

**UA Little Rock Institutional Review Board**

**Request for Protocol Closeout**

# A closeout report should be submitted when data collection and identifiable data analysis are complete.

# NOTE: A study can only be closed under the following circumstances and conditions:

# As a general rule, identifiers should be destroyed. This includes audio and video recordings, stills, and any other information that could identify individuals either separately or in combination with other information.

# It is possible that a protocol can be closed without the identifiers being destroyed.

# If the research team wishes to close a protocol but retain identifiers, it is required that: 1) the informed consent document states that the identifiers will be retained; and 2) the PI should confirm to the IRB (on this form) that they understand that any further use, analysis, or study of that data will require a new protocol.

# The UA Little Rock IRB does not reopen closed protocols.

# This form does not extend the approval period for a protocol.

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| 1. ***Investigator Information***
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| **Principal Investigator:**       | **Email:**       |
| **Department:**       | **Phone:**       |
| **Co-Principal Investigator:**       | **Email:**       |
| **Department:**       | **Phone:**       |
| **Co-Principal Investigator:**       | **Email:**        |
| **Department:**       | **Phone:**       |
| **Co-Principal Investigator:**       | **Email:**        |
| **Department:**       | **Phone:**       |
| **Faculty Advisor:**       | **Email:**        |
| **Department:**       | **Phone:**       |
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| 1. ***Protocol Information***
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| **Title of Protocol:**       |
| **IRB Protocol #:**       |
| **Protocol Expiration Date:**       |
| **Identify your study’s funding source (Industry funded, Federal grant, Internal UA Little Rock grant, None, Other):**       |
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| 1. ***Contact Information***
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| **Who should the IRB contact with questions?** |
| **Name:**       | **Telephone:**       |
| **Email:**       |

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| **1. If IRB Approval 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.*       |

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| **2. Research Status** |
| **Select one of the statuses (A – D) below. If none are applicable, this research may not be eligible for closure.** |
| **[ ]  A. Research has not started (i.e., no subjects enrolled and study never commenced).**Explain why this study never commenced below, then skip, sign, and submit this form to the Office of Research Compliance.       |
| **[ ]  B. Enrollment closed; research activities limited to data analysis only.*** *All of the following conditions must apply*

**[ ]** No data is being obtained through intervention or interaction with participants,[ ]  Data is not identifiable (i.e., data has been de-identified and code keys linked with identifiers have been destroyed); and**[ ]** Only de-identified data is being analyzed |
| **[ ]  C. Study complete/data analysis is complete.*** *All of the following conditions must apply*

**[ ]** No data is being obtained through intervention or interaction with participants,**[ ]** Data is not identifiable (i.e., data has been de-identified and code keys linking to identifiers have been destroyed); and**[ ]** Data is not being analyzed; or, for multi-site study, UA Little Rock site is no longer engaged. |
| **[ ]  D. Study and data analysis complete. Retaining identifiers for possible future use or for safety purposes.*** *Maintaining individually identifiable information or data with plans for future research. Was this explained in the approved protocol and Informed consent?*

**[ ]  Yes** **[ ]  No****[ ]  If yes,** the PI is aware that any future use requires IRB approval.**[ ]  If no,** contact the IRB. |

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| **3. To assess whether closing is appropriate, please complete the following:** |
| 1. **For All Studies:**
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| * Have all participants 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 participants 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**, closure with the IRB is not appropriate at this time. | **[ ]  Yes** **[ ]  No** |

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| 1. **Thesis or Dissertation:**
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| * Is this a thesis or dissertation?
 | **[ ]  Yes** **[ ]  No** |
|  **\*If yes,** have all third parties signed off saying the work is complete?  | **[ ]  Yes** **[ ]  No** |
|  **\*If no,** closure with the IRB is not appropriate at this time. |

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|  **C. Outstanding Items Assessment:**  |
| * Are there any pending actions related to previously submitted items (Modifications, Exceptions, Deviations, Reportable Events) that have not yet been addressed or any items not previously submitted to the IRB that require submission to the IRB at this time?
 |  **[ ]  Yes\*** **[ ]  No** |
|  **\*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 this request for closure. |

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| **4. Adverse Events or Unexpected Problems** |
| *Were there any adverse events or unexpected problems encountered during the study?***[ ]  Yes**  **[ ]  No** *(***\*If yes***, please complete and submit the Adverse Events form - https://ualr.edu/irb/home/irb-**forms/)* |
| *Have all adverse events or unexpected problems been reported to the IRB?***[ ]  Yes** **[ ]  No** (**\**If no****, attach a letter of notification with an explanation.*) **[ ]  N/A** |

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| **5. Publications, Presentations and Recent Findings** |
|  *Have there been any presentations or publications (or any publications pending) resulting from this study?***[ ]  Yes** **[ ]  No** |
|  *If yes, please cite references.*       |

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| **Required Signatures:** |
| *Signature of Principal Investigator:*       *Date:*       |
| *Signature of Faculty Advisor/Committee Chair:*      *Date:*      |

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| **IRB USE ONLY** |

**Date of Screening:**

* Are all basic requirements for closure satisfied by this application:**[ ]  Yes**  **[ ]  No**

**- If no**, please summarize outstanding issues and responses.

* Screener’s final recommendation and reviewer assignment:

**APPROVED VIA EXPEDITED IRB REVIEW:** **[ ]**

**Issue(s) Identified – Referred to IRB Staff with Instructions:** [ ]  **Yes** [ ]  **No**

**Signature of Expedited Approver:**       **DATE:**