University of Pittsburgh | Department of Anesthesiology and Perioperative Medicine

INVESTIGATOR-INITIATED RESEARCH TASKS/EXPENSES WORKSHEET

Protocol Title _____

Principal Investigator _____

Is there a drug or materials cost associated with the proposed study intervention? Yes _____ No _____

If yes, please explain: _____

_____

Study-Related Task	Who will complete the task? (choose one)	Time to Complete Each Task (work with Amy Monroe)
IRB application and ICF creation	Choose One	8-10 hours
IRB clarifications and maintenance	Choose One	8-10 hours
ClinicalTrials.gov application and clarifications	Choose One	8-10 hours
ClinicalTrials.gov maintenance	Choose One	8-10 hours
Subject screening/recruitment	Choose One	
Consent (approaching subject, explaining study)	Choose One	
Education of clinical and surgical staff on protocol as applicable	Choose One	
Case Report Form (CRF) creation	Choose One	
Database creation	Choose One	
Primary outcome data collection	Choose One	
Secondary outcome data collection	Choose One	
Data entry into CRFs and database	Choose One	
Adverse Event reporting	Choose One	
Manuscript preparation and submission to journals	Choose One	

PI Signature _____ Date _____