Procedure/Policy title:	Key changes:	Approval month:
Research Participant Information and Consent Forms *(new procedure)*	New procedure to align with current National Standard Operating Procedures. Informs readers that Monash Health will accept either NHMRC Information and Consent form template, or the InFORMED approach for ethics review, and provides general information that is to be included in all consent forms.	March
REDCap Access Procedure *(new procedure)*	• New procedure. Monash Health recently built a server for REDCap and have appointed a Systems Administrator. REDCap is available via the Clinical Portal. To provide clarity on how to access REDCap, the sorts of uses it is approved for and training a PROMPT procedure has been developed by RSS, Library and the Systems Administrator.	August
Research Data Storage, Retention, Privacy & Confidentiality	• Updated to clarify that access to the My Health Record is restricted to the Monash Health research team only. Specific consent must also be obtained on the Monash Health Participant Information and Consent Form.	August
Research Governance and Site Specific Authorisation (SSA)	Procedure updated to add the following information: • Step-by-step guide to making an SSA submission and receiving SSA Authorisation before a project can commence at Monash Health. • Data Governance & Artificial Intelligence Steering Committee approval is required if the study involves Artificial Intelligence or a large amount of data such as a Clinical Quality Registry. • Approval from the Chief Digital and Information Officer or nominee is required if the project involves data being obtained via Business Intelligence. • Include Health Studies Australian National Data Asset (HeSANDA) Program - a new national online portal to help researchers access and share data from health studies. It is a catalogue of clinical trials and data sets collected across Australia by universities, medical research institutes, clinical trials networks and health services. If researchers would like to consider sharing project data in the future, Monash University has developed a simple request form to initiate the process to register the study on the HeSANDA Monash Node.	August
Site Specific Authorisation Checklist for Research Projects *(new tool)*	This is a new document developed to assist researchers with putting together a clean and efficient SSA submission for the Research Governance Office. This checklist lists all the supporting documents required to make an SSA submission and includes the following key information: • Data Gov & AI Steering Committee approval is required if the study involves AI or a large amount of data such as a Clinical Quality Registry	August

	• Approval from the Chief Digital and Information Officer or nominee if the project involves data being obtained via Business Intelligence • Include Health Studies Australian National Data Asset (HeSANDA) Program - a new national online portal to help researchers access and share data from health studies. It is a catalogue of clinical trials and data sets collected across Australia by universities, medical research institutes, clinical trials networks and health services. If researchers would like to consider sharing project data in the future, Monash University has developed a simple request form to initiate the process to register the study on the HeSANDA Monash Node.	
Remote Access to Electronic Medical Records (EMR) by Sponsors of Commercially Sponsored Clinical Trials	Updated broken links under 'References' on page 6.	August
Good clinical practice training research	Content updated to advise: • GCP compliance reports will be reported annually to the Research Strategy & Governance Group to establish monitoring of GCP compliance and meet the requirements of the National Clinical Trials Governance Framework and the Ernest & Young Audit. That the ICH E6(R3) are expected to be adopted in January 2026 by the Therapeutic Goods Administration with a 12-month transition period, enabling sponsors, trials sites and other stakeholders time to meet the updated requirements. Monash Health will align with this timeframe and require all researchers to have completed updated ICH GCP training on R3 by February 2027.	September
Research Related Feedback (Complaints and Compliments)	Content updated to clarify: • The complaint delegation pathway as not all complaints go to Head, Research Operations. • The definition of formal complaints.	September
Research Progress, Final and Site Closure Reports	Content updated to: • Inform that progress reports must be submitted by 30 April and there will be a grace period up until 30 May, after which the form will close. • Projects that do not submit a progress report for two consecutive years, will be prioritised for a research governance audit, which will also involve the principal investigator demonstrating that invoicing and reconciliation are completed in accordance with the research agreement schedule of payments.	September

Monash Health Research Support Services Self Audit for Researchers	This is an existing resource available to Monash Health research staff to help researchers to ensure that their study documentation and records are compliant with the National Statement on Ethical Conduct in Human Research (NHMRC). This is now available on PROMPT.	September
Honorary Researcher Appointment Application	Updated to reflect a change from Director of Clinical Research to Director, Research & Innovation.	October
Human Research Ethics Review and Site Authorisation Human Research Ethics Review Checklist for Research Projects	These procedures and checklists have been updated to include Health Studies Australian National Data Asset (HeSANDA) Program - a new national online portal to help researchers access and share data from health studies. It is a catalogue of clinical trials and data sets collected across Australia by universities, medical research institutes, clinical trials networks and health services. If researchers would like to consider sharing project data in the future, Monash University has developed a simple request form to initiate the process to register the study on the HeSANDA Monash Node.	October
Research Ethics and Governance - Safety Reporting	This procedure has been updated to advise the following: • All SUSARs are to be reported on **ERM** and not RiskMan. • Incident reporting must follow Monash Health Clinical Incident Reporting policy. • Remove outdated content about reporting of research related fatal events that occur in Monash Health participants (see page 4 of 8) • A complaint should be reported and managed as per the Consumer Feedback (Complaints & Compliments) Procedure. • Transfer the procedure onto the current PROMPT procedure template.	November
Research Conduct Under the Clinical Trials Notification Scheme *(new procedure)*	This is a new procedure to advise researchers about how Clinical Trial Notifications are lodged and who is responsible for the lodgment. This procedure was created to reduce the number of queries raised about how CTN application is to be completed.	November

Total of 15 procedures were updated in 2025