|  |
| --- |
| **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 task?**  **(circle one)** | **Time to complete each task**  **(work with Amy Monroe)** |
| IRB application and Informed Consent Form (ICF) creation | PI/Coordinator/Fellow/ Resident | e.g. 8-10 hours |
| IRB clarifications and maintenance | PI/Coordinator/Fellow/ Resident | e.g. 8-10 hours |
| ClinicalTrials.gov application and clarifications | PI/Coordinator/Fellow/ Resident | e.g. 8-10 hours |
| Clinicaltrials.gov maintenance | PI/Coordinator/Fellow/ Resident | e.g. 8-10 hours |
| Subject screening/recruitment | PI/Coordinator/Fellow/ Resident |  |
| Consent (approaching subject, explaining study) | PI/Coordinator/Fellow/ Resident |  |
| Education of clinical and surgical staff on protocol as applicable | PI/Coordinator/Fellow/ Resident |  |
| Case Report Form (CRF) creation | PI/Coordinator/Fellow/ Resident |  |
| Database creation | PI/Coordinator/Fellow/ Resident |  |
| Primary outcome data collection | PI/Coordinator/Fellow/ Resident |  |
| Secondary outcome data collection | PI/Coordinator/Fellow/ Resident |  |
| Data entry into CRFs and database | PI/Coordinator/Fellow/ Resident |  |
| Adverse Event reporting | PI/Coordinator/Fellow/ Resident |  |
| Manuscript preparation and submission to journals | PI/Coordinator/Fellow/ Resident |  |

Please contact Amy Monroe, Director of Clinical Research Operations, at [monroeal@upmc.edu](mailto:monroeal@upmc.edu) for assistance with the IIR worksheet