Version Tracking Date:

|  |  |
| --- | --- |
| **Aurora IRB*****IRB Application*** | For IRB Office Use Only |
| *Facilities where research will be conducted:*Aurora Medical Center (list sites):      AMG/Aurora Clinic (list sites):      VLCC (list sites):       |

# SECTION I: General Information

|  |
| --- |
| Protocol Title: |
| Protocol number:  |  |
| Study sponsor:  |  | Identify all source(s) of funding for the project: |  |
| Does this study require ICH GCP compliance? [ ]  Yes [ ]  No | Will the results of the study be submitted to or held for inspection by the FDA (i.e. FDA regulated)? [ ]  Yes [ ]  No | Is this a PHS funded study?[ ]  Yes [ ]  No |
| In your opinion, is this study[ ]  **biomedical or** [ ]  **social- behavioral** in design (see glossary for definitions)? NOTE: this classification will determine which CITI human subject research certification\* course that all key personnel must complete. Contact the RSPP Office if you have questions on Research Certification requirements. The Aurora RSPP will make the final determination on the nature of the study design. |
|  |
| Principal Investigator (**INCLUDE EARNED DEGREES**): |  | Department/Office: |  |
| PI’s Telephone: |  | PI’s E-mail: |  |
| Are you (the PI) employed by Aurora Health Care? [ ]  Yes [ ]  No |
| [ ]  By checking this box, I attest that the **included** Delegation of Authority (DOA) Log identifies all **Investigators/Key Personnel\*^** participating in this study (See Glossary for definition). Note: Only those individuals listed on the DOA log will be considered approved researcher personnel for this project until a modification is submitted/approved by the IRB. |
| List any Investigators/Key Personnel who are **NOT** employees of Aurora Health Care. [ ]  N/A |  |
| Primary contact person who will be responsible for the research files/documents/ correspondence with the RSPP office regarding this study: |  |
| Telephone: |  | E-mail: |  |

|  |
| --- |
| ***The IRB meeting agenda has a limit of 6 protocols per meeting. The RSPP office must receive all of the applicable items listed in Section II by NOON of the submission deadline to be considered a complete submission. If there are extenuating circumstances, you may call the RSPP Director to request a deadline extension; however, extensions are not guaranteed.*** |
|  |

# SECTION II: Submission Requirements: these documents/requirements must be included/met prior to acceptance by the Aurora IRB.

|  |
| --- |
|  ***All documents must be submitted electronically to*** ***irb.office@aurora.org*** ***(complete protocol title must be referenced in the e-mail) OR uploaded into Cyber IRB*** |
| **RAP authorization - Written administrative acknowledgement from the Aurora Research Institute (****Research Administration Pre-authorization – RAP****) is required prior to submission to IRB. Note: please inform RAP if 1) data/specimens are leaving Aurora OR 2) the research will be conducted on employees or physicians, as acknowledgement of their inclusion must be received prior to IRB review.** |
| Completed Submission Form [Word document and PDF of signed form if **NOT** uploaded into Cyber IRB] |
| Informed consent document using Aurora IRB’s recommended template language [Word document] (if applicable). If appropriate, you may request a waiver of consent/documentation of consent in this application. |
| Complete protocol (from sponsor or lead investigator) **Include** Version Date/Tracking Information listed here:  |
| Sponsor’s sample informed consent document (unless not provided by the sponsor) |
| If applicable, Investigator’s Brochure, Package Insert (for approved drugs), or Device Operator’s Manual: Date or tracking information:  |
|  |
| Delegation of Authority Log (Preferred format is found on the [Aurora RSPP website (form 402-C)](https://medicalprofessionals.aurorahealthcare.org/irb/irb-forms.asp). A sponsor’s DOA log may be used as long as all necessary information (as indicated on the Aurora preferred form) is included.  |
| Surveys, questionnaires, case report forms (as necessary) |
| Recruitment materials (fliers, posters, etc.) and all materials to be seen by subject (diary’s, information cards) (if applicable) |
| Form 502.1 for Preparatory to Research Activities or form 502.3 for Waiver Of Authorization (if applicable) |
| PI’s current CV or other supporting material evidencing privileges/experience necessary to conduct research  |
| **\*** Aurora – required Research Education completed for the PI and each Investigator/Key Personnel (listed on Delegation of Authority log). Verified by RSPP Staff prior to acceptance of application. See [Aurora RSPP website](https://medicalprofessionals.aurorahealthcare.org/irb/research-certification.asp) or call the RSPP Office at 414-219-7744 for more information. |
| **^** PI and all Investigators/Key Personnel (listed on Delegation of Authority log) have completed their Significant Interest Disclosure . Verified by RSPP Staff prior to acceptance of application. See [Aurora RSPP website](https://medicalprofessionals.aurorahealthcare.org/irb/conflict-of-interest.asp) or call the RSPP Office at 414-219-7744 for more information. |

# SECTION III: IRB Review Fees

**As of 11/1/18**, annual IRB Review fees will be charged for this study (see guidance document entitled **IRB Review Fees** on the [RSPP website](https://medicalprofessionals.aurorahealthcare.org/irb/index.asp)). Certain studies may qualify for a waiver of the fees. The established waiver criteria are listed below. If you wish to request a waiver, and your study qualifies for one of the following, please check the appropriate box. Consideration of your request will be given by the Aurora RSPP office.

*Extenuating circumstances* - If your study does not meet one of the listed waiver criteria, you may make a request for a waiver from the Advocate Aurora Compliance department. An email should be sent to the Research Compliance Officer outlining your request, and justification. If approved by Compliance, this **MUST** be included with this form. If not included, an IRB Review Fee invoice will be generated and sent to the PI.

**IRB Review Fee Waiver criteria (check one):**

[ ]  unfunded research conducted to fulfill specific or general academic or accreditation requirements of students or training programs affiliated with Advocate Aurora Health [AAH] (e.g., residents, fellows, nursing students) or research by other students (e.g. Aurora or Advocate employees obtaining an advanced degree) that aligns with AAH’s mission;

[ ]  investigator-initiated research **led by an Advocate Aurora Health team member** that is not funded either internally or by an external organization

[ ]  research funded by a federal, state, or local government entity that doesn’t allow inclusion of IRB fees or the amount of funds granted is so limited that paying for IRB review services would not allow the research to go forward;

[ ]  an activity requiring IRB review but conducted for clinical, non-research purposes (i.e., Emergency Use, Compassionate Use, Expanded Access, HUDs)

[ ]  an activity funded solely by a not-for-profit group/entity and the group/entity either does not allow the charging of IRB fees or the amount of funds granted is so limited that paying for IRB review services would not allow the research to go forward

[ ]  Check here if your study does not qualify for a waiver. You will be invoiced for IRB Review Fees.

You will be notified if your study qualifies for a waiver of the IRB Review Fee. If it does **NOT** qualify for a waiver, an invoice for IRB review fees will be sent to the PI of the study/cc’d to the study contact. The invoice is to be paid within 60 days of the date of the invoice. **The PI is expected to pay the fee per the invoice instructions OR forward the invoice to the study sponsor/grant funder for payment.** There may be times (**these will be noted on the invoice**) where the Aurora Research Institute will contact the sponsor/grant funder on behalf of the PI.

# SECTION IV

1. Expected length of project in years (for multicenter studies, give sponsor’s expected duration)
2. Subject Enrollment

Projected Study-wide enrollment:

Local Enrollment (Please check one)

[ ]  Less than or equal to 10 subjects

[ ]  Greater than 10 subjects – provide a range

1. Please check if any of the following individuals are participating in this study:

[ ]  a Medical Resident or Fellow? [ ]  a student (whether or not an Aurora employed caregiver)?
[ ]  a Volunteer?

**If Yes, this individual must be listed as "Investigator/Key Personnel" on the DOA log (see section I of this form).**

1. FDA Determination(s)

Note: The fact that the study may use FDA-approved drug(s), biologic(s), or device(s) does not automatically exempt the study from IND or IDE requirements. Contact the study sponsor or RSPP office for guidance.

**Does this protocol involve the use of a DRUG in a human other than the use of an approved drug in the course of medical practice?**

**Does this protocol involve the use of a BIOLOGIC in a human other than the use of an approved biologic in the course of medical practice?**

**Does this protocol evaluate the safety or effectiveness of a DEVICE in research subjects, a control group, or their biological specimens?**

If you answered **YES** to any of the categories above, you must complete the section(s) below associated with that category.

If **DRUG** is answered **YES**:

List the drug(s) being evaluated in the submitted protocol (the drug(s) that are being evaluated for safety or effectiveness, or for another indication):

Note: All drugs that are being administered as part of the submitted protocol for clinical purposes that would be administered regardless of the study, or that are being administered because of the experimental agent (e.g., an approved anti-emetic being administered due to the side effects of the experimental chemotherapy agent being studied, an anti-clotting agent being administered in a stent protocol) should be accounted for in the submission application [in SECTION V SYNOPSIS] but do not require an IND.

Is there at least one IND number assigned to the protocol?  **and complete the appropriate box:**

|  |
| --- |
| IF **YES** [to IND number]:Enter all IND numbers: Indicate who holds the IND? Will the sponsor provide all drugs without cost to the institution or subject? If the IND number(s) is not printed on the sponsor’s protocol, attach a copy of one of the following for the protocol: * Communication from the sponsor verifying that the IND number provided is the correct IND for the submitted protocol.
* Communication from the FDA issuing the IND number.
 |
| IF there is **NO** IND number associated with the protocol, ALL drugs fall into one of the categories of exemption from Part 312 (and does not require IND — an “IND Exemption”):[ ]  **Exemption Option*** The sponsor has received a letter of IND exemption from the FDA for the submitted protocol. If this is the case, attach a copy of the IND exemption letter to the submission.

[ ]  **Exemption [312.2(b)(1)] [ALL of the following must be true]*** ALL drugs/biologics are lawfully marketed in the United States.
* The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
* The research is not intended to support a significant change in the advertising for the product.
* The research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
* The research is conducted in compliance with the marketing limitations described in 21 CFR 312.7.

[ ]  **Exemption [312.2(b)(2)] [ALL of the following must be true]*** A clinical investigation for an *in vitro* diagnostic biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; (3) Anti-human globulin.
* The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
* The diagnostic test will be shipped in compliance with 21 CFR 312.160.

[ ]  **Exemption [312.2(b)(5)]*** A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.
 |

If **BIOLOGIC** is answered **YES**:

List the biologic(s) being evaluated in the submitted protocol (the biologic(s) that are being evaluated for safety or effectiveness, or for another indication):

Note: All biologics that are being administered as part of the submitted protocol for clinical purposes that would be administered regardless of the study, or that are being administered because of the experimental agent should be accounted for in the submission application [in SECTION V SYNOPSIS] but do not require a BB-IND.

Is there at least one BB-IND number assigned to the protocol?  **and complete the appropriate box:**

|  |
| --- |
| IF **YES** [to BB-IND number]:Enter all BB-IND numbers: Indicate who holds the BB-IND? Will the sponsor provide all drugs without cost to the institution or subject? If the BB-IND number(s) is not printed on the sponsor’s protocol, attach a copy of one of the following for the protocol: * Communication from the sponsor verifying that the BB-IND number provided is the correct IND for the submitted protocol.
* Communication from the FDA issuing the BB-IND number.
 |
| IF there is **NO** IND number associated with the protocol, ALL biologics fall into one of the categories of exemption from Part 312 (and does not require BB-IND “IND Exemption”):[ ]  **Exemption Option*** The sponsor has received a letter of BB-IND exemption from the FDA for the submitted protocol. If this is the case, attach a copy of the IND exemption letter to the submission.

[ ]  **Exemption [312.2(b)(1)] [ALL of the following must be true]*** ALL drugs/biologics are lawfully marketed in the United States.
* The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
* The research is not intended to support a significant change in the advertising for the product.
* The research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
* The research is conducted in compliance with the marketing limitations described in 21 CFR 312.7.

[ ]  **Exemption [312.2(b)(2)] [ALL of the following must be true]*** A clinical investigation for an *in vitro* diagnostic biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; (3) Anti-human globulin.
* The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
* The diagnostic test will be shipped in compliance with 21 CFR 312.160.

[ ]  **Exemption [312.2(b)(5)]*** A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of a BB-IND.
 |

If **DEVICE** is answered **YES**:

List any device(s) being evaluated for safety and effectiveness as part of the submitted protocol:

Note: Any device(s) being administered as part of the submitted protocol for clinical purposes [that is, would be administered regardless of the study, or that are being administered because of the experimental agent (e.g., the delivery system for the experimental drug)], but is not being evaluated for safety and effectiveness, should be accounted for in the submission application [in SECTION V SYNOPSIS] but not listed here.

IDE/HDE Requirements (ONE must be “**YES**”).

The protocol has an IDE/HDE (If “YES”, complete ***IDE/HDE Validation*** section)

The protocol indicates the device qualifies for an abbreviated IDE (“NSR”) (If “YES”, complete ***Abbreviated IDE*** section)

The protocol indicates ALL devices qualify as exempt from IDE requirements (If “YES”, complete ***IDE Exemptions*** section)

|  |
| --- |
| ***IDE/HDE Validation Section*** Enter the IDE/HDE number(s): What is the device category?  [ ]  Category A [ ]  Category B. *If the device has an IDE number and is a Category B device, a copy of the letter to the Fiscal Intermediary requesting Medicare benefit coverage will be reviewed by the Aurora Billing Department*.  [ ]  Unknown at this time. Who holds the IDE?  Will the sponsor provide the investigational device(s) without cost to the institution or subject? If NO, and the device/services (either hospital or professional) will be billed to Medicare, prior notification to Medicare is required. Contact Aurora’s Special Projects Billing Representative in the Central Business Office at clinicalresearchbilling@aurora.org or 414.649.7589 for a copy of Medicare’s requirements.*A copy of FDA’s IDE letter giving clearance for the study to begin must be forwarded to the Aurora IRB office before subject enrollment may begin. If there are conditions placed on the study by the FDA, a copy of the* ***unconditional*** *letter must be forwarded to the Aurora IRB office when available. Subjects may not be enrolled into the study until the FDA has issued an IDE letter stating that enrollment may begin.* |
| ***Abbreviated IDE Section* (Non-Significant Risk device “NSR”) determination (All must be checked)**[ ]  The device is not banned.[ ]  The device is not a significant risk device (all of the following must be true):* The device is not intended as an implant and does not present a potential for serious risk to the health, safety, or welfare of a subject;
* The device is not purported or represented to be for use supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
* The device is not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject; or
* The device does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

[ ]  The investigator/sponsor will label the device in accordance with FDA regulations (21 CFR 812.5).[ ]  The investigator/sponsor will comply with FDA requirements for monitoring investigations (21 CFR 812.46).[ ]  The investigator/sponsor will comply with requirements for records and reports (21 CFR 812.140, 21 CFR 812.150).[ ]  The investigator/sponsor will not market or promote the device (21 CFR 812.7). |
| ***IDE Exemptions*: ALL devices falls into one of the categories of exemption from Part 812 (and does not require IDE):**[ ]  **Exemption [812.2(c)(1) or 812.2(c)(2)]** [ALL of the following must be true]* The device was not regulated as a drug before enactment of the Medical Device Amendments (Transitional Device)**.**
* The device is FDA-approved/cleared.
* The device is being used or investigated in accordance with the indications in the FDA-approved/cleared labeling.

[ ]  **Exemption [812.2(c)(3)]** [ALL of the following must be true]* The device is a diagnostic device.
* The sponsor will comply with applicable requirements in 21 CFR 809.10(c).
* The testing is noninvasive.
* The testing does not require an invasive sampling procedure that presents significant risk.
* The testing does not by design or intention introduce energy into a subject.
* The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

[ ]  **Exemption [812.2(c)(4)]*** The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

[ ]  **Exemption [812.2(c)(7)]*** The device is a custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
 |

1. Does this research study meet the criteria for registration with ClinicalTrials.gov by the [International Committee of Medical Journal Editors](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html) and/or the Food and Drug Administration Amendments Act of 2007 ([FDAAA 801 Requirements - ClinicalTrials.gov](http://clinicaltrials.gov/ct2/manage-recs/fdaaa))? If yes, has the study been registered? Contact the RSPP office with questions.
It is the Principal Investigator’s obligation to determine whether registration is required. You may not be able to publish if your research met the criteria for registration and you did not comply. The IRB is not responsible for this requirement.
2. Is this a multi-site study (that is, a study conducted at sites outside the Aurora system) in which the Principal Investigator would be considered the lead investigator of the study or Aurora would be considered the lead site?

If YES, describe the plan for coordinating center responsibilities (see RSPP guidance document on RSPP web site for more information):

1. For research that is not industry-sponsored, list any non-Aurora facilities, clinics, or departments where you will be conducting this research:

You are required to make arrangements with the administrators of the non-Aurora facilities to facilitate this research and secure IRB approval from the additional sites. Attach proof of IRB and administrative approval for each site listed. If IRB approval from the additional site(s) has not been obtained, or the site does not have an IRB, final and unconditional Aurora IRB approval will not be granted until all sites have issued IRB approval or entered into an IRB Authorization Agreement deferring oversight to the Aurora IRB.

If you wish to request that the Aurora IRB be the IRB of record for the non-Aurora facility, contact the Aurora RSPP Office at 414.219.7744 to obtain information on this request.

1. Has this protocol been submitted to and disapproved by another Institutional Review Board? If **YES**, list by name:
2. Does this research involve Aurora caregivers or employed physicians as research subjects?

If **YES**, RAP authorization (see section II) **MUST** include clearance for the inclusion of these individuals in the research study. Aurora IRB review will not proceed until this clearance is received from RAP.

1. Does the study involve the use of radioactive material or recombinant DNA or a hazardous biologic?

If **YES**, you are required to obtain Radiation Safety Committee or Institutional Biosafety Committee approval and provide the RSPP office with a copy of the approval. Final Aurora IRB approval will not be issued without this documentation. Contact the RSPP office with questions.

1. Does the undertaking of this research require participation of facilities, clinics, or departments of Aurora Health Care?

If **YES**, in the table below (attach additional sheets as necessary), provide the name and signature of responsible administrator (a written or e-mailed acknowledgment from the administrator may be attached in lieu of signature):

|  |  |  |
| --- | --- | --- |
| **Facility/Department Name** | **Arrangements made?** | **Signature of appropriate administrator**  |
|  |  |  |
|  |  |  |
|  |  |  |

# SECTION V: Synopsis

The Aurora Health Care Institutional Review Board (IRB) is required by federal regulations to ensure that all research involving human subjects is adequately reviewed for specific information and is approved prior to inception of any proposed activity. The IRB use a “primary reviewer” system to review protocols. As such, one or two IRB members review all materials prior to the convened IRB meeting. Federal regulations require that when a primary reviewer system is used, each committee member receive, at a minimum, a copy of the consent document(s) and **a summary of the protocol in sufficient detail to determine the appropriateness of the study-specific statements in the consent document**. Consequently, it is important that you answer **ALL** questions accurately **USING LAY TERMS and it is not appropriate for you to cut and paste sections from the informed consent document and/or the sponsor’s protocol to answer questions**. If you need help or have questions about how to complete this application, please call the Aurora IRB office at 414.219.7744 or e-mail us at IRB.office@aurora.org.

Please provide the requested information in the shaded text boxes. As you type, the text boxes will expand as needed. Alternatively, in lieu of a typed response, you may reference in the text box specific section/page numbers from a prepared protocol (a document separate from this application). Please be sure to provide the specific location of the requested information so that the IRB may locate the needed response. **NOTE: If the IRB cannot locate an appropriate response to the question based upon your answer, your study may be tabled/deferred to a later meeting or provided a condition of approval until the necessary information is provided.**

**BACKGROUND** (provide concise narrative review of the literature or previous studies that support the scientific aims of the research and basis for this study. This should be a relatively detailed overview of past scientific investigations, but the language should be understandable to the non-scientific IRB members. *If the study involves an unapproved device that does not have an IDE, include the rationale for a Non-significant Risk determination.*

**OBJECTIVE** (briefly state the objective – aims and hypotheses to be tested)

**ENDPOINTS** (briefly state the study endpoints)

**DESIGN AND PROCEDURES *Note: The IRB must understand all activities that are considered part of the protocol and what components are done solely for research purposes (even if not considered experimental).***

1. Provide a comprehensive synopsis of the protocol. Include, as applicable, specific details about all activities performed (procedures/tests/interventions), study visits (to include standard of care follow-up visits), randomization, study groups, how drugs will be administered (routes and dosages), how devices will be deployed, sub-studies (e.g., genetic or future unspecified research). Indicate if you are not participating in a particular element of the study as described in the protocol.

1. List the procedures or interventions being performed for research purposes:
2. Are there procedures or interventions being performed for diagnostic or treatment purposes (meaning these procedures or interventions would be done even if the subject were not enrolled in the research study)? If YES, then list.
3. Is there a “follow-up” component to this study? If **YES**, briefly summarize below:
	1. If applicable, describe research related interventions **required** **per protocol** that occur in the case of relapse/reoccurrence/device failure. This includes treatments, interventions, tissue sample collection or diagnostic tests that the subject **would not** undergo outside of the research study. (The IRB would consider this **active follow-up**):
	2. If applicable, describe follow-up activity that is limited to the review and collection of information from medical records or contacting subjects, and/or review of survival status either by contacting the subjects or querying the National Death Index. (The IRB would consider this **post-intervention follow-up**):
4. Will subjects be required to discontinue or modify any current medications or be denied any standard of care treatment(s) for any condition in order to be eligible for or participate in this study? If YES, provide a justification for your response.
5. Design aspects (i.e., placebo control, blinding, randomization, number of study arms, etc.). If the study is placebo controlled, provide a justification for the use of placebo in this study.
6. Describe data collection methods. Surveys, instruments, case report forms (if available), etc. must be attached.
7. Who will be collecting this information? List by title (i.e., study coordinator, principal investigator):
8. Statistical methods, data analysis, and interpretation (include the factors considered in determining an appropriate sample size) ***(NOTE: this information does not need to be included for FDA regulated studies that have an IND/IDE or are Phase IV)***:
9. List any known or anticipated factors that would lead to early termination of subject participation or early study completion.

**BIOLOGICAL SAMPLES**

[ ]  Check if biological samples will be taken for purposes related to the main research study or protocol-defined sub-study. If checked, answer the questions in this section.

1. What is the reason for the collection of samples (check all that apply):

[ ]  Testing/analysis related to the main research study

[ ]  Optional research sub-study

[ ]  Other Explain:

1. Will the collected samples be personally identifiable?
2. Will samples be sent outside of Aurora?

If YES, answer the following:

* 1. Where will the samples be sent?
	2. Will the samples be de-identified or coded before release?
	3. Will the receiving individual/sponsor/group have access to the sample code?
1. Will the research testing/analysis include genetic testing?

Will/May the genetic testing involve whole genome testing?

1. Will clinically relevant results of the research, including individual research results, be provided to the subject?

If NO, why?

1. May the biological specimens be used for commercial profit by the sponsor?

Will the subject share in these commercial profits?

1. Will the biological samples be destroyed after the testing/analysis is completed?

If YES, indicate the plan for disposal once the main study is completed:

If NO, what is the plan for the remaining sample?

[ ]  Check if biological samples will be stored (banked) for future unspecified/unrelated research.If checked, answer the questions in this section. The information provided in this section should be included in the informed consent document.

1. Is this collection optional (that is, subjects may participate in the main study without participating in the sample collection)?
2. The samples collected for future research will be

[ ]  personally identifiable

[ ]  coded

[ ]  de-identified (all HIPAA identifiers removed)

1. Will samples be sent/stored outside of Aurora?

If YES, where will the samples be sent?

1. If the samples will be identifiable or coded, answer the following:
	1. Will the subject’s Protected Health Information (PHI) will be accessed in the future and sent to the holder of the sample? [If **YES**, this must be clearly stated in the informed consent/authorization.]
	2. What PHI will be linked to the code:  {This should be consistent with the information in the informed consent document.}
	3. Who will have access to the sample code:
2. Will the research testing/analysis include genetic testing?

Will/May the genetic testing involve whole genome testing?

1. Will clinically relevant results of the research, including individual research results, be provided to the subject?

If NO, why?

1. May the biological specimens be used for commercial profit by the sponsor?

Will the subject share in these commercial profits?

1. How long will the samples be stored?
2. Indicate the plan for disposal of the sample once the future research is completed.
3. Which IRB is overseeing the future unspecified/unrelated research?

**STUDY RESOURCES** The Aurora IRB, in deciding the appropriateness of study resources, will consider whether there are medical interventions or subject interactions (eg. questionnaire, survey, etc) vs. chart review activities occurring in the study, Please address your responses to the following questions considering all aspects of the study design.

**Facility/Location of Research or Medical Record Access**

1. Where will the activities take place? (check all that apply)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intervention/Interaction | ChartReview |  | Intervention/Interaction | ChartReview |  |
| [ ]  | [ ]  | Aurora Medical Group office or clinic | [ ]  | [ ]  | Non Aurora hospital/clinic |
| [ ]  | [ ]  | Aurora hospital | [ ]  | [ ]  | Other location:  |
| [ ]  | [ ]  | Physician’s private office or clinic | [ ]  | [ ]  | Other location:  |

1. Describe the on-site emergency equipment available for the research subjects if applicable. If the study is conducted in an Aurora hospital or clinic it is assumed that appropriate emergency equipment is available. (Check all that apply): [ ]  NA – chart review study only – no interactions/interventions

[ ]  NA – study conducted in an Aurora hospital or clinic

[ ]  Crash Cart

[ ]  Emergency Meds

[ ]  CPR certified staff

[ ]  911 services

[ ]  Other (describe)

1. If needed during the study, what resources will be available to subjects? (check all that apply)

[ ]  Medical treatment

[ ]  Psychological counseling

[ ]  Genetic counseling

[ ]  Financial assistance (e.g. Aurora-based fund, drug company program)

[ ]  Interpreters

[ ]  All of the listed resources

[ ]  Other

[ ]  Not applicable to this protocol

**Principal Investigator**

1. Have you as Principal Investigator formally delegated research procedures to Investigators/Key Personnel? If **YES**, attach a copy of the sponsor’s Delegation of Authority Log or complete and attach form RR 402-C – Aurora IRB Delegation of Authority Log. The RSPP office expects that the DOA log will be updated as research personnel change (you must include a revised DOA log with the Aurora IRB modification when adding/removing research study personnel). You are expected to keep copies of all logs for the duration of the study.
2. Does the research study include a novel technology/technique? [ ] No [ ] Yes If **Yes**, describe your experience and training in the field or with the investigational article (include information about appropriate Aurora Medical Staff Privileges (credentials) and study-specific training):
3. Are you, as Principal Investigator of this study, aware of any institutional significant interests related to the proposed research? [ ]  Yes [ ]  No
4. Do you, the Principal Investigator, certify that you have made your required annual significant interest disclosure and that your disclosure is up to date? [ ]  Yes
5. Do you believe any disclosed significant interests are related to the proposed Research? If **Yes**, Describe which interest(s):

**Research Staff/Key Personnel** [ ]  Check if not applicable to this study

1. Describe the process for ensuring that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions:
2. If this research study involves a medical procedure in which medical staff privileges/credentials are required (ie. a device or medical procedure is used), provide a listing of the procedures performed **and who will conduct them**. This information will be reviewed by the Aurora Medical Staff Office to validate that key personnel have the appropriate medical privileges/credentials to conduct the research. [ ]  Check if not applicable to this study.
3. Is there protocol specific training that will be required of the Key Personnel (e.g. instruction/mentoring in placement of the investigational device; instruction in conducting research questionnaires or scales)? [ ]  Yes [ ]  No If **Yes**, please explain what training is required, when the training will occur, and who will conduct the training:

**Investigational Agent** [ ]  Check if not applicable to this study

1. Discuss in detail how you plan to control **(store/dispense/prepared/managed/dispose)** investigational drugs/devices/biologics and/or placebo? Provide the name and title of the responsible person for these activities at each location where research will be conducted.
2. If the research study involves the use of drugs (whether study-supplied or commercial), the research team must submit the document entitled [*Investigational Drug Study Pharmacy Notification*](https://iconnect.aurora.org/DotNetNuke/LinkClick.aspx?fileticket=c4tZp7mN0LI%3d&tabid=8874) to the Aurora Pharmacy.Have you submitted this form?

***DOES THE RESEARCH INVOLVE ANY OF THE FOLLOWING?***

|  |  |
| --- | --- |
|  | Deception of subjects |
|  | Sexually explicit materials or questions about sexual orientation, experience, or abuse |
|  | Biological samples (e.g. drug screens) or questions looking for illegal or illicit activity |
|  | Purposeful creation of anxiety |
|  | Any procedure that might be viewed as an invasion of privacy |
|  | Physical exercise or stress |
|  | Extraction or use of blood, body fluids, or tissues |
|  | Genetic research (DNA) |
|  | Health Economic Sub-Study conducted by the sponsor or another entity |

**If you have chosen YES above, justify:**

**RESEARCH SUBJECTS**

This research involves

***Does the research specifically require the inclusion of subjects from any of the following categories?***

|  |  |  |
| --- | --- | --- |
|  |  | Aurora staff/physicians (Aurora RSPP will obtain administrative clearance) |
|  |  | Children {if **YES** indicate age range  and submit an assent document is appropriate} |
|  |  | Children who are wards of the State (e.g., a child in the legal custody or guardianship of the state of Wisconsin, a child in foster care, etc.) –***{NOTE: If an enrolled child becomes a ward of the State, you must notify the RSPP office immediately.}*** |
|  |  | Over 65 years of age |
|  |  | Physically disabled |
|  |  | Individuals with impaired decision-making capacity |
|  |  | Economically or educationally disadvantaged |
|  |  |  |
|  |  | Fetuses or abortuses or neonates |
|  |  | Subjects in emergent care setting |
|  |  | Subjects in institutions (e.g., halfway houses, nursing homes, etc.) |
|  |  | Prisoners ***{NOTE: The Aurora IRBs are not duly constituted to review research involving prisoners. If you intend to enroll prisoners, or if an enrolled subject becomes a prisoner, you must notify the RSPP office immediately.]*** |
|  |  | Non-English speaking subjects (Please see the Informed Consent guidance document on the Aurora IRB web site for more information or call the RSPP Office.) {If **YES** indicate language understood by the prospective subject or the legally authorized representative. **}** |
|  |  | Decisionally Incapacitated (You must address specific questions about the use of a surrogate decision maker for decisionally incapacitate subjects in section VI of the submission form.) |

**Any of the categories above (a-n) may be considered by the IRB to be vulnerable to coercion or undue influence, depending on the research being conducted. If your research specifically requires the inclusion of subjects from any of those categories, please address the following questions.**

1. Provide a justification for the inclusion of the above subjects in this study:

1. Provide a description of additional safeguards included in the protocol to protect these subject’s rights and welfare or to eliminate their vulnerability to coercion or undue influence. Examples include: use of an interpreter throughout research participation; translated research documents; handicapped accessibility to clinic; need for transportation from nursing home, etc.

1. Unless specifically excluded by the protocol, and you intend to exclude an otherwise eligible class of persons who might benefit from the research (e.g., pregnant women, minors, educationally or economically disadvantaged, etc.), provide an ethical and scientific justification for this exclusion:

**SUBJECT RECRUITMENT** {**Please note:** The RSPP office will be requesting information regarding the ethnicity/race and gender of subjects accrued at the time of continuing review.}

1. List subject inclusion and exclusion criteria, as well as any unique qualifiers required for participation (if the list is longer than one page, you may attach a copy of the inclusion and exclusion criteria to the end of the submission form):

1. Indicate how you will identify potential research subjects. The IRB must know if you anticipate enrolling subjects from a physician/investigator’s private practice, referrals from other physician groups, from a database of prior research participants, or from advertisements.

If you are identifying potential research subjects (pre-screening) by **obtaining/recording** identifiable private information on them, you must complete and include Form 502.3 with your submission. This form will allow the Privacy Board for Research to grant you access to the protected health information (PHI) in a Preparatory to Research capacity. **Note that *you may not collect identifiers or identifiable patient information on potential research subjects or contact a potential research subject prior to IRB approval of the research, and you must have a a treating relationship with that patient in order to make this contact.***

1. Describe your access to patient populations that will allow you to recruit the necessary number of subjects for this study.
2. Describe recruitment procedures (include fliers, posters, radio or TV scripts, recruitment letters, etc.). There may be Aurora logo requirements that must be met. If recruitment is by referral, detail procedure and submit letters to be sent to referring physicians. *Please note that IRB approval of an advertisement does not constitute administrative approval to post the advertisement within Aurora. Please contact Aurora Creative Services for more information.*

1. If the first contact that the prospective research subject has is with a receptionist who follows a script to determine basic eligibility for the specific study, describe the procedures that will be followed and how the receptionist is qualified and trained. Additional questions to address are: How is the personal information collected and stored? What happens to personal information if the caller ends the interview or simply hangs up? Does a marketing company gather the data? If so, are names, etc. sold to others? Are names of non-eligible subjects maintained in case they would qualify for another study? Are paper copies of records shredded or are readable copies put out as trash? Include a copy of any scripts.

1. Indicate whether the research subject will be paid for participation or given other recruitment incentives for participating. The amount of all payments or other compensation for participation (e.g., gift certificates) and the proposed method and timing of disbursement must be described here, and set forth in the informed consent document:

1. If a potential subject is eligible to participate in more than one research study being conducted by this Principal Investigator, give selection criteria that will be used to determine the most appropriate study for the subject to enroll (if there are no competing studies, that is an appropriate answer).

**RISK – PROTECTION – BENEFITS** Answers for the questions below are central to research involving human subjects and is a major consideration for the IRB. You must demonstrate a reasonable balance between anticipated risks to research subjects, protection strategies, and anticipated benefits to participants and/or others.

1. **Risks for Subjects.** Identify any reasonably foreseeable physical, psychological, economic, or social risks for subjects, and if possible, provide an estimated frequency of occurrence (i.e., “common”, “less common”, “rare”), distinguishing research risks from therapeutic risks. State that there are “no known risks” if appropriate.

1. **Minimizing Risk.** Describe *specific* measures used to minimize or protect subjects from anticipated risks related to research procedures or investigational articles (e.g., additional lab tests, more frequent physical assessments or exams, pregnancy tests, birth control, etc.).

1. **Privacy.** Describe the provisions to protect the privacy interests of subjects (i.e. the interests of individuals in being left alone, limiting access to themselves, and limiting access to their information).

1. **Risk of Breach of Confidentiality.** Identify any reasonably foreseeable risks for subjects that would result from a breach of confidentiality (e.g., loss of insurability or employability, invasion of privacy, loss of social or financial standing).

1. **Minimizing Risks of Breach of Confidentiality.** Describe how you intend to store protected health information related to the subject. For example, will the information be stored in hard copy in a locked filing cabinet or a secured computer or computer file? Indicate whether there will be restricted access to the maintained file, indicate whether the name of the subject or other identifiers will be removed by the research staff, and whether a code is assigned to the subject’s information before the research data is sent to the sponsor or governmental agency and indicate who will have access to this code (reminder: only medical records related to the research study should be given to the sponsor or others). Finally, state your plan for destroying the subject identifiers and documents once the study is closed, include how such destruction will take place and indicate how long you plan to keep these documents before destroying. Indicate whether a Certificate of Confidentiality has been or will be obtained, if applicable.

If this study involves collection and storage of biological samples for future unspecified research (banking) and the samples contain subject identifiers or are coded (meaning there is a link to identifiable health information), state the plan for destroying subject identifiers or link to the subject’s identifiable health information, once samples have been used up, destroyed or the study is completed and closed at the Aurora IRB.

1. **Monitoring Plan** If this research involves more than minimal risk\* to subjects, describe in detail the provisions for monitoring the data collected to ensure the safety of subjects. Include whether there will be interim analyses, stopping rules, if any; and any other pertinent information. *\* NOTE: if you have questions regarding whether the study meets the requirements for a “minimal risk” study, please contact the Aurora IRB office*.

Indicate whether a DSMB/DMC has been/ will be created, its composition and the frequency of meetings. Also indicate whether the DMC will operate in accordance with FDA Guidance for Clinical Trial Sponsors *Establishment and Operation of Clinical Trial Data Monitoring Committees*. You also have the option of submitting a DSMB/DMC charter.

1. **Pregnancy surveillance or outcomes monitoring.** Does the protocol include provisions for the collection of data from research subjects or research subjects’ partners who become pregnant during while receiving study interventions?

If yes, is the data collection solely for safety monitoring or part of the clinical trial objectives? Please review Aurora IRB guidance document for details.

1. **Benefits.** Describe any reasonably expected benefits for research subjects, a class of subjects, or society as a whole. If no benefits are expected for the individual subject, this should be stated. Provide more detailed information than what is provided in the informed consent document. Payment for research participation is not considered a “benefit”.

1. **Alternatives.** List the alternative procedures or courses of treatment that may be available for subjects in this study. If palliative treatment is the only option, state that. The choice to not participate is always an option. If this is not a treatment study, you may indicate N/A below.

Remember: if the study requires ICH GCP compliance, you MUST include the important risks and benefits of each alternative in the subject consent. An Alternatives matrix is provided in the Aurora IRB consent template.

# SECTION VI: Informed Consent Process

**The Process of Consent:** Since the central requirement for human subject research is that people participate voluntarily, the consent process is one of the most important parts of planning a research proposal. The process must assure that the potential subject understands the study and its risks and benefits and can certify his or her willingness to participate. The informed consent process should occur throughout the subject’s participation in the research study. Prepare a copy of the informed consent document, using the Sample Informed Consent Template as a guide. The Aurora IRB policy states that the **Principal** **Investigato**r must conduct the consent interview unless he or she delegates his or her responsibility for conducting the informed consent interview to another individual who is both knowledgeable about the research study and under the Principal Investigator’s direct supervision. In addition, the FDA Information Sheets state **“FDA does not require the investigator to personally conduct the consent interview. The investigator remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.” “If someone other than the clinical investigator conducts the interview and obtains consent, this responsibility should be formally delegated by the clinical investigator and the person so delegated should have received appropriate training to perform this activity.”** However, Wisconsin state law**\*** requires the physician-investigator to inform the subject about the availability of [per Steering Committee recommendation 6/12/15] alternate, viable medical modes of treatment and about the benefits and risks of these treatments. This discussion can take place anytime prior to the subject signing the consent document, but any attempt to discharge this responsibility to another individual would constitute a breach of the physician’s duty to provide informed consent under state law. The informed consent document contains a place to document that this discussion took place and by whom. Please contact the Aurora IRB office if you need more information regarding this requirement, or the training of persons designated to obtain informed consent.

1. List the titles (not names) of individuals who will be involved in the informed consent process (principal investigator, nurses, research assistants, coordinators, etc.) and indicate their roles in the consent process (i.e., screening participants, obtaining informed consent, etc.) [note that these individuals would meet the definition of Investigators/Key Personnel):
2. Does this research study involve a medical/clinical intervention (even if part of the routine care for the patient) for which a physician would routinely obtain informed consent? Per the interpretation of Aurora Legal Counsel for Research of Wisconsin state law (see above **\***) it is expected that a physician investigator conduct the discussion about the availability of alternate, viable medical modes of treatment options, and the benefits and risks of these treatments.

Have you formally delegated the risk/benefit/alternative consent discussion to someone on your research team other than a physician-level investigator? If YES, include this delegation on a Delegation of Authority log included with the submission.

1. Indicate specifically where the initial consent process will take place (e.g., waiting area, exam room, investigator’s office). If you intend to conduct any part of the consent process by telephone or mail, provide a description of the intended procedures.

1. Describe specifically when informed consent will be obtained in relation to the first research-related activity. Include how much time will be allotted for the informed consent process and whether there is any waiting period between informing the subject and obtaining the consent.

The IRB recommends that the pre-enrollment discussion with the subject occur at least several days before obtaining the consent and the initiation of the study unless *clinical* considerations preclude this from happening. Describe any foreseeable clinical situations where the informed consent process may be compromised. The IRB also recommends that the unsigned informed consent document be given to the subject to review in private well before the subject is asked to sign the document. If the amount of time is less than one day, please explain the reasons.

1. Indicate how you will ensure that the potential subject understands the study well enough to enroll (e.g., assessing subject’s ability to follow simple commands and ask appropriate questions about the study, asking open ended questions about risks, benefits, alternatives and documenting subject’s responses, asking for the subject to summarize aspects of the study, etc.):

1. What steps will be taken to minimize the possibility of coercion or undue influence during the consent process?

1. Indicate where subsequent visits will take place and how you intend to ensure the subject continues to be willing to participate in the study:

1. If you are enrolling children in this research study, answer the following questions. If N/A check here [ ] .

Provide your plan for obtaining age-appropriate assent:

If you are not planning on obtaining assent, indicate why:

If you are obtaining assent of the children, will assent be documented? (Indicate N/A if you are not obtaining assent.) If YES, how will it be documented?

**Based upon the risk level of the research study, the IRB will determine whether the permission of one parent is sufficient or whether permission of both parents is required.**

If you intend to obtain permission of both parents for the research study, regardless of risk level, check here [ ] . Provide a rationale for your decision.

1. For research involving children in categories 45CFR46.406 or 45CFR46.407 (see  [HHS FAQs](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html)), if you are enrolling children who are wards of the State in this research study, answer the following question. If N/A, check here [ ] .

For this research, an advocate is required for a child who is a Ward of the State (this cannot be someone who has already been appointed to act on behalf of the child, e.g., a social worker or a *guardian ad litem*). Indicate your plan for appointing the advocate, and describe their background or experience and their willingness to act in the best interest of the child throughout the child’s participation in the research.

# SECTION VII: Decisionally Incapacitated Subjects (complete this section only if you are requesting the use of surrogate decision maker s to enroll subjects into the research study)

When mental impairments or other conditions render a potential adult research subject unable to give consent to participate in a prospective research study, federal research regulations state that the investigator must obtain written informed consent from a “legally authorized representative” prior to enrolling the potential subject into the research study. Federal research regulations define a “Legally Authorized Representative” as an “individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research”. Federal regulations provide no specific information about who may or may not qualify as a “legally authorized representative.” Wisconsin state law is silent about who may provide consent for research participation on behalf of a mentally incapacitated adult, except when experimental treatment is aimed at individuals being treated for mental illness, developmental disabilities, alcoholism or drug dependency. It is the IRB’s position that in limited circumstances, it may be appropriate, and in the subject’s best interest, to allow a decisionally incapacitated prospective subject to be enrolled into a research study based on the consent of the subject’s guardian, health care agent, or other surrogate decision maker(s).

Are you requesting that a surrogate decision maker (power of attorney for health care, legal guardian, or other surrogate, such as next-of-kin) be allowed to provide permission for a decisionally incapacitated adult (one who is incapable of giving their own informed consent) to be enrolled into this research study? If you are, the following must be completed:

Could the research be conducted with decisional subjects (provide explanation and include discussion of limiting factors)?

Could the subject receive the same medical management they will receive in this study outside the setting of a research protocol? Explain the compelling reasons for conducting the research study with these decisionally incapacitated subjects?

Will participation in this study increase the risk of harm or discomfort compared to that expected with medical management that the subject would receive if they do not participate in this study? Provide an explanation:

Will participating in this study increase the chance that the subject will experience a favorable outcome compared to that expected with the medical management that the subject would receive if they did not participate in this study? Provide an explanation:

What is the magnitude of the benefit that future patients, or society in general, may experience as a result of the subject participating in this research study? Provide an explanation:

Who will be assessing the prospective subject’s likely preferences regarding research participation, and how will that assessment be performed?

Who is the independent physician(s) who will be making the incapacity determination and completing Form IC-702A entitled “Declaration of Incapacity for Research Purposes” to be filed in the subject’s medical record and the research record?

**Please note, if the prospective research subject has designated a Health Care Agent or has a Legal Guardian, the investigator is not authorized by the IRB to seek consent from another surrogate decision maker** (see Aurora RSPP guidance document (*Legally authorized Representatives*) for who can be considered a surrogate decision maker).

If you did not anticipate enrolling subjects with the above conditions at the time of IRB submission but unexpectedly encounter a vulnerable subject during the study, you should contact the RSPP office for guidance before enrolling such subject.

# SECTION VIII: Requests for Waiver(Complete this section only if you are requesting a waiver of consent or documenation of consent)

If you are requesting a consent procedure that does not include, or alters, some or all of the required elements of informed consent, or you are requesting a waiver of the requirement to obtain a signed consent form, please complete one or the other section below (please note that the IRB must concur that your research involves no more than minimal risk).

Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials requires a different set of regulations. Does this study fall under these regulations and a waiver or alteration is being requested? If yes, contact the RSPP office.

[ ]  **I am requesting a waiver or alteration of informed consent (some or all of the required elements of informed consent, or an alteration of same).**

In order for the IRB to grant (a) a waiver of informed consent, or (b) a waiver of the consent procedure requirement to include all or alter some or all of the elements of informed consent [45CFR46.116(d)], please complete the following:

1. In your opinion, does the research involve no more than minimal risk?
2. Check the appropriate box(es) indicating why the waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects:

[ ]  The clinically indicated intervention or tests were already completed, or would be completed, regardless of this research activity.

[ ]  Results of this research activity would not affect clinical decisions about the individual’s care because they are being analyzed after the fact.

[ ]  Subjects are not being deprived of clinical care to which they would normally be entitled.

[ ]  Other (describe):

1. Describe why the waiver or alteration is necessary and how it would not be practicable to conduct the research without the requested waiver/alteration:
2. Does the research involve using identifiable private information or identifiable biospecimens? If YES, describe how the research could not practicably be carried out without using such information or biospecimens in an identifiable format:
3. Describe how you will provide subjects with additional pertinent information after their participation, or why it is not appropriate:
4. Explain whether the entire informed consent is being waived or only certain required elements are being waived (and if so, list which ones):

**You must also request a Waiver of HIPAA Authorization. Please submit Form SC-502.3 along with this submission.**

***Note: If the IRB finds that your research involves no more than minimal risk and a waiver of informed consent is granted under the above conditions, documentation of informed consent (i.e., signed consent form) is also waived. Even if a waiver is granted, the IRB may require other conditions. The IRB may require you to provide subjects with an information sheet (written summary) about the research.***

[ ]  **I am requesting a waiver of documentation of informed consent**

In order for the IRB to grant a waiver of the requirement to obtain a signed consent form for some or all subjects [45CFR46.117(c)], you must be able to answer **YES** to at least one of the following:.

Is the only record linking the subject and the research the consent document; and the principal risk is potential harm resulting from a breach of confidentiality. [Each subject (or legally authorized representative) should be asked whether he/she wants documentation linking the subject with the research, and the subject’s wishes will govern.]

Is the subject or legally authorized representative a member of a distinct cultural group or community in which signing forms is not the norm; the research involves no more than minimal risk of harm to subjects; and there is an appropriate alternative mechanism for documenting that informed consent was obtained?

In your opinion, does the research involve no more than minimal risk of harm to the subject; and involves no procedure for which written consent is normally required outside of the research context?

Describe the reason(s) the waiver of documentation of informed consent is necessary:

**You must also request an Alteration of HIPAA Authorization. Please submit Form SC-502.3 along with this submission.**

***NOTE: If the IRB finds that your research involves no more than minimal risk and a waiver of documentation of informed consent is granted, the IRB may still require other conditions. For example, the IRB may require that you provide subjects or legally authorized representatives with an information sheet (written summary) about the research.***

# SECTION IX: Principal Investigator Assurance for Research Involving Human Subjects

1. Research Involving Human Subjects: By signing below, I acknowledge and accept primary responsibility for protecting the rights and welfare of human research subjects, and that such rights and welfare take precedence over the goals and requirements of the research. I hereby represent that I have reviewed the following documents and agree to conduct my research in compliance with: (1) the Belmont Report; (2) the Department of Health and Human Service’s (“HHS”) and Food and Drug Administration’s (“FDA”) regulations; (3) the Federalwide Assurance applicable to this research study; and (4) the Aurora IRB policies and procedures governing human subject research. Contact the RSPP Office with questions.
2. Conduct of the Study: This research study or project will be performed in the manner described in this proposal, and in accordance with Aurora RSPP policies and procedures, applicable laws, regulations, and guidelines. I hereby agree to refrain from enrolling subjects into this proposed research study prior to its review and approval by the Aurora IRB. I understand that any modification from the procedures detailed herein must be submitted to the IRB and be approved by the IRB prior to implementation unless the change is made to eliminate an apparent immediate hazard to subjects (see RSPP #9 - *Changes to Previously Approved HS Research – Submission & Implementation Requirements*) .
3. Protected Health Information: I hereby assure that the information obtained in the course of this research will only be used for the purposes previously stated. The final product of the research will not reveal information that may serve to identify the patient without the documented informed consent of the patient. I agree that I will not reuse or disclose to any other person protected health information obtained or accessed by virtue of this research except as authorized by the subject, or permitted or required by law and shall require my research staff to also comply with this section. See Aurora system Policy #140 - *Use and/or Disclosure of Protected Health Information for Research.*
4. Informed Consent: I hereby agree to obtain, document, and maintain records of informed consent from each subject (or legally authorized representative) as required under HHS and FDA regulations, applicable laws, Aurora IRB policies and procedures, and as stipulated by this IRB.
5. Training: I agree to complete and require any Investigator/Key Personnel participating in this research study under my direction and control to complete any and all educational training required by the study sponsor, Aurora Health Care or the Aurora IRB prior to initiating their part in the research study. I assure that all personnel working with human subjects described in this application (“key personnel”) are technically competent in the duties assigned to him/her.

All Investigators/Key Personnel (listed on page 1 of this form) are required to have completed human subject research training prior to acceptance of this application by the Aurora RSPP.

1. Credentials: If the research involves medical treatment or intervention, a qualified clinician responsible for all health care decisions dictated by the protocol must be designated as an Investigator/Key Personnel. In addition, the qualified clinician must provide for referrals for needed healthcare during the research and for follow-up after the research has ended, as necessary.

***If this research project uses a device or involves a medical procedure, this submission will be sent to the Aurora Credentials Department for verification that the named individuals have the appropriate Aurora medical credentials/privleges.***

1. Conflict of Interest: All Investigators/Key Personnel are required to comply with Aurora System Policy #269 – *Conflict of Interest in Research - Individual*. All Investigators/Key Personnel listed on this submission are required to have completed their annual significant financial interest disclosure prior to acceptance of this application by the Aurora RSPP.

***No submission will be accepted for review each Investigator/Key Personnel has completed their annual interest disclosure.***

1. Malpractice Insurance (if applicable): I agree to notify my malpractice carrier that I am conducting human subject research and will participate in the Wisconsin State Patient’s Compensation Fund.
2. Quality assurance activities: The Research Compliance Officer, Research Quality Specialist or designee conducts reviews to ensure that compliant and high-quality research practices are used in human subject research at Aurora. The research quality and compliance reviews are frequent and include different types, ranging from focused reviews of a few specific items in many protocols to a full review of an individual protocol. Reviews will be conducted on IRB approved protocols to ensure compliance with the protocol, SOPs, accreditation standards, applicable federal regulations and guidance, ICH Good Clinical Practice (GCP) Guidelines as adopted by the FDA, and according to Aurora’s Federal Wide Assurance with DHHS, as well as applicable state and local laws. You will be notified if your protocol is selected for a full review or if issues are identified that require your attention during any type of review.
3. Extramural Funding: If funded by an extramural source, I assure that this application accurately reflects all procedures involving human subjects as described in the grant/contract proposal to the funding agency. I also assure that I will notify the Aurora IRB and the funding/contract entity if there are modifications or changes made to the protocol after the initial submission to the funding agency.
4. Continuing Obligations: I understand that it is my responsibility to conduct this research in an ethical manner, protecting the rights and welfare of the enrolled human subjects, and as approved by the Aurora IRB. I also understand it is my responsibility to provide timely and accurate information when pertinent or requested, and to notify the Aurora IRB in a timely manner when my study has been revised, amended, or modified in any way, placed on hold, suspended, completed, or otherwise is no longer active to subject enrollment or follow-up. Lastly, I understand that it is my obligation to submit reportable events as indicated in the Aurora RSPP SOPs (found on the [RSPP Website](http://www.aurora.org/irb)).

|  |  |  |
| --- | --- | --- |
| (Principal Investigator Signature) ***Signature must be on file in the IRB office.*** **Cyber submission: this entry may be skipped. Signature will be captured in Cyber.** |  | (Date) |