**Study Closeout Report**

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| General Information | |
| Relying site name:  Principal Investigator of relying site:  Study Title:  IRB Number:  Expiration Date: |  |
| Study Status at Close-out: | |
| Study was completed  Study was started but closed prior to completion  Study was not started  Study is being transferred to another institution  Reason study was not started or was closed prior to completion: |  |
| Check the boxes if any of the following apply: | |
| Local enrollment to the study is ongoing  Local research-related interventions are ongoing Local participant follow-up is ongoing  Data analysis or manuscript preparation that involves use or access to individually  identifiable information is ongoing  Biological specimens associated with individually identifiable information are being maintained in a repository that was approved as part of this study or upon which analysis or research is ongoing (if specimens were transferred to a separate repository that has ongoing IRB approval, then the study may be closed)  Your study has an external sponsor and you have not received permission from your study sponsor to close the study with the IRB |  |

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| Study Summary Information  \* Did this study involve the collection, storage, or use of any human biological specimens: | |
| Yes No  If YES, explain what will happen with the specimens at the close of this study: |  |

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| Summarize the results of this research project, even if only for the study cohort enrolled locally: | |
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| Have there been any presentations or publications resulting from this study since last study renewal? | |
| Yes No  If YES, summarize the content and cite references: |  |
| Recruitment and Enrollment: Was there any participant contact since the date of last renewal? | |
| Yes No |  |
| Reporting and Summary of 10-day Reportable [Adverse Events](http://www.research.ucsf.edu/chr/Guide/Adverse_Events_Guidelines.asp) and other Safety Information: | |
| Are you submitting any new or missed 10-day AE reporting forms now?  Yes No  Are you submitting any new or missed DSMB or other multi-center oversight reports now that were not submitted previously?  Yes No  Were there any other unexpected safety developments that the IRB should know about?  Yes No  If YES to question #3, explain:  If you need to submit an AE Summary Log, attach it here: |  |
| Reporting and Summary of [Protocol Violations and/or Protocol Incidents](http://www.research.ucsf.edu/chr/Guide/Violation_Incident_Guidelines.asp): | |
| Are you submitting any new or missed 10-day Violation/Incident reporting forms now?  Yes No  Were there any other unexpected developments in study conduct that the UCSF IRB should know about (e.g., problems with study activities or participant complaints)?  Yes No  If YES to question #2, explain: |  |
| Study Activity after IRB-Approval Expiration: Please answer the following questions if the IRB study approval has expired. | |
| If the IRB-approval for this study has expired, did any research-related activity(ies) occur during the lapse in approval?  Yes No  If YES, answer the following questions:  Were any participants enrolled during the period of protocol lapse?  Yes No  Did any other research-related activity(ies) continue during the period of protocol lapse?  Yes No  How did the approval lapse occur?  What will be done do to prevent this from happening in the future for other studies?  If YES to either questions #1 or 2, describe all research activities that continued and whether the activities were done solely for participant safety. Include the number of participants involved and any adverse events or incidents that occurred after expiration of the approval. |  |