**PROTOCOL APPROVAL AND SIGN-OFF FORM**

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| **Protocol Title:** |  |
| **Protocol #:** |  |
| **Protocol Version & Date:** |  |
| **Sponsor-Investigator/CPI:** |  |
| **Sponsor:** |  |

*Note: It is mandatory that this process is completed prior to the protocol being submitted to the Human Research Ethics Committee (HREC) for review. Any subsequent protocol amendments should also follow this same approval and sign-off process.*

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| **CLINICAL TRIAL COORDINATOR APPROVAL**I have read and reviewed the above protocol and approve it to proceed to HREC Review: |
| Name:  |
| Signature: |  | Date of Approval: |  |

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| **STATISTICIAN APPROVAL**I have read and reviewed the above protocol and approve it to proceed to HREC Review: |
| Name:  |
| Signature: |  | Date of Approval: |  |

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| **SPONSOR-INVESTIGATOR/CPI APPROVAL**I have read and reviewed the above protocol and approve it to proceed to HREC Review: |
| Name: |
| Signature: |  | Date of Approval: |  |