**Checklist for Investigational Studies in UNCH Perioperative Services**

It is the intent of UNCH Perioperative services to facilitate scholarly investigation of new devices and procedures in a manner that seeks to ensure such work is consistent with University and Hospital policies and will accomplish its goals. All research done within Perioperative Services must be approved by the UNC Institutional Review Board. **Prior to this approval, the research protocol must be reviewed and approved by Perioperative Services to ensure it can be done in an efficient, safe, and sound manner.**

All studies requiring additional devices or equipment must have a clear and acceptable method to offset any additional costs involved with the use of the device(s) or equipment. The investigator is encouraged to get Perioperative Services involved as early as possible in the planning process for the study.

1. Briefly describe the study protocol
2. Is the device being studied FDA approved for this indication?
3. In what CPT codes will the study be performed?
4. What is the anticipated additional procedure time required if any?
5. If the study involves devices or equipment not presently in Perioperative Services, who is supplying and funding this?
6. How are any devices or equipment going to be supplied (brought in my vender, stocked in business office, act)?
7. List the company name and contact person for any devices or equipment being studied.
8. Give a detailed description of the tasks expected of any PeriOperative staff (PreCare, PreOP, OR, PACU)
9. How is the Perioperative staff who will be involved (PreCare, PreOp, OR, PACU) going to be oriented to the study and what is expected?
10. How will you identify to the Perioperative staff that a particular procedure involves a study?
11. Does the study involve any extra precautions in terms of hazardous materials, risk to staff, instrument preparation and sterilization and if so, what are these.
12. Who is the contact person at UNC for issues related to this study?

Name Telephone number: Email address:

1. How long and how many cases will the study involve?
2. Are there study considerations which go beyond Perioperative services into the rest of the hospital? (examples: changes in registration time, precautions on the floor)
3. Who is responsible for data collection and documentation for the study while in Perioperative Services?
4. If the study involves additional equipment where will this be stored when not in use?

**Submit this completed form along with a PDF copy of your IRB application to Moe Lim at** **moe\_lim@med.unc.edu** **AND John Hudson at** **john.hudson@med.unc.edu**

**Do NOT submit this form to the IRB.**