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| --- | --- |
| Principal Investigator:  Address:  Email: | IRB# |
| **Part A – Primary Reason for Terminating Study** | |
| |  |  |  | | --- | --- | --- | | Study completed | Unfavorable Risk/Benefit ratio | Other: explain | | FDA determination | PI resigned/relocated | | DSMB request | Loss of funding | | |
| **Part B – Activity Report** | |
| 1. Since the study began, how many subjects have been entered into this research study at all sites under the authority of the University of Pittsburgh IRB? Do not include those subjects who failed to meet the inclusion criteria during screening.    1. What was the total number of subjects approved to undergo research related procedures at all sites under the authority of the University of Pittsburgh IRB? | |
| 1. Did subject accrual reflect the ethnic and racial demographics of Pittsburgh and the surrounding area and/or the relevant patient population of the UPMC; or the demographics of the alternate site(s) where this research is being conducted?  Yes  No    1. If **No**, provide a justification: | |
| 1. Have there been any other unanticipated problems, not previously reported, that meet the University of Pittsburgh IRB reporting guidelines (e.g., adverse events, medication or laboratory errors, unintended disclosure of confidential information or privacy issues, etc.)?  Yes  No    1. If **Yes**, complete and attach an Unanticipated Problem Report for Paper Submissions | |
| 1. Have you already provided, or do you plan to provide, your study participants with a summary of study results?    1. Attach copy of the communications if applicable. | |
| 1. Which research personnel, based on role or position, participated in the monitoring?    1. How often did the monitoring take place?    2. Has the frequency or severity of the adverse event profile differed from that expected?  Yes  No       1. If Yes, describe:    3. Has the adverse event profile changed the risk/benefit assessment?  Yes  No       1. If Yes, describe:    4. Have there been any concerns or complaints by subjects or others?  Yes  No       1. If Yes, describe: | |
| 1. Have all the original signed consent forms been retained?  Yes  No    1. If **Yes**, explain: | |
| 1. Has this study been monitored/reviewed/audited by an outside monitor, sponsor, or agency?  Yes  No    1. If **Yes**, specify the entities that performed the review, attach summary reports, and address any deficiencies identified: 2. Attach the summary report to this submission | |
| 1. Does this study have a local and/or external Data and Safety Monitoring Board (DSMB) or other Data Monitoring Committee (DMC) providing oversight of this study?  Yes  No    1. If **Yes**, specify the entity that performed the review, attach summary reports, and address any deficiencies identified: | |
| 1. Summarize the outcomes and conclusions of this study. Describe the extent to which the specific aims of this study were addressed and discuss the study's impact on the relevant scientific/medical issues: | |