**Aurora University**

**Institutional Review Board**

**STUDY CLOSURE FORM**

Complete this form when your IRB approved study has been completed. Please see the definitions and questions below to determine if it is appropriate to submit for closure of the study. DO NOT complete this form if the study is ongoing and set to expire (please complete the “Project Renewal Form”). Upon submission and acceptance of study closure, the study materials will be archived and kept for 3 years. Studies that are not appropriately closed through submission of this form will be administratively withdrawn and closed by the AU IRB after failure to communicate from principal investigator(s).

 **Researcher(s):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study Title:**

**IRB Approval Number (from electronic approval letter):**

**Date of IRB approval:**

***Provide contact information for the researcher. If more than one, provide information for main contact person for study.***

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ AU E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor (if researcher is a student): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ AU Email: \_\_\_\_\_\_\_\_\_\_\_\_

**I. Determination of Study Closure**

1) Have ALL research participants completed all research-related activities? Yes\_\_\_\_\_ No\_\_\_\_\_\_

 \*If “No,” the study is not ready to be closed. If expiration is close, submit “Project Renewal Form”

2) Has ALL participant enrollment in the study ceased? Yes\_\_\_\_\_\_ No\_\_\_\_\_\_

 \*If “No,” the study is not ready to be closed. If expiration is close, submit “Project Renewal Form”

3) Are any research-related contacts with participants needed? Yes\_\_\_\_\_\_ No \_\_\_\_\_\_\_

 \*If “Yes,” the study is not ready to be closed. If expiration is close, submit “Project Renewal Form”

4) Have ALL remaining data sets under analysis been stripped of identifiers and is further access to identifiable participant data is no longer required? Yes\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_

 \*If “No,” it is possible the study is not ready to be closed. Please contact the IRB.

**II. Additional Details\***

5) Are there any IRB-related reviews pending regarding this research, such as project renewal, study modification, or the reporting of adverse events? If yes, please identify these below and provide an explanation of your submission for study closure. If no, please mark N/A.

6) Provide any additional relevant details regarding the submission of study closure below. If none, please mark N/A.

**I certify that the information on this form is accurate to the best of my knowledge.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Researcher Signature Date**

**This form has been reviewed and the study will be closed and archived.**

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**\***The IRB will communicate steps to principal researcher(s) should any additional details indicate the study should not be closed or that there is a need for further clarification