Work Instruction Title: Telephone Contact with potential or consented research participants

Work Instruction Number: 04

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Review History

Version No.	**Date**	**Amendments**
SOP 5 V1	19/10/09	2.1, 4.7, 4.9, 4.11
SOP 5 V2		Re-written to WI format
	21/01/10	*Title, 1, 2, 3.1, 4.1, 4.2, 4.4, 5.1 – 5.24, 6.*
WI 04 V3	02/07/2012	Title, 1, 4, 5, 5.1, 5.2, 6.2
V3	01/07/2013	Minor change: Removal of PCT reference
Version No.	**Initials**	**Amendments**
V.4	HJ	Major changes to Section 5 to cover contact before and after consent to a study. Minor changes throughout. Author previously PCRN EoE Network Co-ordinator
V.5	MC KP	Addition of Community where applicable. Minor changes throughout.
V.6	CF, BJ	

1. Introduction, Background and Purpose

This Work Instruction (WI) describes the correct procedure for all staff making initial and follow up telephone contact with potential or consented research participants. The term 'Staff', in this WI refers to anyone who has been delegated responsibility for the task and works in the Primary Care and/or community setting.

This instruction protects the potential research participants' rights & information; providing a choice to the participant, about who their information can be disclosed to. It is important that staff adhere to all legal procedures and ethical guidelines concerning participant contact and the disclosure and use of information is handled with appropriate care.

2. Abbreviations

See Reference Document CRN Glossary of Terms and Abbreviations.

3. Scope

This WI applies to CRN Primary Care or study site staff in Primary Care and Community Services. The WI applies to all staff delegated with the responsibility for contact with potential study participants and consented study participants. This WI must be read in conjunction with the study protocol.

4. Responsibilities

Staff must be familiar with all responsibilities regarding the Data Protection Act and GDPR, ICH GCP, NHS Code of practice, NMC The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates (if applicable) and any local policies. If in doubt, further support, training or advice should be sought from your line manager, before carrying out this role. Please note that the information governance applying to sharing data with third party staff ultimately rests with the data owners.

5. Procedures

The individual must have appropriate expertise and knowledge of the study protocol prior to contacting the potential/existing participant to ensure the process strictly adheres to what the protocol sets out. Clinical queries arising from such calls must be dealt with or followed up by an appropriate person and documented on the telephone contact log. The individual must not be seen to be putting undue pressure on the potential/existing participant by making repeated phone calls. Phone calls to potential/existing participants must always be made from the practice, site, trust landlines or business mobiles as per local Information Governance / Remote Working policies.

5.1 Prior to initial telephone contact

Refer to the study specific protocol and Ethics submission for the approved method of approach during recruitment. Ensure that confidentiality can be maintained throughout the telephone call.

Using the 'return reply slip' system

- Where an invitation letter with a 'return reply slip' has been mailed to the potential participant with the participant information sheet (PIS), completion and return of this slip with contact details expressing interest in the study implies consent and signals agreement for the potential participant to be contacted.

- These 'return reply slips' contain participant identifiable information and must be stored according to national/local guidelines and policies for the management of manual and electronic records.

- It is important to check what the reply slips give permission for. It may allow an individual to contact the potential participant, specifically give consent for the researcher to access their clinical notes or allow the researcher to collect other information from their GP.

- If 'return reply slips' are not being used by the study team for initial approach to potential participants, individuals not directly employed by the practice or community service, even with a Research Management & Governance approved letter of access, may not access participants details in any form prior to participant consent unless there has been explicit agreement between the data owner and the individuals concerned. This agreement should involve the organisation's Caldicott Guardian.

Written consent

- When the potential participant has previously given written consent for access to their details (and a copy of this is available) ensure there is Research Management and Governance approval in place for this specific activity.
- The individual must hold a valid letter of access or honorary research contract and this access is consistent with the organisation's internal policies on data access, then the information required and approved for that participant may be shared.

Verbal consent

- Verbal consent may have previously been given by the potential participant allowing GPs/clinical staff to pass initial information over to the researchers so that the research team can contact them about a study. This process will be outlined in the study protocol. This verbal consent should be documented in the participant's clinical records.

If a CRN Research Nurse has a documented agreement with the practice, which has been approved by the practice Caldicott Guardian, there may be local permission for these nurses to access details and approach patients prior to Informed Consent.

For those individuals directly employed by a practice or community service and permitted to access potential participant records, please refer to the study protocol, your local Information Governance policy and your employing organisation's internal arrangements for guidance.

5.2 Making calls

- It is not appropriate to make the first contact through a text message to the mobile phone number of the participant where this has been provided on the return reply slip. Text messaging should only be used after the participant has stated it is their preferred method of communication using standard text or wording approved in the study protocol.

- It is advisable to have a preferred contact time to reduce the incidence of repeated calls.

- During all points of telephone contact check you have the correct respondent (a father and son in the same household may have the same name).

- Once you have reached the correct respondent, if this is the first contact, introduce yourself clearly, stating for example that you are a NHS Research Nurse working with the practice and Dr X has asked me to contact you.. Thank the respondent for their initial interest in the study and ask if it is an appropriate time to discuss the study (they may have given you their work telephone number). If it is an inappropriate time, agree a time to call back. If there is a telephone script approved for the study this should be used.

- If it is convenient to go ahead with the call, check whether the respondent has read the PIS, go over the main points of the study and answer any initial questions they may have. If stated in the protocol, check appropriate inclusion/exclusion criteria with the respondent.

- Inform the respondent of how many visits over what time scale may be required and invite them to the initial appointment as per protocol, but reassure them that they are under no obligation to commit to the study at this point and it will be discussed in more detail at the visit.

- If the potential respondent has agreed to an initial visit, and an approved appointment letter is available for the study, send out confirming the date and time, with your contact details. If there is no approved letter a standard appointment letter can be sent from the practice confirming the date and time of the appointment or these details can be recorded on the study telephone log stored in the Site File.

- Document the date, time, purpose and outcome of the phone call, whether there is a reply or not and store all communications in the study Site File. See Appendix 1 Telephone Contact Log'. The telephone contact log must be stored in the study Site File unless a CRN nurse is contacting potential/existing participants. Under these circumstances the telephone log can be kept away from the Site File in a locked cabinet with restricted access. The telephone log must be returned to the appropriate site and filed in the study Site File once complete.

5.3 Follow-up calls

- If a patient has already consented to a study, check the records for their preferred method and time of contact.

- If there are long delays between initial contact and follow-up calls check to ensure that the potential/existing participant has not had any changes in circumstances before calling.

5.4 Incoming calls

- Some studies will include the research site telephone number and/or email on the PIS and request that the patient contacts the site staff directly.

- If there is an answer phone for the study, provide the respondent with the option to leave their name, contact number and a suitable day and time for you to phone them back or ensure your message includes what day and time you will be in the office so that they may contact you again if they prefer not to leave a message. (Where there is large scale recruitment such as where media advertising is used, it is important that the study team ensures that there is sufficient recording capacity on their answer phone device. Also the team must ensure that proper procedures are in place to ensure that all calls are captured, recorded and responded to promptly).

- Details of the incoming calls should be recorded on the telephone log. See appendix 2: Telephone Summary.

5.5 Unanswered calls

- If confident you have reached the correct number, leave a message for the named individual, simply requesting they phone your number. Unanswered calls to previously contacted patient can be left a message to say it is the NHS research nurse regarding a research they have signed up for.

- Do not leave information with any other household member. If the person answering the phone asks who is calling or offers to take a message can say it is the NHS research nurse about a research the patient signed up for and you will call back, or they may phone you.

- You may only leave messages with another household member if the participant has given verbal consent for this. The name of the other household individual should be noted and that verbal consent has been given for leaving messages written in the participant's clinical record.

- After repeated unanswered calls notify the study team. If there is an approved letter for contact, this may be used.

6. Related SOPs, Work Instructions and Reference Documents

6.1 SOPs

SOP 01 Informed consent
SOP 03 Study set up
SOP 04 Study conduct

6.2 Work Instructions

WI 01 Informed consent: Minors
WI 02 Informed consent: Adults lacking capacity
WI 06 Opportunistic recruitment
WI 08 Initiation visit
WI 09 GCP and training records
WI 10 Study files and filing

WI 12 Data protection
WI 16 Audit and inspection
WI 23 Informed consent: competent adults

6.3 Reference Documents

Declaration of Helsinki
ICH Good Clinical Practice (GCP)
EU Clinical Trials Directive (EUCTD)
Research Governance
CRN Glossary of Terms and Abbreviations
Research Ethics Committees
Indemnity guidance
Registering with the Information Commissioner's Office

7. Appendices

Appendix 1: Telephone Contact Log

Appendix 2: Telephone Summary

APPENDIX 1

TELEPHONE CONTACT LOG

Study					
Site					
Principal Investigator					
Name (potential participant)	**Phone Number/s**	**Call 1** Time/date/comment/sign	**Call 2** Time/date/comment/sign	**Call 3** Time/date/comment/sign	**Outcome**

Appendix 2

Telephone Summary

Study:	**Principal Investigator:**
Date:	**Time:**
Call Participants:	**Topic:**

Summary of conversation:

Print name…….....

Signature…….

Role……...

Date…….....