**Protocol Closure Form**

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| **DIRECTIONS: Complete this form in its entirety in lieu of a Continuing Review form for Protocol Closure.**  |

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| Submission Date: |  | Original Approval Date: |  |
| PROJECT TITLE | **PROTOCOL ID** |
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|  PRINCIPAL INVESTIGATOR  |
| Name (Last, First) |  |
| **Faculty Advisor (If Principal Investigator is student)**  | Name(Last, First) |  |

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| **Participant Enrollment & Drop Out Status** |
| **Number of Participants enrolled:** |
|  | Since last approval | TOTAL Since initial approval |
| Complete (No further follow up): |  |  |
| \*Voluntary Withdraw: |  |  |
| \*Dropped by Investigator: |  |  |
| TOTAL: |  |  |
| \*Provide a summary explanation for any dropouts: |

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| The following questions refer to all sites involved in the research: |
| Yes\* | No |  |
| [ ]  | [ ]  | Since the last IRB continuing review, have participants experienced any harms (expected or unexpected)? |
| [ ]  | [ ]  | Since the last IRB continuing review, have there been any unanticipated problems involving risks to participants or others since the last IRB review? |
| [ ]  | [ ]  | Since the last IRB continuing review, have any participants or others complained about the research? |
| \*Attach a summary explanation or description for each question whose answer is “Yes.” |

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| In order to close this study, it MUST meet ALL of the following requirements: |
| Yes | No\* | \*If you answer NO to any of these 4 criteria – closure is not appropriate at this time |
| [ ]  | [ ]  | All participant recruitment and enrollment is complete (i.e., no new participant recruitment or enrollment are ongoing)  |
| [ ]  | [ ]  | All participant specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained)  |
| [ ]  | [ ]  | No further contact with participants is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary)  |
| [ ]  | [ ]  | Analysis of participant identifiable data, records, specimens are complete (i.e., use or access to participant identifiable data is no longer necessary. Note: this includes review of source documents by study sponsors.) |

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| **Please provide a brief summary of the study results at this point in the space below.**  |
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| Study is Closed / Terminated (No further enrollment; study is completed) |
| Effective Date: |  |
| Reason:  |  |
| Additional comments:  |  |
| **Investigator or Faculty Advisor Signature:**  |  |

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| **IRB USE ONLY:**  |  |

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|  **Comments:**   |  |