

Study Title:
Principal Investigator:

Subject Name _____ Date ICF Signed _____

The above named study was discussed with this subject by _____, the person who obtained the informed consent. The subject had an opportunity to ask questions about the study. All questions were answered to the satisfaction of this subject. This subject received a copy of the signed and dated ICF.

The following italicized items are not required by the current policy 15.5 but are strongly recommended to fully document the consent process:

Note particular questions the subject had or that the subject had no questions, if applicable.

Note who else was present during the informed consent process.

Note how the subject responded when asked to describe his understanding of the study and its benefits and risks.

Add any items that the protocol indicates are to be specifically mentioned to every subject (or to a particular group of subjects). Indicate that these items were covered point-by-point with the subject.

Leave space to handwrite any other particulars about the informed consent process for this subject, such as the presence of a translator; presence of a Legally Authorized Representative(LAR) and the reason for the LAR; the reason for any delays in informed consent form signatures; etc. Any deviations from the inclusion/exclusion criteria may also be addressed in the informed consent process note; have the PI sign this note if such a deviation applies. (Note that additional recordkeeping, including IRB reporting, is required for this kind of deviation.)

Person Obtaining Consent

Date

This is only an example of an informed process note template. Modify this document as needed to best suit your study.