

Consent and Eligibility Medical Record Annotation

The consent process and a participant's eligibility to take part in a study should be formally documented in a participant's medical notes, study workbook and/or the Case Report Form.

We recommend the use of a pre-printed consent sticker/continuation sheet that can be filled in with the participant-specific information and added to their medical notes.

This will ensure that:

- the annotation contains all the relevant information required to evidence that informed consent has been obtained properly and in accordance with the ethical approval for a study, and
- that the annotation of consent is standardised for all participants, preventing the occurrence of deviations.

Where a screening visit is required prior to eligibility being confirmed:

1. The consent annotation should state that screening investigations to confirm a participant's eligibility have been undertaken.
2. Once the results of the screening investigations are available and have been reviewed, a second entry **must** be made in the medical records confirming whether or not a participant meets the inclusion criteria (or where, relevant, meets an exclusion criteria) and is therefore eligible to participate (or not).

A sticker should also be added to the inside cover of a participant's medical notes to flag that the participant is taking part in a research study/trial.

An example inside cover sticker is provided below:

PATIENT TAKING PART IN A CLINICAL TRIAL/RESEARCH STUDY

Study name <insert details>

Participant ID: <insert details>

Principal Investigator: <insert details>

Telephone number: <insert details>

Date consent form signed: <insert details>

Notes must be retained for X years after the study has concluded.

Do not destroy records before (date will be added upon conclusion of the trial/study): <insert details>

An example of a pre-printed eligibility and consent sticker/continuation sheet proforma that can be adopted is provided below:

University of Leicester Sponsor Ref: <insert reference number> <study Title>
Participant ID: <insert ID number>

Participant was given PIS version X.X Dated DD/MM/YYYY on DD/MM/YYYY at HH:MM.
The participant confirmed consent to participate in the study by signing and dating version X.X DD/MM/YYYY of the consent form on DD/MM/YYYY at HH:MM.
Consent was obtained by <insert name of research>
The original copy of the consent form is filed in the TMF/ISF with additional copies given to the participant and filed in the medical notes.

Delete as necessary

<Screening investigations to confirm the participants eligibility have been undertaken and confirmation of eligibility will be documented in due course.>

or

<The participant meets all the inclusion criteria and none of the exclusion criteria and is therefore able to take part.>

Delete as necessary

The participant has been randomised to: <insert details>
The participants next study visit is scheduled for: <DD/MM/YYYY>

Entry made by: <insert name>
Date: <insert date>
Signature: <insert signature>