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| **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:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **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 for assistance with the IIR worksheet