POLICIES AND PROCEDURES STATUS UPDATE 2023

Procedures RETIRED:	Reason for retiring:
Authorship for Research	**RETIRED** – this procedure is addressed in the Authorship NHMRC guideline (2019) supporting the Australian Code for the Responsible Conduct of Research (2018).
Communication with Human Research Ethics Committee, Trial Sponsor and Insurer	**RETIRED** – This procedure is addressed in **Standard 05** of the National Standard Operating Procedures for Clinical Trials.
Documentation of Investigation Site Qualifications, Adequacy of Resources and Training	**RETIRED** - This procedure is addressed in **Standard 03** of the National Standard Operating Procedures for Clinical Trials.
Handling of Research Misconduct and Resolving Allegations	**RETIRED** - This procedure has been incorporated in the Research Related Complaints Resolution procedure.
Investigator Responsibilities	**RETIRED** – This procedure is addressed in **Standard 02** of the National Standard Operating Procedures for Clinical Trials.
Low Risk Human Research Ethics Review and Site Authorisation	**RETIRED** - Low Risk Panel has been disbanded at the end of 2022.
Peer Review	**RETIRED** - this procedure is addressed in the Peer Review NHMRC guideline (2019) supporting the Australian Code for the Responsible Conduct of Research (2018).
Privacy and Confidentiality in Research	**RETIRED** - This procedure is to be retired, as it has been incorporated into the Data Storage, Retention, Privacy & Confidentiality Procedure.
Protocol and Investigational brochure Content, Design, Amendments and Compliance	**RETIRED** - This procedure is addressed in **Standard 04** of the National Standard Operating Procedures for Clinical Trials.
Publication and dissemination of research findings	**RETIRED** - this procedure is addressed in the 'Publication and dissemination of research' NHMRC guideline (2019) supporting the Australian Code for the Responsible Conduct of Research (2018).
Research and Ethics Informed Consent and Writing Patient Informed Consent Forms	**RETIRED** - this procedure is addressed in **Standard 09** of the National Standard Operating Procedures for Clinical Trials.
Receipt and handling of investigational product	**RETIRED** - This procedure is addressed in **Standard 11** of the National Standard Operating Procedures for Clinical Trials.
Site initiation and close out	**RETIRED** - This procedure is addressed in **Standard 06 (Site Initiation)** and **Standard 13 (Site Close-out and Archiving)** of the National Standard Operating Procedures for Clinical Trials.

POLICIES AND PROCEDURES STATUS UPDATE 2023

Study site master File and documents	**RETIRED** - This procedure is addressed in **Standard 07** of the National Standard Operating Procedures for Clinical Trials.
Supervision of research trainees	**RETIRED** - This procedure is addressed in **Standard 03** of the National Standard Operating Procedures for Clinical Trials, and the 'Supervision' NHMRC guideline (2019) supporting the Australian Code for the Responsible Conduct of Research (2018).
Procedures UPDATED:	**Key changes:**
Early Phase Clinical Trials - Human Research Ethics Review Policy & Procedure	Document title change, updated National Statement on Ethical Conduct in Human Research reference from 2018 to 2023, removed information about low risk ethics review, and added reference to the GMO and Gene Therapy Procedure.
EMR Alerts in Clinical Research	Content updated to indicate the step by step process of creating, modifying and removing EMR alerts for patients participating in research.
Good clinical practice training research	Content updated to reflect that the Australian Clinical Trials Education Centre (A-CTEC) will be our preferred provider for GCP training, and regular reports will be provided to Monash Health upon training completions.
Handling and shipping of infectious substances for clinical trials	National Statement on Ethical Conduct in Human Research year updated from 2018 to 2023.
Honorary Researcher Appointment Application	Content updated to clarify that an Honorary applications may be granted in exceptional circumstances to be departmental appointments.
Human Research Ethics Review and Site Authorisation	Definitions updated within procedure and National Statement on Ethical Conduct in Human Research reference updated from 2018 to 2023.
Human Research (Strategic)	Document transferred on new Monash Health Policy template and National Statement on Ethical Conduct in Human Research year updated from 2018 to 2023.
Medicare Eligibility for trial participation (Operational)	Previously a policy document, has been transferred onto a Monash Health procedure template.
Research Data Storage, Retention, Privacy & Confidentiality	Content updated to incorporate information from the Data Privacy & Confidentiality procedure, as both procedures are similar in nature and are communicated better when merged together.
Research Ethics and Governance - Safety Reporting	Content updated to explain that SUSARs/USADEs occurring in Monash Health Participants are to be reported on RiskMan and not ERM to establish organisational visibility.
Research and Ethics Electronic Informed Consent (eConsent)	Removed broken links from document.

POLICIES AND PROCEDURES STATUS UPDATE 2023

Research Governance and Site Authorisation (updated title)	Procedure title changed from 'Research Governance' procedure to 'Research Governance and Site Authorisation', and National Statement on Ethical Conduct in Human Research reference updated from 2018 to 2023.
Research Related Feedback (complaints and Compliments – (AKA Research Related Complaint Resolution)	Content updated to state that research related feedback is to be reported on RiskMan instead of ERM and National Statement on Ethical Conduct in Human Research reference updated from 2018 to 2023.
Sponsor Responsibilities in Investigator Initiated Studies	Content updated to replace Clinical Trials Exemption Scheme (CTX) with the Clinical Trials Approval Scheme (CTA) as per the Australian Clinical Trials Handbook (2021).
Use of Human Biospecimens in Research	Title change and content update to include information about tissue biobanking and clarify steps involved in making a HREC application for the use of human biospecimens in research.