OBTAINING SIGNATURES ON THE INFORMED CONSENT DOCUMENT

The Informed Consent process requires that a minimum of 2 individuals be present when the document is being signed: 1) the participant, and 2) the individual who obtains the Informed Consent from the participant. In some instances, federal regulations and/or the study sponsor may require that a 3rd party (a witness) be part of the signature process. HRPP “recommends,” but does not require, a witness signature.

1) The Participant, in his/her own handwriting, should print his/her name, sign, and date here.

2) The Person who Obtains Consent from the Participant should, in his/her own handwriting, print his/her name, sign, and date here. This individual must be either the Principal Investigator (PI) or an individual who is “designated” by the PI to perform this function in his/her place. This individual must have adequate knowledge about the study to be able to answer questions posed by the participant.

In addition, individuals who obtain consent from participants:
- Must be listed as “key study personnel” on the HS-1A
- Must complete all required education which includes reading the “Belmont Report” and completing the NIH human research subjects protection tutorial (online). A copy of the completion certificate for the NIH tutorial must be submitted to IRB along with the HS-1A.

3) A Witness: Recommended but optional (unless otherwise required by the Study Sponsor or for other reasons - e.g., potential for coercion, subject has limited mental capacity, etc.). If a witness signature is included on the form, a line or two of explanation as to what the witness is attesting to should be included above or below the signature line. The witness is the individual who witnesses the signing of the Informed Consent by both the participant and the individual who did the consenting. Unless otherwise required, it is not necessary for the witness to be present for the entire consenting process. The witness, in his/her own handwriting, should print his/her name, sign, and date here.

4) PI Signature: If the PI is not the individual “obtaining” consent from the participant, but is required by the Study Sponsor, or wishes to sign the document, his/her signature should go here. Inclusion of the PI’s signature here may document his/her acknowledgement/approval of the “designee” who conducted the consent interview with the participant in his/her place. In this instance, the PI may sign the document at a later time (i.e., need not be present when the other signatures are obtained).

Comments and suggestions for future “HRPP Topics” are welcome and should be submitted to:
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