

Guidelines for Signatures on Consent Forms

These guidelines will assist the Principal Investigator and the team in designing the signature page of the consent form.

The ICH Good Clinical Practice: Consolidated Guideline (hereinafter "GCP") requires that the written consent form be signed and personally dated by the participant or the participant's Substitute Decision Maker¹ (hereinafter "SDM"), and by the person who conducts the consent discussion. (GCP s. 4.8.8)

Prior to participation, the participant (or the SDM) must receive a copy of the signed and dated written consent and information form, and any other written information provided to the participants.²

1. Witnesses to the Consent Process or the Signature Only

The Principal Investigator (hereinafter "PI") may be called upon from time to time to provide evidence that neither the investigator, nor the study staff, coerced or unduly influenced a participant to participate or to continue to participate in a study.³ A witness's involvement may be one way to ensure the lack of coercion or undue influence.

If the participant, or a Substitute Decision Maker, is unable to read, an impartial witness should be present during the entire consent discussion. (GCP s. 4.8.9)

¹ Substitute Decision Makers include (listed in order of rank): attorney for personal care (appointed by the person, or appointed by the Court); representative appointed by the Consent and Capacity Review Board; spouse or partner (but not if living separate and apart) child or custodial parent; access parent; brother or sister; or any other relative; and Public Guardian or Trustee (if there is no one else).

² GCP states that a copy of the information and consent form should be provided to the participant. The wording used above is mandatory.

³ See GCP 4.8.3 which states "Neither the investigator, nor the study staff, should coerce or unduly influence a participant to participate or to continue to participate in a study." The Research Ethics Board, as part of its duty to monitor ongoing research on human participants, may require evidence of this.

An impartial witness is a person, who is independent of the study, who cannot be unfairly influenced by people involved in the study. (GCP s. 1.26) A witness to the consent discussion and process must be impartial. A witness to signature only need not be impartial.

In other circumstances, there are no hospital requirements and no specific requirements in the GCP (GCP s. 4.8) for an impartial witness to the consent process, nor for a witness to the signature only of the study. Thus if no witness is present, the signature line for the witness may be left blank.

Upon signing the consent form, the witness must indicate the role that the witness played:

- If the witness is a witness to the consent discussion, the witness attests that the information in the consent form, and any other written information was accurately explained, and apparently understood by the participant or the participant's SDM, and that the consent was freely given by the participant or the participant's SDM. (GCP s. 4.8.9)
- If the witness is a witness to the signature of the participant only, then the witness attests that he or she has witnessed the participant (or the SDM) signing the consent form, and the consent was freely given by the participant (or the SDM).

2. Person Who Conducts the Consent Discussion

The person who conducts the consent discussion, including those explanations set out in CGP section 4.8.10 (i.e. purpose and nature of the study, risks and benefits, alternative treatments, voluntary participation and withdrawal, etc.) is the person who should sign the consent form to so indicate. On occasion, this may be more than one person substantially involved in the explanation of the study to the participant. The role of each study personnel in the consent discussion should be noted on the consent form or in the supporting documentation.

3. Signature of the Principal Investigator

There is no requirement in the GCP for the signature of the PI on the consent page. It is suggested that the PI sign the consent page to provide the participant with the assurance that the PI is involved with every aspect of the study, including the consent process. However, steps should be taken to ensure that the PI's signature does not indicate that he or she was present during the consent discussion, if this is not the case. Thus, the PI's signature may be located under a statement to the following effect:

" Investigator Signature

I _____(printed name of Principal Investigator) am
the investigator responsible for the conduct of this study at St.
Michael's Hospital, and I have delegated the explanation of this study
to this patient to _____ (name conducting the
consent discussion).

Signature of PI Date"

If the Principal Investigator is routinely involved in the consent process, together with
another person, then a sentence may be added to the above paragraph to the following
effect:

"I have also had a discussion with the participant regarding the study
to confirm that the participant understands the nature of the study."

*mlzm
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