# Remote Access to Electronic Medical Records (EMR) by Sponsors of Commercially Sponsored Clinical Trials Procedure

## TARGET AUDIENCE and SETTING

- Principal Investigators and all staff conducting clinical trials at Monash Health.
- Commercial Sponsors including their monitors and auditors of clinical trials conducted at Monash Health.

This Procedure only applies where the Sponsor is required to view information held in an Electronic Medical Record (EMR).

## PURPOSE

To allow remote access to EMR for the purposes of monitoring research projects.

## DEFINITIONS

**CIRA**: Clinical Investigation Research Agreement.

**CRG**: Collaborative or Cooperative Research Group

**CRO**: Contract Research Organisation or Local Sponsor

**CTRA**: Clinical Trial Research Agreement.

**EMR**: Electronic Medical Records.

**GCP** (Good Clinical Practice): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

**HREC**: Human Research Ethics Committee.

**Institution**: Monash Health for the purposes of this procedure.

**Principal Investigator**: An individual responsible for the conduct of a research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines.

**Research Governance**: Processes used by institutions to ensure that they are accountable for the research conducted under their auspices. To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy.

**Schedule 7 or 4**: A Schedule outlining variations to the body of the Medicines Australia Clinical Trial Agreements templates or the Medical Technology Association of Australia Clinical Investigation Agreement.

**Source Documents**: Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

**Sponsor**: For the purposes of this Procedure, Sponsor means a commercial company, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. The Sponsor can be the Local Sponsor (CRO) or CRG. Many sponsor functions may be delegated to third parties, such as CROs.

## PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure. This Procedure will be in force until 31

December 2020 prior to which time a decision will be made as to whether to amend it, extend it or cease it.

## STANDARD REQUIREMENTS

All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), the National Statement on Ethical Conduct in Human Research (NHMRC 2018), the Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

All personnel accessing EMR must complete the Latte EMR training module and the "Application for Monash Health Non-Employee System Access" form.

## PROCEDURE

**The Sponsor and Institution acknowledge that:**

The Electronic Medical Record ('EMR') is any electronic (digital) patient record which holds Personal Information of the Institution's patients;

The Institution is responsible for ensuring the security of the EMR for the purposes of this Procedure; and

The Sponsor requires various personnel (Sponsor Personnel) to have access to view the EMR to facilitate monitoring and audit visits required in **clause 4.7** of the Medicines Australia CTRAs and Medical Technology Association of Australia CIRA's.

For the purpose of EMR access, and as between the Institution and the Sponsor, the Sponsor agrees to be responsible for the acts and omissions of Sponsor Personnel in relation to the visits required in **clause 4.7**, to the extent that such responsibility would attach to the Sponsor in accordance with its obligations under this Agreement or under common law on the basis that the Sponsor Personnel is acting as an employee of the Sponsor.

**Approval for access to EMR**

The Sponsor's Personnel are not permitted to access the EMR under this Procedure unless the Institution has granted, in writing, approval for the Sponsor's Personnel to access the EMR.
The Sponsor and the Sponsor's Personnel must submit a request for EMR access approval in accordance with the Institution's policies and procedures.

**Conditions of access to EMR**

If EMR access is granted by the Institution under this Procedure, the Sponsor agrees that it must comply with, and ensure that the Sponsor Personnel comply with, each of the following requirements:

a) access is limited to the EMR of the Study Participants who are the subject of the Study;

b) access is read-only access;

c) access is limited to monitoring and auditing as required under **clause 4.7** of the CTRA or CIRA;

d) relevant training is satisfactorily completed before access

e) comply with such terms and conditions as specified in the written approval;

**Monitoring of access to EMR**

The Institution has the right to keep, maintain and update written records about Sponsor Personnel and their access to and use of the EMR under this Agreement

The Institution may undertake routine and random audits of the EMR to determine whether the Sponsor Personnel's use and access of the EMR is within the scope of the approvals and in compliance with this Agreement.

The Sponsor must provide such assistance to the Institution as the Institution may reasonably require to conduct such audits.

**Termination of access to EMR**

The Sponsor acknowledges and agrees that the Institution may at any time immediately suspend or terminate access to the EMR under this Procedure for any or all of the Sponsor Personnel where the Institution considers it necessary to do so (in its absolute discretion).

**Confidentiality of Personal Information and Health Information**

In addition to the requirements of **clause 10.1** of the Medicines Australia CTRAs and Medical Technology Association of Australia CIRA's, the Sponsor and Sponsor's Personnel must comply with:

- Relevant Privacy Laws in relation to Personal Information;
- Relevant State health records and health information laws.

**Intellectual property rights**

Any Intellectual Property of the Institution in any Personal Information is retained by the Institution despite any disclosure to the Sponsor or the Sponsor's Personnel under this Agreement.

**Remedies**

The Sponsor acknowledges and accepts that the Institution may take legal proceedings against the Sponsor or third parties if there is any actual, threatened or suspected breach of this Procedure that will be documented in any approval given by the Institution for the Sponsor to access EMR, including proceedings for an injunction to restrain such breach.

The Sponsor acknowledges and accepts that in addition to any other remedy which may be available to the Institution in law or equity, the Institution is entitled to injunctive relief to prevent a breach of this Schedule 7 and to compel specific performance of this Schedule 7 by the Sponsor.

The Sponsor must immediately reimburse the Institution for all costs and expenses (including legal costs and disbursements on a full indemnity basis) incurred in enforcing the obligations of the Sponsor under this Procedure.

**Indemnity**

In addition to any other indemnity provided by the Sponsor pursuant to this Procedure, the Sponsor indemnifies and will keep indemnified the Institution from any Loss suffered or incurred by it and arising out of or in connection with:

- any access to, use of, release or disclosure of any Personal Information or health information or health records of a Study Participant by;
- the negligent, wilful or reckless acts or omissions of;
- any breach of law (including Relevant Privacy Laws and relevant health information or health record laws) by; or
- any breach of this Agreement by,
- the Sponsor or the Sponsor's Personnel, other than where such Loss is caused by or to the extent contributed to by the wilful or reckless act of the Institution.

  "Loss" for the purposes of this clause includes any direct loss, cost, expense, claim, damage or liability (including any fines or penalties and legal costs on a full indemnity basis) whether present or future, fixed or unascertained, actual or contingent and whether arising under contract (including any breach of this document), in equity (including breach of an equitable duty, breach of confidentiality or breach of fiduciary duty), under statute (including breach of statutory duty) (to the maximum extent possible), in tort (including for negligence or negligent misrepresentation) or otherwise (including in restitution)

## RELATED DOCUMENTATION

Application for Monash Health Non-Employee System Access

Latte EMR training module

## BACKGROUND

**Medicines Australia CTRA and Medical Technology Association of Australia CIRA clauses (partially amended dependent upon the relevant agreement).**

**Clause 4.7: Institution Obligations**

Subject to **clause 9**, the Institution will allow regular monitoring visits in accordance with the GCP Guideline, access for the purposes of audit and as required by Regulatory Authorities or as specified in the Protocol and permit access to the Essential Documents (including original records), Study records, reports, other Study related materials and its Personnel as soon as is reasonably possible upon request by the Sponsor, Regulatory Authority, Reviewing HREC or any third party designated by the Sponsor. Any such access is to take place at times mutually agreed during business hours and subject to such reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

**Clause 9: Confidentiality**

**9.1** Subject to **clause 9.2**, each party must not, and must ensure their Personnel do not, use or disclose any Confidential Information of the other party, other than where and only to the extent that such use or disclosure is necessary for the performance of the Study, the exercise of its rights or the performance of its obligations under this Agreement.

9.2 The Institution may use or disclose Sponsor Confidential Information in any of the following circumstances:

1. for the purposes of complying with the Institution's internal complaint procedures, accident

reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events and/or reportable incidents;

2. for the purposes of disclosing any material risks, identified during the Study or subsequent to it, to Study Participants, Principal Investigators, medical practitioners administering treatment to Study Participants**,** Reviewing HRECs and Regulatory Authorities;
3. for the purposes of complying with the requirements of any Regulatory Authority;
4. to enable the Reviewing HREC to monitor the Study;
5. where the Sponsor consents in writing to the disclosure;
6. as part of a publication issued under the provisions of **clause 11** of the Medicine's Australia agreement template;
7. where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the Sponsor, and subject to the Institution upon request providing reasonable assistance to enable the Sponsor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure;
8. for the purposes of the Institution seeking legal advice; or
9. disclosure to the Institution's insurer.

9.3 Where Confidential Information is disclosed in accordance with **clause 9.2 (1)**, **(4)**, **(8)** or **(9)** the Confidential Information must only be used in connection with the legitimate purposes of the Institution, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.

9.4 The Sponsor may disclose Institution Confidential Information to its lawyers for the purposes of obtaining legal advice or to its Affiliates but only on a needs to know and confidential basis. The Sponsor may disclose Institution Confidential Information if required by law, with notice as soon as reasonably practical to the Institution, and subject to the Sponsor upon request providing reasonable assistance to enable the Institution to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure.

9.5 The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 9**, and are bound in similar terms to keep such information confidential.

9.6 Information will not be Confidential Information and subject to the provisions of this **clause 9** where:

1. the information has been independently received from a third party who is free to disclose it;
2. the information is in or has entered the public domain other than as a result of a breach of this Agreement;
3. the party already knew the information, the prior knowledge of which it can document by prior written records; or
4. the party independently develops, discovers or arrives at the information without use, reference to, or reliance upon, the Confidential Information.

**Clause 10: PRIVACY**

Each party must ensure that any Personal Information of Study Participants or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in

accordance with the Relevant Privacy Laws.

Each party will promptly report to the other party any unauthorised access to, use or disclosure of Personal Information of Study Participants ("Incident") of which it becomes aware, and will work with the other party to take reasonable steps to remedy the Incident.

## KEY STANDARDS, GUIDELINES OR LEGISLATION

NHMRC *National Statement on Ethical Conduct in Human Research* 2007 updated *2018*

Health Privacy Principles: *Health Records Act* 2001:

http://www.health.vic.gov.au/healthrecords/overview.htm

Australian Privacy Principles:

https://www.oaic.gov.au/privacy/australian-privacy-principles/

## REFERENCES

Medicines Australia Clinical Trial Research Agreements

https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/

Medical Technology Association of Australia Clinical Investigation Research Agreements

https://www.mtaa.org.au/clinical-investigations-research-agreements

Southern and Eastern Border States Schedule 7 / Schedule 4

https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/

## KEYWORDS

Research, Sponsor, EMR. Monitoring.

| **Document Governance** | |
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| **Supporting Policy** | Human Research (Strategic) |
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