Office of Research Integrity
Florida International University

IRB Study# or Short title_____

Subject ID Number / Initials: _____ Date: _____

Informed Consent: Process and Documentation
(Place mark if done)

	Informed Consent Process Requirements
	1. Person obtaining consent has CITI training and is approved by the IRB (Study Personnel).
	2. Potential subject is given time to read the consent and consider participation.
	3. The potential subject's understanding of the information presented in the consent form has been assessed to be adequate.
	4. Subject's questions were answered.
	Informed Consent Document Requirements
	1. First page on FIU letterhead.
	2. IRB approval stamp on all pages of document.
	3. Current consent version used.
	4. Subject completed option checkboxes, if any.
	5. Subject completed all subject lines themselves (best practice for most research).
	6. Person obtaining consent completed Person Obtaining Consent lines.
	7. Subject received a full copy of signed consent for their records.
	8. Researcher kept the original, fully-signed consent.

These requirements were completed by:

Signature _____ Date _____