Home Visits to Clinical Trial Participants by Clinical Trial Staff Procedure

TARGET AUDIENCE and SETTING

- All Investigators and staff involved in clinical trials who are required to visit clinical trial participants outside Monash Health premises.
- Any staff member must be included in the delegation log and signed off by both the Principal Investigator and the staff member making the visit.
- The Position Description of the Nurse or Research Coordinator must include home visits. If not, change impact statement is required to include this duty on the Position Description.

PURPOSE

To allow clinical trial investigators or staff members involved in clinical trials to visit participants of clinical trials at their home or place of residence in order undertake clinical trial procedures when it is impractical or not possible for the clinical trial participant to attend Monash Health.

PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure.

The Position Description of the Nurse or Research Coordinator must include home visits. If not, change impact statement is required to include this duty on the Position Description.

EQUIPMENT

Mobile Phone

MePACS® Personal Alarm

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).

When undertaking any clinical interaction with a patient, staff are expected to;

- Perform routine hand hygiene. Refer to the Hand Hygiene Procedure.
- Introduce themselves to the Patient and Carer/ Family if in attendance
- Check patient identification. Refer to the Patient Identification Procedure.
- Obtain consent as per the Consent to Medical Treatment Procedure.

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Document interaction in the electronic medical record or health record using black pen; including date, time, signature and designation.

PROCEDURE

Prior to a decision being made as to whether any procedures may be undertaken remotely, the Principal Investigator, who has the responsibility for the clinical trial activities must ensure the following:

- Ensure that clinical studies are carried out according to International Council on Harmonisation (ICH), regulatory authority's requirements and any other local requirements.
- Have an understanding that when a trial is sponsored by an agency/pharmaceutical company, they may be requested to follow their procedures in order to comply with company obligations.
- Ensure that the persons delegated to perform the duties required for home visits are appropriately qualified to conduct the trial and entered into the delegation log, signed and dated by both the Principal Investigator and the person undertaking the home visit before any visit is made.
- Ensure the personnel undertaking home visits are re-trained on aspects of the protocol that impinge on procedures to be undertaken at the clinical trial participant's premises.
- Ensure the Position Description of the Nurse or Research Coordinator must include home visits. If not, a change impact statement is required to include this duty on the Position Description.
- Maintain a chronological list of any delegated duties with respect to home visits, and the persons and qualifications of those persons to whom the duties are assigned.
- Ensure that no protocol deviation from the procedure occurs without Human Research Ethics Committee endorsement, unless it is required to prevent imminent harm to participants.
- Ensure an "AMBULATORY & COMMUNITY CARE AGREEMENT FORM (MRD37)" is completed for each patient.
- Ensure an "OFFSITE VISIT RISK SCREENING TOOL – PART 1 (MRA83)" is completed for each patient prior to the home visit.
- Submit written summaries of the home visits on the Research Governance site specific annual research report.

For personnel undertaking home visits the following must be adhered to the following:

1. Home Visits must be done in accordance with the OHS Off-Site Client Visiting Risk Management Procedure and the OHS Off-Site Client Visiting Safety and Security Guide Implementation Tool. Personnel undertaking home visits must be familiar with the OHS Workplace Occupational Violence and Aggression Procedure.

2. Personnel undertaking home visits must carry a mobile phone and a MePACS® Personal Alarm in accordance with the MEPACS® Personal Alarm Procedure.

3. Home visits must be done with Monash Health fleet vehicles and in accordance with the following policy, procedure, background and implementation tool documents:

- Fleet Vehicle Operational Policy
- Fleet Vehicle Booking Procedure
- Fleet Vehicle Conditions of Use Implementation Tool
- Fleet Vehicle Driver Registration and Declaration Form
- People and Culture Use of Vehicles for Business Purposes Procedure
- OHS Work Related Driving Risk Procedure

4. Where Personal Protective Equipment (PPE) is required, personnel must be familiar with and use PPE in accordance with the OHS Requirements for Personal Protective Equipment (PPE) Procedure and the Personal Protective Equipment (PPE) Application and Removal Procedure.

   Personal Protection and Equipment Information is available through the following link:
   https://coronavirus.monashhealth.org/protecting-yourself/ppe-info/
   Personal Protective Equipment Compulsory Standards are available through the following link:
   https://coronavirus.monashhealth.org/protecting-yourself/
   In the event that a Clinical Trial Participant or resident at the Clinical Trial Participant's residence is suspected or has been diagnosed with Novel Coronavirus (COVID-19), the COVID-19 (Novel Coronavirus) Procedure must be adhered to.

5. In the event of a deteriorating patient, the Deteriorating Patient Hospital in the Home Procedure must be adhered to and the "Code Blue Home Visits for Hospital In the Home" as follows:

   Patient unresponsive with nil or abnormal breathing (do not check airway until PPE applied)
   DO NOT LEAVE THE PATIENT Call for local help (i.e. family member)
   Call 000

   If the staff member has Basic Life Support equipment with them i.e. bag mask circuit, the staff member is to apply Tier 3 PPE and then commence Basic Life Support.
   Or
   If the staff member has no Basic Life Support equipment with them, the staff member is to apply Tier 3 PPE and place a Surgical Mask on the patient. The staff member is to commence compression, only by CPR.

   Continue management until MICA arrives and takes over patient care

6. At the end of visitation or at any other appropriate time, equipment cleaning must be in accordance with the Clinical Equipment Cleaning Procedure.

Indemnity

In addition to any other indemnity provided by the Sponsor pursuant to this Procedure, the Sponsor will need to confirm that it will keep indemnified the Institution from any Loss suffered or incurred by it and arising out of or in connection with home visits.

RELATED DOCUMENTATION

Ambulatory & Community Care Agreement Form (MRD37) must be completed for each patient.

Clinical Equipment Cleaning Procedure

Consent to Medical Treatment Procedure

COVID-19 (Novel Coronavirus) Procedure

Deteriorating Hospital in the Home Procedure

Fleet Vehicle Booking Procedure

Fleet Vehicle Conditions of Use Implementation Tool

Fleet Vehicle Driver Registration and Declaration Form

Fleet Vehicle Operational Policy

Hand Hygiene Procedure

MEPACS® Personal Alarm Procedure

Off-Site Visit Risk Screening Tool (MRA83) must be completed for each patient prior to home visit.

OHS Requirements for Personal Protective Equipment (PPE) Procedure

OHS Work Related Driving Risk Procedure

OHS Off-Site Client Visiting Risk Management Procedure

OHS- Off-Site Client Visiting Safety and Security Guide Implementation Tool

OHS Workplace Occupational Violence and Aggression Procedure

Patient identification Procedure

People and Culture Use of Vehicles for Business Purposes Procedure

Personal Protective Equipment (PPE) Application and Removal Procedure

BACKGROUND

Due to the coronavirus outbreak it has become impractical or not possible for clinical trial participants to attend Monash Health for procedures. Non compliance with protocol procedures could raise safety issues for patients so this procedure has been developed to allow for clinical trial procedures to be conducted at the residences of clinical trial participants.

KEY STANDARDS, GUIDELINES OR LEGISLATION

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

Australian code for the responsible conduct of research (NHMRC, 2018),

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6 (R2) (2016)

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

PROMPT Policies and Procedures

KEYWORDS

Clinical Trial, Home Visit, PPE, MRD37, MRA83, MePACS

Document Governance	
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