-013:2015 (23 June 2015)<br>6. Queensland Health Research Management Standard QH-IMP-013-1:2016<br>*7. Queensland Civil and Administrative Tribunal (QCAT)*<br>*8. Guardianship and Administration Act 2000 (Qld)*<br>9. Teletrial Clinical Consultation User Guide |
| **10** | Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods | 1. CaSS Pathology Queensland Dangerous Goods Manual: Manual for Shipper of Infectious Substances and Dry Ice |
| **11** | Management of Investigational Product | **1. Health (Drugs and Poisons) Regulation 1996 (Qld)** |
| **12** | Safety Data Monitoring and Reporting Requirements for Clinical Trials | Nil extra |
| **13** | Site Close-Out and Archiving | 1. Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1<br>2. Queensland Government Contracts Directory GovNet |

# QUEENSLAND SPECIFIC GUIDANCE NOTES TO THE NATIONAL SOPS

## SOP 01 Creation, Implementation and Revision of Standard Operating Procedures

- Any Queensland specific document created to describe a procedure or work instruction **specific to that facility** must use the Queensland Health (QH) templates.
- Approval and Authorisation of the SOP: will follow **local facility policy**

## SOP 02 Investigator Responsibilities

- No Queensland specific guidance notes

## SOP 03 Site Staff Qualifications, Training Records and Capability

- No Queensland specific guidance notes

## SOP 04 Protocol and Investigational Brochure Requirements

- No Queensland specific guidance notes

## SOP 05 Communication with HREC, RGO, Sponsor and Institution's Insurer

- The majority of communication with the HREC and RGO is via Ethics Review Manager (ERM) in particular the application and amendment submissions.
- Notification of insurance matters and claims, by the institution or the Investigator, is made to the relevant QH HHS solicitor
- Communication for insurance matters and claims, by the institution or the Investigator, is made to Queensland Government Insurance Fund (QGIF). All communication will follow QH policy

## SOP 06 Site Initiation

- No Queensland specific guidance notes

## SOP 07 The Study Master File

- No Queensland specific guidance notes

# SOP 08 Case Report Forms and Source Documents

- Records Retention and archiving is as per Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1

# SOP 09 Participant Informed Consent Process and Documentation

### Research Involving Participants who are Unable to Give Consent

- See the *Guardianship and Administration Act 2000 (Qld) matter type* clinical research https://www.qcat.qld.gov.au/matter-types/clinical-research
- For more information, refer to the Queensland Health Guidance "Research involving patients who are unable to give consent 2018" Policy Statement 2018

# SOP 10 Handling and Shipping of Biological Substances (Cat B) and Dangerous Goods

### Handling and Shipping of Biological Substance and Dry Ice in Clinical Trials

- In situations where research personnel do NOT hold current certification, arrangements for biological substance / dry ice shipment are made with IATA certified Pathology Queensland Laboratory staff or External Third Party.

# SOP 11 Management of Investigational Product

- In accordance with the Health (Drug and Poisons) Regulation 1996 (Qld), an endorsement is not required for a person to dispense, prescribe, and supply a restricted drug or controlled drug for an approved clinical trial

# SOP 12 Safety Data Monitoring and Reporting Requirements for Clinical Trials

- No Queensland specific guidance notes

# SOP 13 Site Close-Out and Archiving

### Archiving

- Archiving of clinical trials records / documents is in accordance with Queensland State Archives, Health Sector (Clinical Records) Retention and Disposal Schedule. Section 2.1
- Queensland Government requirements for clinical trial records where the participants are minors are retained for:
  - 15 years from patient/client attaining 18 years of age; AND
  - 10 years after last patient/client service provision or medico-legal action.

- Queensland Government requirements for clinical trial records where the participants are adults are retained for:
    - 15 years from completion of clinical research/trial; AND
    - 10 years after last patient/client service provision or medico-legal action

# APPENDIX 1: REFERENCES


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 and Dry Ice**
   http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=29655

6. **Clinical Trials Exemption (CTA) Form and scheme**
   https://www.tga.gov.au/sites/default/files/clinical-trials-forms-cta-part1.pdf

7. **Clinical Trials Notification (CTN) Form and scheme**
   https://www.tga.gov.au/clinical-trials

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 CTA 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.**
IATA - DG Documentation

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**
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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. ***Public Health Act 2005***
Use of Confidential Health Information | Queensland Health

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

33. **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

34. **Queensland Health** Research involving patients who are unable to give consent Policy Statement (April 2018)

35. **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

36. **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

37. **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

38. **Queensland Health Research Management Standard QH-IMP-013-1:2016**
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39. **Queensland State Archives: Health Sector (Clinical Records) Retention and Disposal Schedule**
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40. **Retention of records – Queensland Health**
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41. **Standardised Patient Informed Consent: See NHMRC website**
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42. **Standard Operating Procedures for Research Governance Officers**
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43. **Teletrial Clinical Consultation User Guide**
https://www.health.qld.gov.au/hiiro/html/regu/regu_home

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

45. **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/