Pre-operative Approach and Informed Consent for Low Risk Research

*Examples: Prospective observational studies, studies that do not involve randomization or an invasive or non FDA-approved drug/device*

When is this appropriate?

- Patients are not under the influence of premedication.
- Risks to the patient and time commitment to the study are not significantly different from routine clinical care.
- After verbal explanation from investigator or research coordinator; patients are given time to read the consent form and consider the risks and benefits. Patients should have an opportunity to raise questions or seek explanation on any points concerning the nature of the study, alternatives, risks, benefits, etc.
- **Able to provide adequate time to consider participation in study.** Often 90 minutes prior to surgery is okay.
- Patients who feel pressure, or require more time to make a decision, should be advised to decline participation in the study.
- Consideration of dual role of investigator/clinician in consent process and issue of undue influence. Those recruiting and obtaining informed consent should ideally not also be involved in that patient/subject’s clinical care.

What to include in IRB application:

- An overview of the approach and consent process.
- Description of when and where the approach and consent process will occur.
- Explanation of why the approach and consent cannot happen earlier (i.e. in the pre-anesthesia clinic, etc).
- Confirmation that approach and consent will happen prior to premedication/sedation.
- Statement that potential subjects will be given enough time to make an informed decision. **State how much time.**
- Statement that the approach and consent process for the study is reasonable in relation to the minimal risks associated with the study.
- Explanation of who will approach the patient and obtain their consent.
- **Statement that the patient’s anesthesiologist will not do initial approach and consent.**

*See sample recruitment/consent language to include in IRB application*