**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 review (continuing or initial), have participants experienced any harms (expected or unexpected)? |
|  |  | Since the last IRB review (continuing or initial), have there been any unanticipated problems involving risks to participants or others since the last IRB review? |
|  |  | Since the last IRB review (continuing or initial), 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 FOLLOIWNG 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** |  |