

Submission Form Version Tracking Date:

## AURORA IRB

### **Protocol for Research Involving Human Subjects Exempt Submission Application**

*Facilities where research will be conducted, or sites where the health information to be collected is located:*

Select a site

Select a site

Select a site

Select a site

Select a site

AMG/Aurora Clinic(s) – list all clinic names: \_\_\_\_\_

VLCC – list all clinic names: \_\_\_\_\_

**For IRB Office Use Only**

### SECTION I: GENERAL INFORMATION

Protocol Title:			
Principal Investigator (including degrees):		Department/Office:	
PI's Mailing Address:			
PI's Telephone:	PI's Fax:	PI's E-mail:	
Study sponsor or funding source (Identify all source(s) of funding for the project):			Is this study federally funded? <b>Choose One</b>
List all Co- and Sub-Investigators (including earned degrees):			
If investigators are physician's, indicate types of practice (including sub-investigators):			<input type="checkbox"/> AMG / <input type="checkbox"/> Private Practice
Primary contact person who will be responsible for the research files/ documents/correspondence with the RSPP office regarding this study:			
Mailing Address:			
Telephone:	Fax:	E-mail:	

### SECTION II: SUBMISSION CHECKLIST

Check	Item required	Number of copies
	Completed Submission Form with original signatures (can be submitted with signatures pending) Submit the file electronically to <a href="mailto:IRB.office@aurora.org">IRB.office@aurora.org</a> (complete protocol title must be referenced in the e-mail)	ORIGINAL + 1 COPY ELECTRONIC
	Surveys or questionnaires	2 COPIES
	Data collection sheets (required for studies that involve records collection)	2 COPIES
	Information sheet or written materials to be seen by subjects	2 COPIES
	Grant application if HHS-supported and Aurora is awardee institution ( <a href="http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm">http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm</a> )	1 COPY
Pending	NIH Tutorial training certificate for all investigators listed above <a href="http://phrp.nihtraining.com/users/login.php">http://phrp.nihtraining.com/users/login.php</a>	COPY, unless already on file in RSPP office

### SECTION III: REQUIRED PRE-REVIEW AND ADMINISTRATIVE ACKNOWLEDGEMENT

- A. Is the research being conducted by a resident investigator? Choose One**  
 If **YES**, the Aurora RSPP office requires that your project undergo pre-review to obtain written administrative acknowledgement. This acknowledgement should be obtained prior to submitting your proposal. Please review the document entitled "STEPS TO CONDUCT A RESIDENT RESEARCH PROPOSAL AT AURORA HEALTH CARE", which can be found at [www.aurora.org/irb](http://www.aurora.org/irb) under "Resident/Fellow Research Projects"
- B. Is the research being conducted by a nurse investigator or nursing student investigator, or does the undertaking of this research target Aurora nursing staff as a subject population? Choose One**  
 If **YES**, the Aurora RSPP office requires that your project undergo pre-review to obtain written administrative acknowledgement. This acknowledgement should be obtained prior to submitting your proposal. Please review the document entitled "STEPS TO CONDUCT A NURSING RESEARCH PROPOSAL AT AURORA HEALTH CARE", which can be found at [www.aurora.org/irb](http://www.aurora.org/irb) under "Nursing Research"
- C. Does the undertaking of this research involve Aurora staff or employed physicians as research subjects? Choose One**  
 If **YES**, the Aurora RSPP office will forward your submission to obtain clearance to allow the participation of Aurora staff or employed physicians from the Senior Vice President of Human Resources or designee. This clearance is required prior to approval being issued.
- D. Does the undertaking of this research require participation of facilities, clinics, or departments of Aurora Health Care? Choose One**  
 If **YES**, you must ensure you have appropriate administrative acknowledgement in addition to IRB approval before you conduct the study.
- E. Do you intend to send data/specimens outside the Aurora system? Choose One**

If **YES**, you are required to obtain written acknowledgement from the Vice President of Research and Academic Affairs. This acknowledgement is required prior to approval being issued.

## SECTION IV: EXEMPT DETERMINATION WORKSHEET (COMMON RULE CRITERIA 45 CFR 46)

**Use this worksheet to determine whether your research study qualifies for exempt status from IRB review according to federal regulations. The final determination regarding exempt status will be made by RSPP staff, in conjunction with the IRB chair or designee. If your study does not qualify for exempt status based on the information presented below, you will be directed to complete the Aurora IRB Protocol Submission Form (FO 301-A).**

1. Does the study involve (answer each question):

a.	<b>Choose One</b>	Non-hereditary genetic research in which samples are linked/coded or identifiable?
b.	<b>Choose One</b>	Hereditary genetic research?
c.	<b>Choose One</b>	Surveys or interviews of minors?
d.	<b>Choose One</b>	Any procedures that may cause a subject either physical or psychological discomfort, or could be perceived as harassment above and beyond what a person would experience in daily life?
e.	<b>Choose One</b>	Deception?
f.	<b>Choose One</b>	Observation of minors when the investigator will participate in the activities being observed (unless there is a federal statute covering the activity)?
g.	<b>Choose One</b>	The study of a rare trait/disorder such that there is some risk of exposing the identity of sample donors, or the research poses the risk of community or cultural harm?
h.	<b>Choose One</b>	Research involving the delivered placenta, dead fetus, macerated fetal material; or cells, tissue, or organs excised from a dead fetus?
i.	<b>Choose One</b>	Prisoners?
j.	<b>Choose One</b>	The results of the project are required to be submitted to or held for inspection by the FDA.

**NOTE: If you answered YES to any item above, STOP. The study will not qualify for exempt status. You will need to complete the Aurora IRB Protocol Submission Form (FO 301-A).**

2a. Does the study meet the following exempt criteria for 45CFR46.101(b)(4) **(both questions must be answered YES)?**

<b>Choose One</b>	Research involving the collection or study of <b>existing</b> data, documents, records (retrospective medical record review), pathological specimens, or diagnostic specimens (e.g. blood or tissue samples). <b>Existing: means that all the data, documents, records, or specimens are in existence at the time of submission to the IRB; therefore data or specimens obtained prospectively would not qualify for exempt status.</b>
<b>AND</b>	
<b>Choose One</b>	The sources of the information obtained are publicly available, or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. <b>Note: if the data or samples are identified by a study code linked to the subject, and the investigator has access to the code, the information is considered identified and the research will not be eligible for an exempt determination.</b>

**OR** **OR** **OR**

2b. Does the study meet the following exempt criteria for 45CFR56.101(b)(2)?

<b>Choose One</b>	Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior <b>unless</b> information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects <b>and</b> that any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation.
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**NOTE: If you did not answer YES to either 2a OR 2b above, STOP. The study will not qualify for exempt status. You will need to complete the Aurora IRB Protocol Submission Form (FO 301-A).**

3. Answer the following questions about the research study:

<b>Choose One</b>	Is the <b>probability</b> of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?
<b>Choose One</b>	Is the <b>magnitude</b> of the harm or discomfort greater than that encountered ordinarily in daily life, or during the performance of routine physical or psychological examinations or tests?

**NOTE: If you answered YES to either part of question 3, STOP. The study will not qualify for exempt status. You will need to complete the Aurora IRB Protocol Submission Form (FO 301-A).**

## SECTION V: HIPAA DETERMINATION (45 CFR 164)

**Complete this section if you intend to review/collect protected health information as part of this research study:**

- List all health information (diagnoses, procedures, and other data) that will be viewed/collected/recorded to meet the goals of the research. **Data collection sheets to record data for this research activity MUST be attached.**
- Federal regulations require investigators to only obtain the minimum necessary data in order to achieve the goals of the research. Please indicate why the data you are obtaining is necessary to achieve the goals of the research:

- 3) Where will the health information be found or what type of record/chart/database will be accessed (check all that apply)?
- |  |  |
|--|--|
| <input type="checkbox"/> Medical Record/Chart (paper record)     | <input type="checkbox"/> HIV Test Results  |
| <input type="checkbox"/> Computer/Database (electronic record)   | <input type="checkbox"/> Mental Health Records   |
| <input type="checkbox"/> Hospital Administrative/Billing Records | <input type="checkbox"/> Psychotherapy Notes   |
| <input type="checkbox"/> Quality Improvement Records             | <input type="checkbox"/> Data previously collected for research purposes                       |
| <input type="checkbox"/> Lab and/or Pathology Reports            | <input type="checkbox"/> Other types of records (including operating or cath schedules): _____ |
| <input type="checkbox"/> Films/X-rays                            |  |
| <input type="checkbox"/> Drug and alcohol treatment records      |  |

- 4) Will any of the following be associated with the health information? This could be regarding a **study subject, or a subject's relative, household member, or employer**. These are considered identifiers under HIPAA [164.514(b)(2)(i) and (ii)]  
**[NOTE: Collection of the Month and Year (e.g. 12/01) or Quarter and Year as a date are also considered identifiers under HIPAA. To be considered truly "de-identified", only the year or age can be collected.]**

View	Collect		View	Collect	
<input type="checkbox"/>	<input type="checkbox"/>	Name (including initials)	<input type="checkbox"/>	<input type="checkbox"/>	Patient Health Care Records (MRU) Number
<input type="checkbox"/>	<input type="checkbox"/>	Age if 90 and over	<input type="checkbox"/>	<input type="checkbox"/>	Health Plan Beneficiary Number
<input type="checkbox"/>	<input type="checkbox"/>	Street Address	<input type="checkbox"/>	<input type="checkbox"/>	Account Numbers
<input type="checkbox"/>	<input type="checkbox"/>	City or State*	<input type="checkbox"/>	<input type="checkbox"/>	Fax Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Zip Code*	<input type="checkbox"/>	<input type="checkbox"/>	E-mail Address
<input type="checkbox"/>	<input type="checkbox"/>	Geocode*	<input type="checkbox"/>	<input type="checkbox"/>	Certificate/License Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Date of Birth*	<input type="checkbox"/>	<input type="checkbox"/>	Vehicle Identification Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Admission/Discharge Date*	<input type="checkbox"/>	<input type="checkbox"/>	Device Identifiers and Serial Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Dates of Services*	<input type="checkbox"/>	<input type="checkbox"/>	Web Universal Resource Locators ("URLs")
<input type="checkbox"/>	<input type="checkbox"/>	Date of Death*	<input type="checkbox"/>	<input type="checkbox"/>	Internet Protocol (IP) Address Numbers
<input type="checkbox"/>	<input type="checkbox"/>	Telephone Numbers	<input type="checkbox"/>	<input type="checkbox"/>	Biometric Identifiers, including voice and finger prints
<input type="checkbox"/>	<input type="checkbox"/>	Social Security Number	<input type="checkbox"/>	<input type="checkbox"/>	Full Face Photographic Images/ Comparable Images

**NOTE: Only those HIPAA identifiers with an asterisk (\*) [limited data set] may be COLLECTED in this study and have it qualify as Exempt per the federal regulations. If collection of a "limited data set" is being requested, a Data Use Agreement will be required. Documentation of a completed Data Use Agreement will be required prior to the issuance of an IRB letter of exemption. Please contact the Aurora Privacy Officer (414.647.3115) for more information on executing a Data Use Agreement.**

**If you indicated that you will "collect" any of the above identifiers other than those marked with an asterisk (\*), or if you will assign the collected data a study code that links the data to a specific patient, you must STOP and complete the Aurora IRB Protocol Submission Form (FO 301-A).**

- 4) Is there any information that could be used alone or in combination with other information to identify an individual whose information is being collected (e.g. rare disease)? **Choose One** If **YES**, explain:

- 5) Will you be accessing protected health information of decedents? **Choose One**

If **YES**, by signing this form, you are representing and warranting the following to Aurora Health Care:

*I hereby represent that I am reviewing health information only for the limited purpose of research on decedents' health information, and that review of such health information is necessary for the research I am conducting. At the request of Aurora Health Care I will promptly provide Aurora with documentation of the death of the individual whose health information I will review.*

**If you feel that your research study qualifies for exempt status, you should complete the following sections.**

## SECTION VI: PROTOCOL SYNOPSIS

The Aurora Health Care Institutional Review Boards (IRBs) are 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. It is important that you answer **ALL** questions accurately **USING LAY TERMS**. If you need help or have questions about how to complete this application, please call the RSPP office at 414.219.7744 or e-mail us at [IRB.office@aurora.org](mailto:IRB.office@aurora.org).

Please provide the requested information in the shaded text boxes. As you type your answers, the shaded text boxes will expand as needed. If you are unable to prepare this form on the computer, please use it as a guide and complete the requested information as a separate document. If this research study is based on a grant proposal, a copy of the grant must be attached to this form.

**SUBJECT SELECTION:** Estimated total number of subjects enrolled / charts or databases reviewed at all Aurora sites: \_\_\_\_\_ / Number of control subjects (at all sites) (N/A if not applicable): \_\_\_\_\_

**PROTOCOL SYNOPSIS:** Give a brief but complete summary of the study.

### RATIONALE FOR PROTOCOL:

### DESIGN AND PROCEDURES

- A. Clearly describe the study procedures (if the study is solely a record review, indicate N/A).

- B. Does your research study involve a record or database review? **Choose One** If YES, answer the following questions.
- 1) Are all of the records/charts currently in existence (i.e. available at the time of submission of this request)?? **Choose One**
  - 2) What time frame will be covered in your data search?
  - 3) Will Aurora Health Care medical records be accessed in your study? **Choose One**
  - 4) Will medical records of another private physician group or private clinic be accessed in study? **Choose One**  
If YES, list the name(s) of the clinic/group that is the owner of these records.
- C. Will informed consent be obtained from subjects? **Choose One** If NO, provide a justification. (If study is solely a retrospective medical chart review, you may indicate NA as a response.) **NOTE: The IRB may decide that informed consent or an information sheet is appropriate based on the type of research even if the investigator indicates that they are not going to obtain consent from subjects. If you are providing written materials to subjects, please attach to the submission form.**
- D. Indicate all sites where study is being conducted (e.g., physician's private office, hospital, clinic, etc. Indicate N/A if medical record review):
- E. Describe data collection methods (**surveys, instruments, data collection sheets, etc. must be attached**):
- Who will be collecting this information? List by title (e.g., study coordinator, principal investigator):
- F. If the study involves the use of blood or tissue, are the samples in existence at this time? **Choose One**  
Describe whether any protected health information or identifiers will be associated with the samples in any way:

### **SUBJECT RECRUITMENT**

Indicate how you will identify potential research subjects. The IRB must know if you anticipate enrolling subjects from the investigators private practice, referrals from other physician groups, from a database of prior research participants, from advertisements, or from groups of people you otherwise have access to (e.g., you are part of the hospital staff or residents and have access for clinical purposes):

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

a.	<b>Choose One</b>	Minors {if <b>YES</b> indicate age range and see SOP SC 501 to determine if an assent document is necessary}
b.	<b>Choose One</b>	Mentally ill or developmentally disabled
c.	<b>Choose One</b>	Economically or educationally disadvantaged
d.	<b>Choose One</b>	Subjects in institutions (e.g., halfway houses)
e.	<b>Choose One</b>	Prisoners <b>{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}</b>
f.	<b>Choose One</b>	Non-English speaking subjects (please see SOP IC 701 for guidance)

**Note: The research cannot be exempt if the population includes prisoners, or children who are the subject of survey/interview procedures or observations when the investigator participates in the observed activities.**

**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. **Note: surveys or questionnaires and records reviews may carry potential risks to the subject and these should be addressed.**

- A. **Risks for Subjects.** Identify any reasonably foreseeable physical, psychological, or social risks for subjects. Include risks due to a breach of confidentiality (i.e., loss of insurability or employability, invasion of privacy, loss of social or financial standing).
- B. **Privacy Plan.** Describe how the privacy of the subject will be respected in the study. If study is solely a chart review (i.e. there is no interaction with the patient), you may indicate N/A as a response.
- C. **Confidentiality Plan.** Describe how you intend to store health information collected as part of this study. 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. 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:
- D. **Benefits.** Describe any reasonably expected benefits for research subjects, a class of subjects, or society as a whole.

## **SECTION VII: HIPAA AUTHORIZATION**

Investigators who intend to view or collect health information for research purposes are required to obtain HIPAA Authorization from the prospective subject, or to request a Waiver or Alteration of Authorization for the Use of Protected Health Information.

**Please select one of the following:**

- I WILL NOT view or collect identifiable (HIPAA identifiers are associated with the information) health information as part of this research study / OR / the health information that will be viewed or collected is de-identified (no HIPAA identifiers associated with the information). **Complete section VII.**
- I WILL view or collect identifiable health information (including those that are part of a limited data set) as part of this research study. **Please address the next set of questions.** NOTE: if you are collecting identifiers in a limited data set, you must contact the Aurora Privacy Officer (414.647.3115) to execute a Data Use Agreement.

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**If you have indicated above that you WILL review/collect identified health information as part of this study, choose one of the following:**

I will obtain Authorization for the Use/Disclosure of Protected Health Information from prospective subjects using the Aurora Informed Consent/HIPAA authorization template. **Please proceed to the Aurora IRB web site [[www.aurora.org/irb](http://www.aurora.org/irb)] to access the consent/authorization template. You must complete and include with your submission. Please proceed to section VII.**

**OR**

I am requesting a Waiver/Alteration of Authorization for the Use/Disclosure of Protected Health Information. **Please address the next set of questions.**

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**If you have indicated above that you are requesting a Waiver or Alteration of Authorization for the Use/Disclosure of Protected Health Information, complete the following questions.**

Federal regulations permit the Aurora IRB (acting as the HIPAA Privacy Board) to waive or alter the requirement to obtain authorization to use or disclose protected health information (PHI) if certain conditions are met. If you wish to request a waiver or alteration of authorization, provide the following information:

- A. I am requesting a  **full waiver** /  **alteration** of authorization. [Note that an alteration of authorization may include the request to waive documentation of authorization, i.e., the requirement to obtain a signed authorization form.]
- B. List all **protected (identifiable) health information (PHI)** (e.g. diagnoses, procedures, and other data including age) that will be needed to meet the goals of the research:
- C. Please explain why this study cannot be designed without collecting identifiable health information:
- D. If identifiable health information is necessary, regulations require investigators to only obtain the minimum necessary PHI in order to achieve the goals of the research. Please indicate why the PHI you are obtaining is necessary to achieve the goals of the research:
- E. Describe why the waiver or alteration of authorization is necessary and why it would not be practicable to conduct the research without the waiver/alteration:
- F. The proposed use of this PHI presents no more than minimal risk to the privacy of individuals because the PHI will be stored in:  
 A locked file cabinet in the investigator's office and only the investigator and his/her research staff will have access to the cabinet;  
 On a secured computer or computer file to which access is restricted to the investigator and his/her research staff only;  
 Other (describe):
- G. How long will the PHI be maintained by you?
- H. Do you have a plan to destroy subject identification at the earliest opportunity (for example, shredding the PHI after the abstract has been completed or approved for publication)?  **Yes** /  **No**

If **YES**, please describe your plan (include the point at which the information will be destroyed and the method of destruction):

If **NO**, please explain when you will destroy the subject identifiers, and whether any state or federal law requires you to retain the identifiers:

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**SECTION VIII: INVESTIGATOR ASSURANCE FOR RESEARCH INVOLVING HUMAN SUBJECTS**


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- A. 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.
- B. 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. In accordance with Federal regulations [45CFR46.101(b)(4)] and Wisconsin Statute 146.82(2)(a)6, I hereby assure that all information being collected is in existence at this time, will not be released to a person not connected with the study, and 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 understand that I am associated with a medical environment that sets high ethical standards of conduct and that I have a responsibility to protect and uphold the confidentiality of protected health information. I understand that I should not read protected health information except as required for purposes of the aforementioned research study. I will not discuss the protected health information with anyone as a matter of conversation. I further agree to indemnify and hold Aurora Health Care harmless from any loss or liability arising with respect to the unauthorized use or disclosure of any protected health information obtained through my review of health care records of patients of Aurora Health Care.
- C. Training: I assure that all personnel working with human subjects described in this protocol are technically competent, and have a working knowledge of the Belmont Report and applicable federal regulations regarding human subject research [45CFR46 and 21CFR50 and 56].
- All investigators listed on this protocol are required to complete the training tutorial found at <http://phrp.nihtraining.com/users/login.php>.
- Yes, certificate(s) on file in IRB office /  No, certificate(s) will be forwarded
- D. 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. If federally funded and Aurora is the awardee, a copy of the grant must be submitted and reviewed by the RSPP office.
- E. Investigator responsibility: I understand that it my responsibility to notify the Aurora IRB if my study has been revised, amended or modified in any way as this may affect the study's exempt status.

\_\_\_\_\_  
 (Principal Investigator Signature) ***The original signature must be on file in the IRB office.***

\_\_\_\_\_  
 (Date)

- F. Facilitator: For studies being conducted by an investigator who is not an employee of Aurora Health Care, Inc. or who does not have staff privileges at an Aurora Health Care facility, a facilitator is required (see SOP FO 301 to ensure that you understand the role of the facilitator). For protocols involving the "practice of medicine and surgery" a physician is required. If applicable, please provide the name and contact information of the facilitator.

Not applicable

Name:

Department:        / Telephone:        / E- mail address:

\_\_\_\_\_  
 Facilitator's signature (if applicable)

\_\_\_\_\_  
 (Date)

- G. Applicable FWA Numbers:  FWA00000414 (Aurora Health Care) /  FWA00004940 (Aurora Medical Group) /  FWA 00005239 (Aurora BayCare) /  Other: \_\_\_\_\_

**SECTION VIII: HIPAA DETERMINATION** *FOR IRB OFFICE USE ONLY*
**HIPAA Determination**

- |                          |   |
|--------------------------|---|
| <input type="checkbox"/> | No Protected Health Information is being reviewed or collected.   |
| <input type="checkbox"/> | An IRB Waiver of Authorization is granted pursuant to 45CFR164.512 by Expedited IRB Review, and this document is intended to notify Health Information Management of its obligation to keep an accounting of any disclosures related to this request in accordance with 45CFR164.528. |
| <input type="checkbox"/> | An IRB Waiver of Authorization is not granted. The patient is required to provide written authorization.  |
| <input type="checkbox"/> | The information being requested is de-identified.   |
| <input type="checkbox"/> | The information being requested is part of a limited data set. The investigator must present an executed Data Use Agreement, obtained from the Aurora Privacy Officer (414.647.3115), prior to issuance of the IRB letter of exemption..  |

\_\_\_\_\_

Aurora IRB Chair or designee

\_\_\_\_\_

Date

- |                          |  |
|--------------------------|--|
| <input type="checkbox"/> | Copy faxed to each site's HIM on _____ |
|--------------------------|--|