WORK INSTRUCTION

DMR – Recording Research Participation

Scope (Staff):	CAHS and Telethon Kids Institute (TKI) Researchers
Scope (Area):	Research Department

This document should be read in conjunction with this disclaimer

Research Policy (TBC)

Purpose

Describes how participation in a research project is recorded in the DMR, and the responsibilities of the study team.

If a research study or clinical trial forms part of or may impact a patient's clinical care, then the participation must be recorded in the DMR i.e. participation in the research is relevant to the health record.

Additionally, if a patient group is vulnerable to "over-research" then any approach to a patient and their family for research participation should be recorded in the DMR.

Definitions

Principal Investigator (PI): the individual that takes overall responsibility for the conduct of the research project.

Participant Information & Consent Form (PICF): the document for communicating information about the research project to potential participants. It outlines the aims and objectives of the project, what is required of participants, and informs of any risks and/or benefits to participating.

Instructions

Access to the DMR for Researchers (non-CAHS employees):

- See Work Instruction: Onboarding External Researchers

Recording Research consent (or decline) in the DMR

- Before approaching a patient or family for research participation the PI, or delegate, should review the Research section of the DMR to ensure the patient has not been approached multiple times for other studies. As a general rule 3-5 studies is maximum however please consider the burden, duration and type of study.

- Once the patient has been approached for consent then an **MR111.0 Research Participant Record form** should be completed with the study detail and whether the parent/guardian consented or declined. Does not include studies where there a waiver of consent or no consent required.
- The **MR111.0 Research Participant Record form** form must be sent to HIS to be scanned into the Research tab of the DMR.
  NOTE: To send forms to medical records for scanning please place them in a blue folder in the MR collection spaces for medical records to collect. These spaces are in every clinic and most offices (where the buff records are currently picked up/delivered).
- Research staff will need to make sure a webPAS label is on the form or the patient details (URMN) is clearly written on the form.
- The original signed PICF must be kept in the participant's study file. Researchers should send a good quality copy of the consent form to HIS for scanning attached to the **MR111.0 Research Participant Record form** (to ensure there scanned together).

Recording Research Information in the DMR

- Only clinically relevant information should be recorded in the DMR. Research information relevant to clinical care should be recorded as a progress note.
- External Researchers who are *not* CAHS staff (e.g TKI) can only be provisioned with "read-only" access to the DMR to ensure alignment with the HSS write site licence agreement in place with PCH. These researchers can still complete forms and send to medical records for scanning and inclusion in the record, however they cannot directly enter research progress notes.
- Other study specific information should be kept in the participant's study file.

Compliance & Monitoring

Research at CAHS is monitored as per the NHMRC National Statement on Ethical Conduct in Human Research and the CAHS HREC CAHS HREC Standard Operating Procedures.

Related internal policies, procedures and guidelines *(if required)*
Research policy (TBC) Investigator Responsibilities in Research Policy (TBC) CAHS HREC Standard Operating Procedures (SOPs) Clinical Forms (health.wa.gov.au): MR111.0 Record of Research Participation HSS Generic Account Creation and Monitoring Procedure HSS Information and Records Management Policy Acceptable Use of Information and Communications Technology Policy CAHS Access and Use of Health Records

This document can be made available in alternative formats on request for a person with a disability.

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