Informed Consenting Best Practices (the do’s and don’ts):

* The Informed Consent Form (ICF) process begins with you and the patient at the very beginning of the study and continues throughout the duration of the study. The ICF is done BEFORE anything is done on the study. This is a hot FDA topic and many FDA auditors look for this documentation.
* Use a checklist or have a documented process on the ICF process. This ensures all areas of the ICF are discussed and addressed. It also ensures that no procedures were performed prior to the ICF.
* Use Black or Blue ink only. Avoid red, green, pink…etc.
* Know if the ICF should become part of the medical record.
* Keep original signed ICF in your source/records and make sure patient has a copy of the signed ICF.
* Make sure your patients fully understand the ICF and what occurs at each visit. Use questions such as “now you tell me what happens”…
* Give patients 24 hours to think about study unless you have IRB approval to waive the 24 hour time frame. Also, document if time frame was waived.
* If consenting before a procedure make sure patient has uninterrupted time and that patient has not been given any medication that would impede their decision (sedatives, etc.).
* Make sure the PARTICIPANT signs and initials where appropriate on the ICF.
* Witness needs to be unbiased if applicable.
* Answer any questions and continually assess agreement /consent at each visit.
* Take a “time out” and make sure you are using the MOST CURRENT APPROVED VERSION of the ICF.
* For studies that have a “sister” study, also make sure you are using correct version and that it is approved by the IRB.
* Be educated and work with your regulatory staff on amendments.
* Make sure you have been delegated on the delegation log to perform the ICF process.
* Know if the sponsor requires the PI/MD to consent. (GW has company requirement that PI/MD does consenting per CRA.)
* Make sure PI or Sub-I is available to answer questions on the same day you are obtaining ICF and will sign ICF on that day.
* Make sure your patient can read. Hand the ICF to them upside down….
* Make sure the patient knows their signature signifies that they have read and understand ICF and that all their questions have been answered.
* Know the LAR process and who can sign.
* Be familiar with children and the assent ages. Also, know just because the child assents they can waive their assent at any time as well.
* Be familiar with the withdrawal process and what is performed and can be used.
* Understand MDs can pressure patients but NO means NO.
* Patients can withdraw at any point and ALWAYS SAFETY comes FIRST!!!
* Be sure to explain medical technology/procedures so that the patient can fully understand.
* Any changes to a signature or the dates for corrections, etc., should be initialed and dated by the person making the change at the time the change is made. Use a single-line cross-out that does not obscure the original entry.

