**UWG Institutional Review Board**

1601 Maple Street

ORSP Office – 3rd Floor Pafford Social Sciences Building

Carrollton, GA 30118

Phone: 678/839-6119 / irb@westga.edu

**Closure Request Form**

(\*To be submitted no later than 60 days after your research project has been completed. Please complete all information in the form or indicate “NA” as appropriate)

**STUDY DEMOGRAPHICS**

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| Full Protocol (study) Title: |  |
| IRB Approval # & Approval Date: |  |
| Principal Investigator (PI or sPI): |  |
| Faculty Advisor name & email: |  |
| Department(s): |  |
| IRB Approval Date: |  |
| IRB Expiration Date: |  |
| IRB Closure Form Submission Date: |  |

*\*****If IRB Approval Has Expired:*** *No research related activities may occur after the protocol expiration date unless the PI contacts the IRB in advance and it is determined that continuation during expiration is appropriate for subject safety. In the space below, please indicate if any activity has occurred during the lapse in approval. If yes, please describe the activity in the space provided:*

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| **SECTION I – Who should the IRB contact with questions regarding this study?** | |
| Name: | Telephone: |
| UWG Email (or best contact for sPI): | |

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| **SECTION II – Indicate the reason for closing the study as well as any additional necessary information:** | |
|  | Project complete, enrollment ended (closed) |
|  | Project was never initiated\* |
|  | Project began, but no subjects were enrolled, no data collected |
|  | PI does not wish to pursue |
|  | PI is leaving UWG |
|  | Student PI (sPI) is graduating or has graduated |
| \*If the project was not conducted, explain why: | |
| Other/Additional information: | |

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| **SECTION III – Did the research result in any publications (or are there any publications pending)?**  YES  NO - If YES, feel free to provide references in the space below. |
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| Please describe any other plans for using the results: |

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| **SECTION IV – Identify your study’s funding source:** |
| Industry funding  Federal Funding  Internal UWG Funding  Other\*  No Funding |
| If “other,” please explain: |

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| **SECTION V – To assess whether closing is appropriate, please complete the following:** | |
| 1. **For All Studies:** | |
| Have all subjects completed all study related visits and procedures?  \**if* ***no****, closure with the IRB is* ***not*** *appropriate at this time.* | YES  NO\* |
| Is any further contact with subjects needed for reasons related to research?  \**if* ***yes****, closure with the IRB is* ***not*** *appropriate at this time.* | YES\*  NO |
| Is any further access to identifiable subject data required for research purposes (data analysis, manuscript preparations, etc.)?  \**if* ***yes****, study closure with the IRB is* ***not*** *appropriate at this time.* | YES\*  NO |
| 1. **For Industry Sponsored Studies Only:** | |
| Has the sponsor completed a close out visit at all UWG study sites? | YES  NO |
| \**if* ***no****, closure with the IRB is not appropriate at this time or clarification is required from the sponsor stating that a site visit will not be conducted.*  \**if* ***yes****, please provide a copy of the sponsor’s closeout visit letter or other documentation indicating that closure with the IRB is appropriate at this time.* | |

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| **SECTION VI – Outstanding Items Assessment** | |
| 1. **Are there any pending actions related to previously submitted items (modifications, exceptions, deviations, reportable events) that have not been addressed or any items not previously submitted to the IRB that require submission to the IRB at this time?**   \**if* ***yes****, closure with the IRB is not appropriate at this time. Please contact an IRB Administrator to rectify any previously submitted items that have not been fully processed prior to submitting for closure.* | YES\*  NO |
| 1. **Investigator Initiated Trials ONLY**: Have results been submitted to Clinical Trials.gov? | |
| YES: Please submit a copy of the confirmation that results were received | |
| NO: Closure with the IRB is not appropriate at this time. Please submit results to CT.gov before submitting a closure request to the IRB | |
| NA: Study oversight is conducted by an industry sponsor who is responsible for CT.gov posting | |
| NA: Study does not meet NIH criteria of a clinical trial or it was determined that posting was not required. | |

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| **SECTION VII – Subject Engagement** | |
| 1. Number of subjects approved: |  |
| 1. Number of subjects enrolled: |  |
| 1. Total number of consents signed: |  |
| 1. Number of subjects who withdrew: |  |
| 1. Have there been any complaints about the research? | YES\*  NO |
| \**if* ***yes****, provide a detailed explanation:* | |

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| **SECTION VII – Confidentiality of Records** | |
| Data set is:  Anonymous  De-Identified  Identifiable | |
| 1. Describe how the PI, sPI, or FA will store records to maintain privacy and confidentiality: |  |
| 1. Describe where the PI, sPI, or FA will store records to maintain privacy and confidentiality: |  |
| 1. Federal regulations require research records to be stored for at least 3 years past study closure.\* Indicate how long the PI, sPI, or FA will store records past the study closure date: |  |
| ***\*Investigator Responsibilities:*** *Investigators are required to maintain their research records and the original signed informed consent forms for at least three years after the close of the study, according the timeframe approved IRB application and consent documents, or according to sponsor requirements. Signed authorization forms and consent forms that incorporate authorization for the use of protected health information for research and the tracking of disclosures of protected health information for research, must be maintained by the principal investigator for at least six years to comply with privacy regulatory requirements. Records must be accessible for inspection by authorized representatives of federal or accreditation agencies or departments.* | |
| 1. If PI is leaving UWG (new faculty appointment, student graduation, etc.), copies may be taken with PI to new institution. Indicate where at UWG the original data and/or consent forms will be stored per the record retention requirements: |  |

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| **Closure Form Completion**  *\*By signing this form, the principal investigator (PI or sPI) and the person completing the form (if other than the investigator) certify that he/she has disclosed to the IRB all relevant information. The principal investigator and person completing the form acknowledge that any further interaction with the participants in this study or study information that includes personally identifiable information has not been approved by the University of West Georgia IRB.* |
| Name of person completing this form: |
| Signature of person completing the form: |
| Principal Investigator name: |
| Principal Investigator signature: |
| Faculty Advisor name (if sPI): |
| Faculty Advisor signature: |
| Date: |

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| **IRB USE ONLY** | |
| Are all basic requirements for closure satisfied by this application?  \**if* ***no****, please summarize outstanding issues and responses:* | YES  NO\* |
| If Industry Sponsored: Have all additional requirements been satisfied?  \**if* ***no,*** *please summarize outstanding issues and responses:* | YES  NO\*  NA |
| If Industry Sponsored: Has the business administrator verified payment from the sponsor? If payment issues exist, please note and do not place for final approval until resolved: | YES  NO\*  NA |
| Screener’s final recommendation and reviewer assignment:  Approved  Return for Revisions  Disapproved | |

Signature of IRB Reviewer Date