

Consent Process Witness Statement

Study Title: _____

Study Number: _____

Chief Investigator/Principal Investigator Name: _____

Participant Unique Study Identifier: _____

Participant Name: _____

Reason for utilising witnessed consent: _____

I, (*print witness name*) _____ confirm that I / a member of the research team (*print name of researcher*) _____ have read and explained the content of the patient information leaflet, version xxxxx, dated xx/xx/xx and confirm that (*name of participant*) _____ has had any questions answered. I confirm that to the best of my knowledge (*delete as appropriate*) she/he understands this information and is willing to participate.

I confirm that the signature/mark represents the signature of her/him. (*delete as appropriate*)

Witness Contact Details:

Address: _____

Telephone Number: _____

Email Address: _____

When completed: 1 for Patient; 1 for Site File; 1 to be kept with hospital notes

Consent Process Witness Statement Guidance

It is important to note the difference between a 'signature witness' and a 'witness to the consent process'. A 'signature witness' merely sees the participant sign consent, whereas a 'witness to the consent process' is present for the whole consent discussion.

ICH-GCP guidelines require an impartial witness if the consent giver (i.e. the participant or their legal representative) can't read (GCP 4.8.9). In such cases the witness must a) be present for the whole informed consent discussion and b) sign and date the consent form after the consent giver has done so. In signing the consent form the witness is attesting to the fact that all written information was accurately explained and apparently understood by the consent giver and informed consent was freely given by the consent giver.

The consent witness informed consent form and consent witness statement is NOT intended for use where a personal or professional legal representative are giving consent on behalf of the participant.

It is important that all fields are completed to ensure that identification of the study, Principal Investigator, witness and participant can be undertaken.

The name of the witness must be entered, along with the name of the researcher reading/explaining the study (where applicable)

The reason for utilising a witness must be recorded

Please indicate whether the witness or the researcher has read/explained the study
Please record the version number and date of the patient information leaflet provided to the participant

The witness contact details must be recorded for identification purposes

The original copy of the completed witness statement must be filed within the Investigator Site File along with the corresponding completed consent form and patient information leaflet, a copy must be given to the participant along with a copy of the corresponding completed consent form and patient information leaflet and a copy must be filed in the participant's medical records along with a copy of the corresponding completed consent form and patient information leaflet

Documentation of the consent/witness consent process must be recorded in the main body of the participant's medical records