University Hospitals Bristol and Weston NHS Foundation Trust

GD_045 Lost to Follow-up Guidance

1. Abbreviations

Does/Did Not Attend	DNA
Principal Investigator	PI
CRF/eCRF	Case Report Form/ electronic Case Report Form
GCP	Good Clinical Practice
NOK	Next of Kin

2. Purpose and Scope

This document provides guidance for research teams on recording a participant as lost to follow-up if they become uncontactable during the follow-up phase of a trial. It is not designed to be fully prescriptive or replace any available protocol guidance but can be used alongside clinical judgement and a risk assessment of the trial where protocol guidance is not available. In the scope of this guidance document is participants (patients or healthy volunteers) in the follow-up phase of an interventional or observational trial.

3. Background

Complete and robust follow-up data is critical to maintain trial integrity, assess treatment effectiveness and meet trial endpoints. Contributing high-quality data enhances our reputation to deliver research thereby increasing patient access to new treatments. Participation is voluntary and participants may withdraw consent at any time without providing a reason. Where withdrawal occurs, efforts should be made to understand the reason, as this informs future trial design. Consent is an ongoing process and must be reaffirmed at each visit, especially during long-term follow-up when life changes may affect compliance. Research teams have a responsibility to minimise loss to follow-up but must balance this against resource implications and the rights of participants. If a participant becomes uncontactable despite multiple attempts, consent cannot be assumed, and they should be withdrawn from follow-up. All efforts to maintain contact must be documented to demonstrate compliance with this responsibility.

4. Lost to follow-up Process

(1) Arranging a follow-up visit

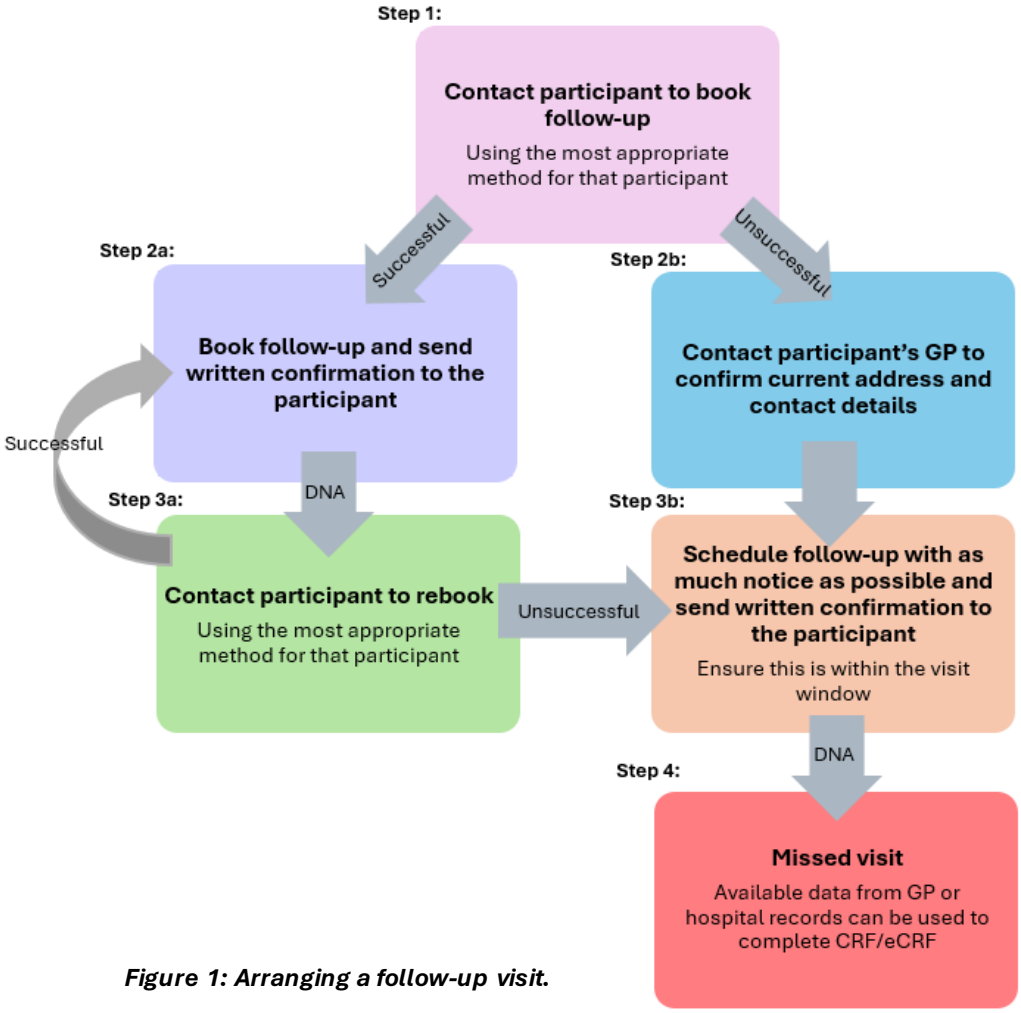

Figure 1: Arranging a follow-up visit.

Step 1: Make at least 3–4 contact attempts using the most appropriate method for the participant. Consider calling via Switchboard on the final attempt to display an unblocked number. Appendix 1 contains an example Research Contact Preference source worksheet which can be used to document a participant's preferred contact methods. It is recommended this information is collected at screening, but it can be updated throughout the study if there are any changes.

Step 2a: If contactable, book a follow-up and send written confirmation of the visit (from the research team directly or confirm outpatient clinic has sent it).

Step 3a: If the participant DNA the scheduled visit, make 3–4 attempts to rebook, but only rebook once. If they DNA again, mark the visit as missed and use any available GP or hospital data to complete the relevant CRFs/eCRFs.

Step 2b: If uncontactable, verify contact details with the GP practice and update Careflow if needed.

Step 3b: Book a follow-up within the protocol window and send written confirmation of the appointment directly from the research team or via the outpatient clinic.

Step 4: If the participant DNA this visit, record it as missed and use any available GP or hospital data to complete relevant CRFs/eCRFs.

(2) Recording a participant as Lost to Follow-up

The number of consecutive missed visits before considering a participant lost to follow-up depends on factors such as visit frequency, planned absences, and attendance at standard of care appointments. Generally, three missed visits should prompt review for withdrawal**.** Clinical judgment and knowledge of the participant should be used to decide the appropriate visit threshold before initiating the process depicted in Figure 2.

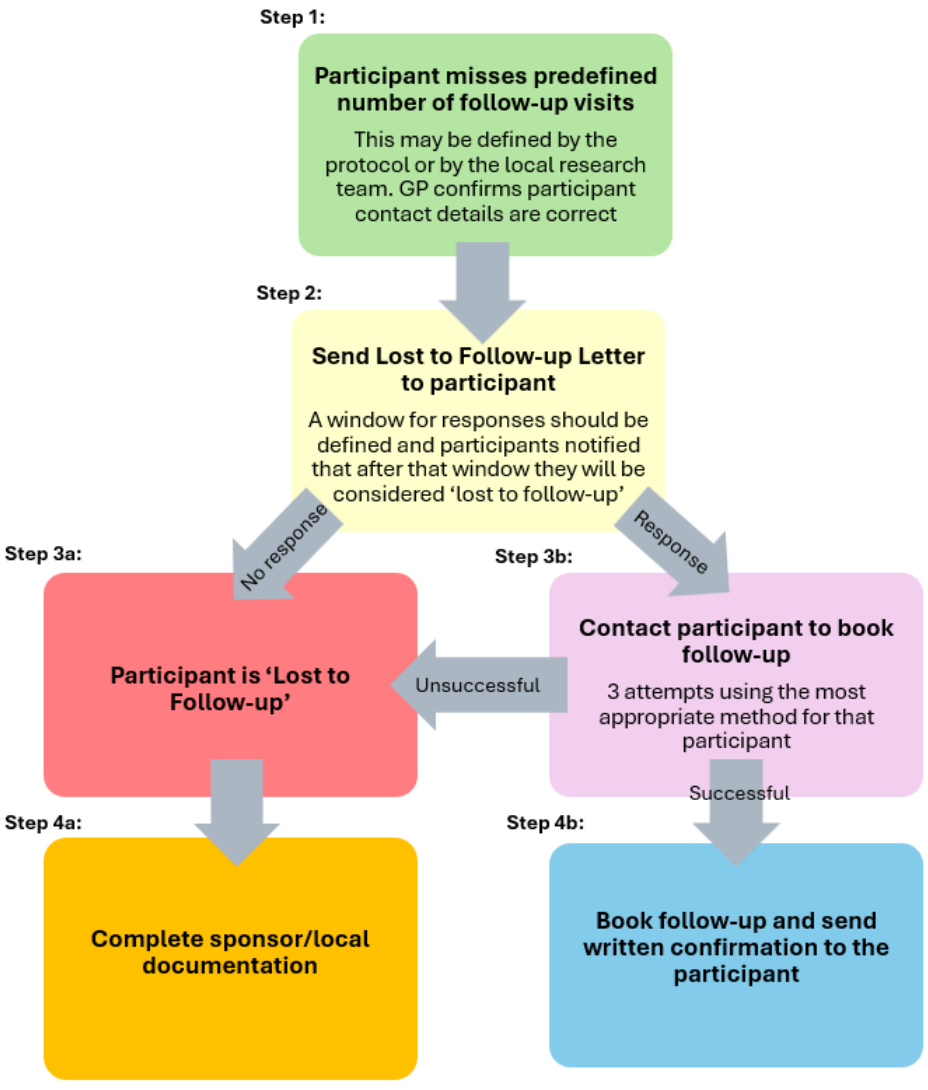

Figure 2: Recording a participant as lost to follow-up

Step 1: If a participant misses the required number of follow-up visits (per protocol or clinical judgment), contact their GP to confirm that the contact details in Careflow—especially postal address—are correct.

Step 2: Send the Lost to Follow-up Letter (see Appendix 2 for an example), specifying a response window—typically 4–6 weeks, but adjust per protocol or sponsor guidance. Advise

that if a response is not received within this window, they will be recorded as lost to follow-up. File a copy of the letter with the participant's source data. If the protocol offers levels of withdrawal to participants, these should be explained in the Lost to Follow-up Letter.

Step 3a: If no response is received, the participant should be recorded as lost to follow-up with a date of withdrawal as the day after the final day of the window.

Step 4a: Complete all required local and sponsor documentation:

a) Document the lost-to-follow-up process in source data (see Appendix 3 for an example worksheet)

b) Complete withdrawal CRF/eCRF

c) Notify sponsor by email

d) Record withdrawal date in Edge

e) Remove any Careflow alerts

f) Update local visit trackers (if applicable)

g) Withdraw the participant in IWRS (if applicable)

h) Refer the participant back to their standard clinical care team (if applicable)

Step 3b: If the participant responds within the window, make 3–4 attempts to schedule their follow-up (**Step 4b**). If they cannot be contacted to confirm a visit date, proceed with withdrawal (**Step 3a**). If they respond after the window, consult the sponsor to determine if trial participation can resume.

5. Protocol guidance

If the protocol provides guidance on minimizing loss to follow-up and when to record a participant as lost to follow-up, the protocol must be followed, as it has REC approval—unless clinical judgment deems it inappropriate. Any deviations must be documented with rationale and reported to the sponsor.

The PI is responsible for trial conduct at UHBW and must be included in all sponsor correspondence regarding participants who are recorded as lost to follow-up to ensure oversight and assist with resolving sponsor queries.

6. Associated documents

(1) ICH E6 (R3) Guideline on good clinical practice (GCP) Step 5

(2) sop_027_informed_consent_for_research_purposes_uhbw_v1.4_22jul2024.pdf

7. Appendix 1: Research Contact Preference source data example

TRIAL NAME (R&D Number)

Patient Name:		**NHS Number:**	
DOB:		**Study Number:**	

Date of completion: ___/___/_____

Contact method to arrange a follow-up	**Yes**	**No**	**Comments** *Confirm contact details matches those listed on Careflow. If different, Careflow must be updated.*
Telephone call to mobile number			
If yes, can a voicemail be left?			
Can a text message be sent? *(if available for the team)*			
Telephone call to home number:			
If yes, can a voicemail be left?			
Email *(confirm this does not get delivered to their junk folder)*			
NOK			
Other (specify)			
Will the participant answer an Unknown number?			
Should written confirmation of appointments (where possible) be provided?			

Completed by: _____ Date: _____

8. Appendix 2: Lost to Follow-up Letter

[Research Team addressograph]

[Date]

RE: [Patient Name] NHS Number: [ ] DOB: [ ]

Dear [Patient Name],

We have attempted to contact you without success to complete your [Follow-up timepoint, i.e. Year 5] [Trial Name/research appointment (check with sponsor if they are happy for the trial name to be included in correspondence] which was scheduled for [Date range, i.e. month, year]. According to your records, it is noted we were also unsuccessful in contacting you for your previous follow-up visit(s).

As part of a clinical trial, it is important to confirm verbally your continuing consent to remain within the trial on follow-up and for the research team to continue to contact you.

Being part of a clinical trial is a commitment and continuing within the trial is completely optional. The contact details of the research team have been provided below and we would be grateful if you could please confirm in writing or by telephone [or email if a research team email exists] whether you are happy for us to continue to contact you [frequency of future follow-ups, i.e. annually] to complete trial follow-ups or if you are happy for the research team to continue collecting any available relevant data from your GP/local hospital records for upcoming follow-up visits. [It may also be possible to reduce the frequency or number of in person visits by replacing them with telephone visits. If this is something you are interested in, please contact the research team and they will discuss the options. (if applicable)]

If a response is not received by [Date 4-6 weeks from date of letter, or as appropriate], we will consider your consent withdrawn and will no longer attempt to contact you for future trial follow-ups.

[Contact details of research team including, at a minimum, address and telephone number]

If you have any questions relating to this letter or any other aspect of the trial, please don't hesitate to get in contact.

Yours sincerely,

[Name of researcher]

[Job Title]

9. Appendix 3: Lost to follow-up source data example

TRIAL NAME (R&D Number)

Patient Name:		**NHS Number:**	
DOB:		**Study Number:**	

Date of last contact:	/ /
How many consecutive follow-up visits has the participant missed?	
Date GP practice confirmed current contact details on record are correct:	/ /
Date Lost to Follow-up letter sent: *(A copy of this must be filed with the participant's source data)*	/ /
Date of withdrawal:	/ /
Date PI informed of participant withdrawal *(A copy of this email/PI oversight meeting agenda/notes must be filed with the participant's source data)*	/ /
Comments:	
Date sponsor notified: *(A copy of this must be filed in the participant's source data)*	/ /
Date Edge status updated to Withdrawn	/ /

Completed by: _____ Date: _____