Identifying Research Participants in the Medical Records and Patient Databases

SOP Identifier		**Identifying Research Participants in the Medical Records and Patient Databases**	
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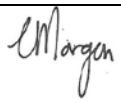
	Signature & Date	 24/07/20	
APPROVER	**Name and role**	Jemma Hughes. R&D Manager	
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Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
1.0	24/07/23	Initial document	/	R&D Committee
1.1	08/10/20	Typo changes in 4.1	1.0	Jemma Hughes, R&D Manager

1. Purpose

When undertaking a research study it is important that:
 Other health professionals are aware of a patient's involvement in a research study via the case notes or databases;
 Other health professionals have access to study information that might be relevant to a patient's medical care;
 Research teams are notified of hospital admissions or adverse events in study patients if required by the trial protocol;
 the case notes for research participants are retained for a specified period following the end of the study.

2. Background

The purpose of this Standard Operating Procedure (SOP) is to describe a system for identifying (either in the patient case notes and/or on Patient Databases (known as Flagging or Alert system), and /or via use of research wallet cards) that a patient participated in a research study.

3. Roles and Responsibilities

This SOP is aimed at investigator teams and all health professionals who come into contact with research participants within the Health Board

4. Procedure

This SOP applies when a patient has consented and enrolled to take part in a research study; the following procedures should be followed:

4.1 Flagging Research Participants in the hospital case notes

Once a patient has consented to take part in a research study **a research label** should be attached to their hospital case notes to indicate involvement. Individual Health Boards may have their own policy as to where a label should be placed. This may be on the inside of patient case notes or on the front. Advice should be sought from the local Information Governance Department if in doubt.

The protocol or research contract will provide guidance on the proposed retention period of a research participant's case notes; advice should be sought from the Sponsor in any instances of uncertainty.

If a sponsor provides labels these may be used in preference, or in addition to the R&D template of research labels. Please check that if a sponsor has provided labels they **do not indicate diagnosis**, and **at the minimum** they specify: **the study short title, study ID number, CI/PI or Research Nurse contact details and retention period.**

Template sheets of labels (Template Labels 1- 'safety reporting required' and
Template Labels 2- 'observational/safety reporting not required')

These are available to download (refer to Section 5) and can be edited and printed for use (size63.5x72mm or Avery labels index code L7164). All blank areas on the label should be completed as applicable.

At each study visit where possible a check should be made to ensure a research label is still clearly attached to the case notes. Ensure that if a patient's case note consist more than 1 volume, each volume has a research label attached. Replace any missing labels. All case

notes should be checked for correct retention dates prior to study archiving. It may be necessary to change the date on the label to reflect actual end date of the study. It is the responsibility of the PI to ensure that all case notes are appropriately labelled (although this may be delegated to a suitably qualified member of the research team).

4.2 Research Documentation in the Case Notes

All relevant research related documentation should be filed in the participants hospital notes. This at the very least will consist of a copy of the completed consent form, patient information sheet and copy of the sent GP letter (where applicable).
Written records of key study events (including each study visit) should be recorded within the appropriate clinical section of the hospital notes unless the protocol states otherwise.

Example of key events to be recorded in the research participants' notes include:

-Provision of the information sheet/invitation to consider study;
-Obtaining informed consent;
-Eligibility decision assessment
-Information not available elsewhere within the notes; e.g. participant change of medication form G.P etc
-Randomisation or trial entry;
-Trial visits or follow-up phone calls required by the protocol;
-Treatment and dosing decisions, including changes to concomitant medications;
-Any trial-related decisions relating to the clinical care of the participant;
-Adverse Events (including seriousness, causality, severity);
-Withdrawal, termination or end of trial involvement
(Source: GCP Guide, MHRA)

4.3 Flagging Research Participants on patient databases for research studies where safety reporting is a requirement (CTIMPs & non-CTIMPs)

Once a patient has consented and enrolled to take part in a research study that requires safety reporting their participation should be registered on the patient databases as soon as possible. The **Alert Flag** is to be used for any study that requires Serious Adverse Reporting (CTIMPs & non-CTIMPs) to give the hospital wards notification about admission of clinical trial patients.

A delegated member of each research team should be appropriately trained to use the patient database alert system. A study template should be set up with appropriate message for the ward stating what the study is and who to contact (including out of hours contact details).
The system is not required to be used for studies where safety reporting is not required (observational studies).
Once the intervention phase for a study participant has finished and Serious Adverse Events reporting is no longer required, the participant's status **must be** changed so that an alert is no longer visible (the flag must be changed to complete).

Note: Alert system should not be used in isolation. It is to be used alongside the alerts in medical notes.

4.4 Wallet cards

Use of patient wallet cards is recommended, particularly for CTIPM studies.
Wallet card is a wallet-sized card containing information about the clinical trial a patient participated in, including who to contact out-of-hours. Some sponsors provide trial specific wallet cards, R&D template is available to download (refer to Section 5) and can be edited and printed for use.

4.5 Advise trial patients (if appropriate)

Once a patient has consented to take part in a research study that requires safety reporting, he/she should be advised to contact the Research Team if admitted to the hospital (or ask the hospital ward staff to contact the relevant Research Team)

5.0 Related SOPs and Documents

-Template Case Note Labels 1-'safety reporting required'
-Template Case Note Labels 2- 'observational/safety reporting NOT required'
-Wallet Cards Template