Teletrial Cluster Approval Process

Queensland Health (Statewide) Guideline

Guideline number: QH-GDL-506
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Supersedes: New Guideline

1. Purpose

This guideline has been developed to provide a non-mandatory, best practice approach to support efficient 'cluster' start-up and approval processes for Clinical Trials conducted using the Australasian Teletrials Model. It assists to provide understanding of the requirements that underpin the teletrial cluster approval process.

2. Scope

This guideline applies to all Hospital and Health Services (HHSs).

This guideline applies to all staff (including employees, contractors, consultants, students, and volunteers engaged by, or performing work for HHSs) involved in submission and approval of Clinical Trials conducted using the Australasian Teletrial Model.

It has been developed to support HHSs in the efficient cluster start up and approval processes for Clinical Trials conducted using the Australasian Teletrial Model and demonstrates how HHSs can provide timely access to clinical trials closer to home for Queenslanders eligible to participate in them by way of teletrials, where available.

In alignment with **National Standard Operating Procedures for Clinical Trials** | Australian Government Department of Health and Aged Care, a cluster is defined as a 'group of sites involved in undertaking the same study, consisting of a Primary Site that assumes overall responsibility for the conduct of the same study and one or more Satellite Sites, which conduct the study under the direction of the Primary Site by, for example, using telehealth. A cluster can be made up of sites in the same HHS or across different HHSs'.

This guideline, including, specifically, the 'Teletrial Cluster Approval Process' specified in section 4 below, applies when establishing a new teletrial cluster, and to the extent possible, when converting a Clinical Trial to a teletrial or adding a Satellite Site/s to an existing cluster.

3. Statement of Intent and Underlying Principles

This guideline recommends HHSs undertake a modified approach to usual research approval processes for teletrials to enable rapid activation of a teletrial at a Satellite Site, while complying with the *Research Ethics and Governance HSD* and *Standard Operating Procedures for Queensland Health Research Governance Officers* to the extent otherwise applicable.

This guideline:

- aims to foster a culture of equity of access to healthcare amongst all stakeholders involved in Clinical Trials within HHSs.
- applies to those involved in submitting Research Applications for teletrials, as well as those reviewing and approving teletrials, at both the Primary Site and Satellite Site including:
    - the research team.
    - those providing internal approvals as part of the Research Application (for example, head of department, finance, supporting departments).
    - those negotiating and reviewing contractual arrangements associated with teletrials.
    - those responsible for reviewing and assessing Research Applications.
    - those who ultimately authorise (or not) the research activity to occur.
- recommends that HHS staff at both the Primary Site and Satellite Site work collaboratively to navigate application and review processes expeditiously, for the benefit of the whole cluster (and ultimately the patient).
- recommends a flexible approach to applying this guideline to allow its application to a variety of circumstances (for example: new teletrials as well as traditional Clinical Trial to teletrial conversions, where the Sponsor is also the Primary Site).
- seeks to limit duplication of effort in review processes.
- recommends a more focused review to be undertaken by those assessing and authorising a teletrial at the Satellite Site by:
    - recognising that the clinical trial/teletrial has already undergone a due diligence assessment at the Primary Site.
    - requiring any subsequent review at the Satellite Site to be limited to Satellite Site considerations and be commensurate with the Satellite Site's involvement.
- encourages HHSs to reduce/minimise the number of internal approvals required at the Satellite Site and/or to delegate these down where appropriate (for example, head of department, finance, supporting departments, executive).
- outlines the expectation that Satellite Sites will, to the greatest extent possible, accept the payments and contract terms previously negotiated between the Sponsor and Primary Site, and not seek to renegotiate costs.
- encourages HHSs to contemplate involvement/future involvement of rural, regional and remote participants as part of budget negotiations for Clinical Trials more generally.
- seeks to reduce the timeframe that HHSs have to authorise (or not) a teletrial at Satellite Sites.

4. Guideline for Teletrial Cluster Approval Process

4.1. The Satellite Site, Site Specific Assessment (SSA) application for a teletrial is prepared by the Satellite Site team and submitted for Research Governance Review. The SSA should include the following:

- confirmation of Satellite Site specific processes for participant identification, recruitment and consent for the relevant teletrial.
- confirmation of resources and logistics required to undertake the Clinical Trial at the Satellite Site by way of a teletrial.
- where applicable, the proposed legally binding contractual arrangement between the organisations conducting the teletrial at the Satellite Site - often a Teletrial Subcontract including, for commercially sponsored trials, a signed form of indemnity provided by the Sponsor.
- documentation evidencing agreement between the organisations conducting the teletrial on the clinical trial budget and provision of information required for funds transfers.
- copy of the notification to the Reviewing Human Research Ethics Committee (Reviewing HREC) of the addition of the Satellite Site to the Teletrial Cluster.
- copy of the signed Supervision Plan between the Primary Site and the relevant Satellite Site.

4.2. If a Satellite Site is joining an already established teletrial cluster, the SSA for the proposed Satellite Site should also include evidence of Primary Site Research Governance Authorisation for:

- the clinical trial/teletrial (initial authorisation); and
- the addition of the Satellite Site to the teletrial cluster.

4.3. Where possible, the Primary Site SSA should be submitted for Primary Site Research Governance Review in parallel with the ethics application. Primary Site Research Governance Authorisation cannot be given until ethics approval has been granted.

4.4. The Satellite Site SSA should be *prepared* as early as possible after Satellite Site feasibility has been confirmed. This may be done while the Primary Site SSA is undergoing review.

4.5. The Satellite Site SSA should be *submitted* for Satellite Site Research Governance Review as soon as possible after Primary Site Research Governance Authorisation has been granted (to avoid duplication in Satellite Site review processes).

4.6. The Satellite Site Research Governance Officer (RGO) may *in their discretion* accept a Satellite Site SSA *before* Primary Site Research Governance Review has been completed, however, Satellite Site Research Governance Authorisation cannot be granted until evidence of Primary Site Research Governance Authorisation has been received.

4.7. The extent of the Satellite Site Research Governance Review should be commensurate to the Clinical Trial activities proposed to occur at the Satellite Site taking into account the capacity of the Satellite Site to conduct the teletrial, the complexity of the teletrial (as it relates to the Satellite Site) and any local Satellite Site considerations or limitations.

4.8. In general, the Primary Site Research Governance Authorisation should be taken by the reviewing Satellite Site Research Governance Officer as evidence that the clinical trial/teletrial

complies with applicable federal and state legislation, policies and procedures and national guidelines applying to the conduct and approval of Clinical Trials. Any conditions imposed by the approving HREC or Primary Site Research Governance Authorisation will apply to the Satellite Site, to the extent relevant.

4.9. In general, a Satellite Site will be subject to the terms agreed for the conduct of a teletrial by the Primary Site as outlined in the applicable Clinical Trial Research Agreement (CTRA) (or equivalent), including those terms relating to finances and fees. In CTRAs, it is common for the Primary Site to receive payment for conducting a Clinical Trial, with any payment to Satellite Sites being the responsibility of the Primary Site and such payments being commensurate with the activity that each Satellite Site contributes to the teletrial.

4.10. A Primary Site should consider at the feasibility stage of a Clinical Trial if any additional costs should be negotiated in the initial CTRA budget with a Sponsor to account for the involvement, or future involvement, of rural, regional or remote participants (for example, extra pathology or pharmacy costs associated with shipping and retrieving pathology samples and investigational medicinal products (IMP) to and from Satellite Sites and or central laboratories).

4.11. A Primary Site and Satellite Site/s should work collaboratively:

- for the benefit of patients and with a “whole of cluster” approach to assist to ensure the timely submission, review and authorisation of their teletrials and to avoid any unnecessary duplication or delay.
- to promptly resolve any issues which may arise during the Research Governance Review of their teletrials and to address any requests for further information in relation to them.
- to assist with the prompt negotiation, review, execution and return of any cluster-related contractual arrangements and indemnities for their teletrials, including provision of any appropriate delegate signatories (if/when required) in a timely manner.

4.12. Satellite Site Research Governance Authorisation, if granted, should be given within 14 calendar days (10 business days) from receipt by the Satellite Site RGO of a valid Satellite Site SSA application which includes the documentation and information specified in section 4.1 (where applicable) of this guideline.

To be clear, to ensure that a satellite site relevant to a particular clinical trial can be activated quickly after identifying a patient eligible to participate in it, if a HHS seeks to conduct the clinical trial using a teletrials model and the clinical trial has been assessed as feasible at the local level site, satellite sites should issue governance authorisation within 14 calendar days (10 business day) from receipt by the Research Governance Officer of a valid site specific application which include both of the following:

- The clinical trial supervision plan; and
- Proposed research agreement (if required).

4.13. Research Governance Review at both the Primary Site and Satellite Site should be expedited to enable rapid activation in circumstances where any potentially eligible and/or eligible patient has been identified and the patient either has no viable alternative treatment options, or the teletrial may offer a potentially better treatment option than standard care.

4.14. The RGO at the relevant site should be informed as early as possible of any request for expedited review.

4.15. Where a Satellite Site Research Governance Review has not been completed within the timeframe specified in section 4.12 of this guideline, an urgent meeting should be convened to resolve any issues/delays with progressing the proposed teletrial activity.

5. Tips for Expediting Cluster Approval Processes

5.1. HHSs are strongly encouraged to engage the Queensland Regional Clinical Trial Coordinating Centre (QRCCC) for early advice and support when establishing and undertaking teletrials. The QRCCC is a specialist statewide service facilitating teletrials across Queensland and can assist HHSs seeking to undertake teletrials by:

- providing cluster start up advice and hands on support with preparation of submission documentation.
- assisting with navigating approval processes including communicating with key stakeholders.
- facilitating meetings with Primary Site and Satellite Site teams to ensure clarity for all involved on the processes, documentation expectations and expedited approval steps relevant to the teletrial.

5.2. It is recommended to inform the approving HREC as early as possible that the HREC will be receiving notification of a proposed additional Satellite Site for inclusion in a teletrial.

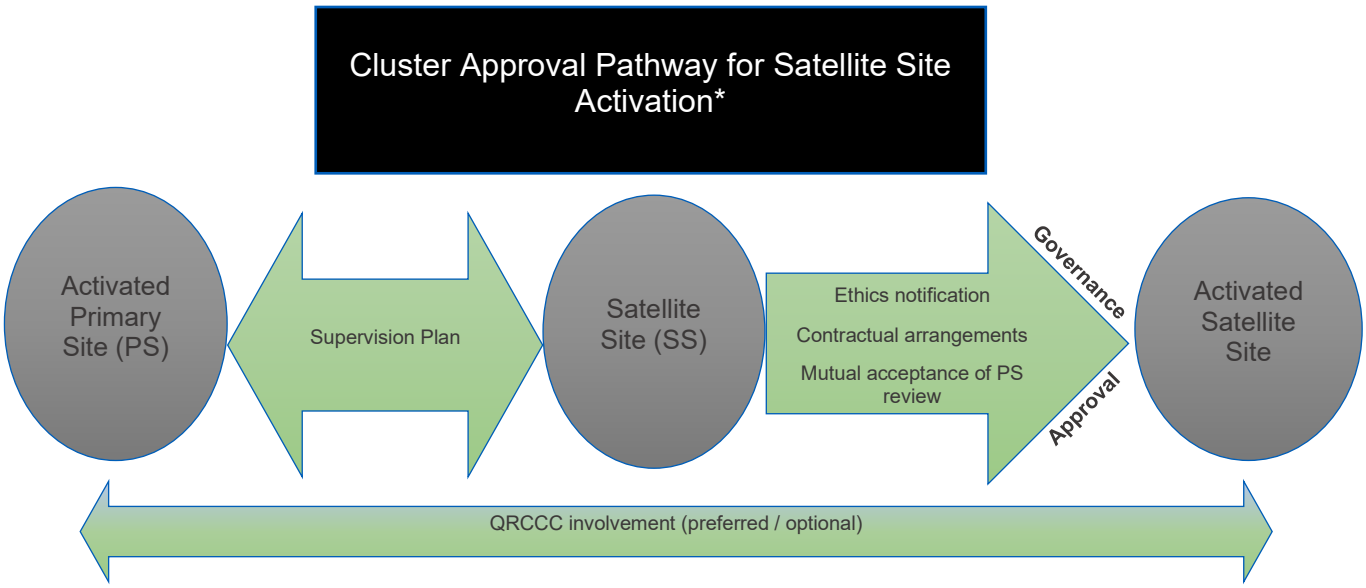
5.3. Early communication to the Primary Site and Satellite Site RGOs when an expedited review is requested for a teletrial is recommended.

5.4. HHSs should consider minimising the number and nature of internal signatures required at the Satellite Site, taking into consideration the Satellite Site's involvement in a particular teletrial and the activities which will be conducted at the Satellite Site.

5.5. To reduce potential delays in processes relating to commencing teletrials, HHSs should establish internal escalation pathways to enable rapid approvals where usual delegate signatories are unavailable.

5.6. It is recommended to plan for the involvement (or potential future involvement) of regional, rural and remote participants for all Clinical Trials at the feasibility stage so that any contingencies (e.g. additional logistical or startup costs) can be factored into Primary Site budget negotiations.

6. Flow Diagram for Cluster Activation



*** Where ethical approval of the Clinical Trial and use of teletrial methodology has previously been granted by the Reviewing HREC**

7. Human rights

Human rights are not engaged by this guideline.

8. Aboriginal and Torres Strait Islander considerations

To provide culturally capable services, Queensland Health uses culturally appropriate processes and communication strategies when working with Aboriginal and Torres Strait Islander people and offers access to Aboriginal and Torres Strait Islander services, such as hospital liaison officers, health workers or health practitioners.

Provision of services to patients from Culturally and Linguistically Diverse (CALD) backgrounds should be in accordance with the Multicultural Queensland Charter as detailed in the *Multicultural Recognition Act 2016*.

9. Supporting and related documents

- Research, ethics and governance | Health service directive | Queensland Health
- National Standard Operating Procedures for Clinical Trials | Australian Government Department of Health and Aged Care.
- RGO SOP 04: Teletrials - Ethics approval and governance authorisation | Queensland Health

10. Definition of terms

Term	Definition / Explanation / Details	Source
Activate	The date the trial has been initiated as per 8.2.20 Trial Initiation Monitoring ICH GCP	ICH Guideline for Good Clinical Practice | Therapeutic Goods Administration (TGA)
Associate Investigator	An individual member of a Clinical Trial team designated and supervised by the Principal Investigator at a teletrial site to perform critical Clinical Trial related procedures and/or to make important teletrial related decisions e.g., associates, residents, research fellows. Where the teletrial model is implemented: • An Associate Investigator when located at a Primary Site may be delegated some or all of the Clinical Trial related activities by the Principal Investigator according to their level of experience and documented in the delegation log. An Associate Investigator when located at a Satellite Site is the local Satellite Site contact for Clinical Trial related matters at the Satellite Site and will be under the supervision of the Principal Investigator at the Primary Site.	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials
Australasian Teletrial Model	The Australasian Tele-Trial Model has been developed by the Clinical Oncology Society of Australia (COSA) Rural and Regional Group in consultation with Clinical Trial Sponsors, clinicians, health administrators and regulatory bodies. The model outlines key considerations for increasing access to Clinical Trials for people with cancer living in rural and remote locations and the contribution of Telehealth models to facilitate Clinical Trial activity across rural and remote locations.	introduction-to-the-cosa-australasian-tele-trial-model.pdf Microsoft Word - COSA Teletrial Model FINAL 19SEP16
Clinical Trial	A research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.	National Clinical Trials Governance Framework and User Guide | Australian Commission on Safety and Quality in Health Care

Clinical Trial Research Agreement or CTRA	Clinical research trial agreements (CTRA) are legally binding agreements used to formalise the obligations and relationship between the Clinical Trial Sponsor, investigator/s and institution where the Clinical Trial is being carried out.	
Research, ethics and Governance HSD	Health Service Directive – Research, ethics and governance (QH-HSD-035)	Research, ethics and governance | Health service directive | Queensland Health
Cluster	In alignment with the National Standard Operating Procedures for Clinical Trials | Australian Government Department of Health and Aged Care, a cluster is defined as a 'group of sites involved in undertaking the same study, consisting of a primary site that assumes overall responsibility for the conduct of the same study and one or more satellite sites, which conduct the study under the direction of the primary site by, for example, using telehealth. A cluster can be made up of sites in the same Hospital Health Service or across different Hospital Health Services.	
Department of Health	The department of the Queensland Government named 'Queensland Health' or its successor.	
Ethics Review Manager or ERM	A secure web-based research ethics database where researchers upload Research Application forms and HREC administrators and RGOs review those applications and report outcomes of HREC and Research Governance Reviews.	Ethics Review Manager website
HHB Act	*Hospital and Health Boards Act 2011* (Qld).	*Hospital and Health Boards Act 2011* (Qld)
HHS	A Hospital and Health Service established under section 17 of the HHB Act.	*Hospital and Health Boards Act 2011* (Qld)
HREC	Human Research Ethics Committee	
HSD	A Health Service Directive issued under section 47 of the HHB Act	
International Council for Harmonisation Guideline for Good Clinical Practice or	The Therapeutic Goods Administration (TGA) has adopted: • the European Union version of the ICH Guideline for Good Clinical Practice in Australia,	ICH Guideline for Good Clinical Practice | Therapeutic Goods Administration (TGA)

ICH GCP	with notes from the TGA relevant to the Australian context, • other international guidelines related to clinical trials, including guidelines on clinical safety data management that cover expedited reporting of adverse drug reactions, • ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice. The National Standard Operating Procedures for Clinical Trials is based on the ICH Guideline for Good Clinical Practice (ICH E6 (R2)).	
Investigator	An individual engaged in the conduct of a Clinical Trial research study at a study site who ensures that the study complies with ICH Guideline for Good Clinical Practice | Therapeutic Goods Administration (TGA) guidelines. An Investigator can be either a Coordinating Principal Investigator, Principal Investigator, or an Associate Investigator.	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials
Primary Site	Under the teletrials model, the primary site coordinates the Clinical Trial across a cluster to enhance participant reach, recruitment and management. The Principal Investigator located at the primary site has full responsibility for conducting the Clinical Trial at their site and any Satellite Site within their cluster under ICH GCP.	National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (health.gov.au)
Principal Investigator	The Investigator responsible for the conduct, management, monitoring and reporting of a Clinical Trial at their own site. Where the teletrial model is implemented, the Principal Investigator at the Primary Site assumes overall responsibility and provides oversight to Satellite Site(s) within a cluster. Associate Investigators at Satellite Site(s) operate under the direction and	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials

	responsibility of the Principal Investigator at the Primary Site.	
Queensland Health	The public sector health system which is comprised of the HHSs and the Department of Health pursuant to section 8 of the HHB Act.	*Hospital and Health Boards Act 2011* (Qld)
Queensland Regional Clinical Trial Coordinating Centre or QRCCC	The centre, or its successor, in the Department of Health that coordinates the setup of clinical trial clusters using the Australian Teletrial Model.	Queensland Regional Clinical Trials Coordinating Centre | Clinical Trials Queensland (clinicaltrialsqld.com.au)
Research application	A research ethics and governance application made using the research ethics and governance application form (as approved by Queensland Health from time to time) and all required supporting documentation.	Standard Operating Procedures for Queensland Health Research Governance Officers
Research Governance Authorisation	Authorisation issued by the HHS Chief Executive (CE) or delegate to allow research to commence at a site within their jurisdiction.	Standard Operating Procedures for Queensland Health Research Governance Officers
Research governance review	Research governance ensures that the principles, requirements and standards of research are upheld. It addresses the protection of research participants, the safety and quality of research, privacy and confidentiality, financial probity, legal and regulatory matters, risk management, and monitoring arrangements. Effective research governance promotes a positive research culture and sustainable practices that facilitate the conduct of high-quality clinical research. Research governance review consists of: • site authorisation by each participating site, following review by the Research Governance Office (RGO). monitoring throughout the project life cycle.	
Reviewing HREC	A HREC that has been allocated to review a human research study and, where approved, is the approving HREC that oversees the study.	Standard Operating Procedures for Queensland Health Research Governance Officers
RGO	Research Governance Officer.	

Satellite Site	A Clinical Trial site that is located in a geographically separate health facility from the Primary Site and responsibility is delegated by the Primary Site (Clinical Trial site) to perform activities associated with the conduct of a Clinical Trial and to support accessibility of remote participants to a Clinical Trial.	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials
Site Specific Assessment or SSA	Refers to research governance/site-specific assessment (SSA), as it is site assessment that is central to governance of the regulatory aspects of research. The SSA form is the core document to manage the requirements of site governance assessment. The SSA form holds the information on how the project will be conducted at the site; it includes supporting documentation and essential signatures	
Sponsor	An individual, company, Institution or organisation which has the responsibility for securing the arrangements, the initiation, management, and/or financing of a Clinical Trial.	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials
Supervision Plan	A plan that outlines processes for a Principal Investigator in the supervision of any individual or party to whom he/she delegates Clinical Trial-related duties and functions conducted at a Satellite Site, which includes, but is not limited to, details on joint consultations using telehealth, collation and monitoring of documents, frequency of joint Clinical Trial meetings across a cluster (with minutes of these meetings) and clarification of activities performed by the Principal Investigator and the Associate Investigator, other Clinical Trial staff and independent third party (i.e. external) service providers. Researchers must submit the Research Application, including the supervision plan, through ERM or its replacement.	National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (health.gov.au) Research, ethics and governance | Health service directive | Queensland Health
Teletrial	A teletrial uses telehealth technology to communicate between the Primary Site and Satellite Site/s and enable delivery of aspects of a Clinical Trial as defined in the Supervision Plan. This technology supports a Principal Investigator to	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials

	supervise Associate Investigator/s to conduct a clinical trial at a Satellite Site which is geographically remote from the Principal Investigator's Primary Site. The Principal Investigator remains responsible for the Clinical Trial. 1. Teletrial is a new, proven model for conducting Clinical Trials by connecting regional, rural and remote Clinical Trial sites to a Primary Site. The Primary Site supports local Satellite Sites in building capacity and capability, promoting equitable health access and may lead to local Satellite Sites becoming Primary Sites in the future. Teletrials involve numerous medical staff and researchers from various hospitals and health services in different locations. They use digital telecommunication to work as one team and conduct Clinical Trials closer to where patients live 2. A teletrial uses telecommunications technology to allow a Primary Site to work with a Satellite Site/s and deliver aspects of a Clinical Trial. This is outlined in a Supervision Plan and allows a Principal Investigator to supervise Associate Investigator/s to conduct a Clinical Trial at a Satellite Site which is geographically remote from the Principal Investigator's Primary Site. The Principal Investigator remains responsible for the trial and supervises the Associate Investigator/s at the Satellite Site/s. A cluster is a group of two or more sites conducting the same trial.	ATP definition guide - Australian Teletrial Program
Teletrial Subcontract	A legally binding agreement that manages the relationship between the Primary Site and the Satellite Site where the Satellite Site is a separate legal entity to the Primary Site.	National Standard Operating Procedures for Clinical Trials in Australia | Australian Clinical Trials
Valid	A Research Application that is in a state appropriate for it to be referred for a decision. A valid Research Governance Review application is one which is considered complete by the RGO (that is, it contains all relevant signatures and supporting documentation uploaded into ERM), and all RGO queries have been addressed.	Queensland Health Standard Operating Procedure for HREC Administrators and RGOs

11. Approval and implementation

Guideline Custodian

Executive Director, Health Service Evaluation Research and Translation Branch, Queensland Health.

Approving Officer

Executive Director, Health Service Evaluation Research and Translation Branch, Queensland Health.

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12. Version control

Version	Date	Prepared by	Comments
0.1	31 Jan 2025	GETU/QRCCC	Early draft.
0.2	30 April 2025	QRCCC/GETU	Feedback incorporated as part of stakeholder consultation.
0.3	2 May 2025	QRCCC/GETU	Feedback incorporated from Directors GETU/ATP
0.4	6 May 2025	QRCCC	Feedback incorporated from Clinical Director QRCCC
0.5	23 October	QRCCC/HSERT	Second round consultation feedback incorporated