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| Aurora IRB***Final Report*** | ***Aurora IRB*** *Acknowledgement***Aurora RSPP Acknowledgement (date):** \_     \_\_\_\_ An acknowledged copy of this form will be returned to the PI. No letter of approval will be issued.**For IRB Use Only**  |
| **Use This Form To Report The Closure Of A Research Study conducted at Aurora (under the oversight of the AHC IRB or an External IRB)**[Study closure should not be confused with closure of a study to subject accrual /enrollment. If you wish to close a study to accrual/enrollment, complete and submit a [*Change*](https://medicalprofessionals.aurorahealthcare.org/irb/irb-forms.asp) form.]OHRP and the Aurora RSPP/IRB consider a research study to continue to involve human subjects as long as the investigators conducting the research continue to obtain: 1. data about the subjects of the research through intervention or interaction with them; OR
2. identifiable private information about the subjects of the research (45 CFR 46.102(f)). OHRP interprets obtaining identifiable private information to include an investigator’s use, study, or analysis of identifiable private information.

This form should be submitted to the Aurora RSPP when human subject research is complete at Aurora. This must occur prior to the expiration/lapse date of IRB approval. **Upon review/acknowledgment, the study will be closed with the Aurora RSPP/IRB.** |

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| **Principal Investigator:** |       | **Date of request:** |       |
| **Aurora IRB Protocol #:**      **Title:**       |
| **Sponsor:** |       |

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| **Number of subjects who met inclusion criteria and participated (even if withdrew early) in the research study** |
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1. Reason for study closure. Check one:

[ ]  The study is completed at Aurora

[ ]  Loss of funding

[ ]  The sponsor or FDA has permanently closed the study at all research sites. Provide explanation (e.g. loss of funding; new information has been collected that leads to an unfavorable risk benefit ratio; low study-wide enrollment; DSMB request; etc). Note that any significant new information supporting this decision may need to be reported as an Unanticipated Problem per RSPP SOP #7:

[ ]  The research was never initiated at Aurora. Provide explanation:

[ ]  The research was initiated but no subjects were ever enrolled at Aurora

[ ]  The local PI is terminating the research at Aurora prior to meeting intended goals/objectives. Provide explanation. Note that any significant new information supporting this decision may need to be reported as an Unanticipated Problem per RSPP SOP #7:

[ ]  The local PI is leaving Aurora, and no one is available to take over the study

[ ]  Other. Provide explanation:

1. [ ]  By checking this box, you are confirming that:
* Enrollment of new subjects at all Aurora sites is permanently closed;
* All enrolled study subjects at Aurora have completed protocol-related interventions/interactions (e.g., tests, physical or psychological exams, administer medications or treatments of unexpected reactions/protocol defined recurrences, etc.) including collection of data for follow-up;
* Individually identifiable private information is no longer being collected on subjects (e.g. contact via phone call, letter, or interview; database or medical record review, etc.);
* Data analysis indicates no new information needs to be provided to enrolled subjects;
* Data or biological specimens collected in the study are anonymized (i.e. there is no personally identifiable information associated with the data or specimens including a code) – unless the identifiable data/samples are being used in another IRB overseen study
* You will be storing the retained data/specimens in accordance with the parameters outlined in the submission application/protocol

**NOTE retained identifiable data cannot be used for any other research purpose without obtaining a new IRB approval. Contact the Aurora RSPP with questions.**

1. I have included research related documents not previously submitted along with this Final Report. Such documents may include: Unanticipated Problem reports; sponsor information (including notification of study closure); publications resulting from the research, etc. [ ]  **YES** [ ]  **NO
If YES, describe:**

 (Printed name of individual submitting report (Date)

[ ]  If Submitter is not the PI, Submitter certifies that PI is aware of the study closure.

 *If an e-mail submission, attach a copy of the form to an email addressed to* *irb.office@aurora.org**. If a Cyber IRB submission, upload a copy of the completed form to Cyber.*