

**Aurora IRB Stamp of Review**

Aurora IRB Protocol #: \_\_\_\_\_  
 IRB approved consent final version date: 3-30-2012  
 Use of this consent form expires on: \_\_\_\_\_  
 (subject's consent/authorization is not affected by this date)

Deleted: 12/15/2011

Subject Medical Record Number: \_\_\_\_\_

Subject name: \_\_\_\_\_ Subject Date of Birth: \_\_\_\_\_

**Aurora Health Care, Inc.**

[Insert name of non-Aurora facility if applicable.]

**INFORMED CONSENT/AUTHORIZATION TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title**

[Insert study title]

This is a research study. A research study is an organized activity to learn more about a problem or answer questions. Many different kinds of research studies are conducted. For example, a study may test a new drug or medical device to see if it is safe and effective. This type of research is called a "clinical trial". A study may be done to determine the best way to treat or prevent an illness. A "subject" is an individual who agrees to participate in research and can be either a healthy person or a patient. Being a subject is different from being a regular patient. When you are a patient, you and your personal doctor make decisions about your health care. When you are a research subject, your treatment and/or follow up is done according to the rules of the research study to answer a research question. The research study has safety rules that the principal investigator and research staff follow to minimize the risks to you.

You can choose whether or not you want to participate in this study. The information in this informed consent form will help you decide if you want to be part of the study or not. Please take your time to decide, and talk about this study with your personal doctors, family members, and friends if you like. If you decide you do not want to sign this consent form, you cannot take part in this research study, however other options are available to you (see the section in this form called, "**What are your options if you don't take part in this research study?**").

**You are being asked to take part in a research study.**

You are being asked to voluntarily take part in a research study of [insert general statement about study]. You are being asked to take part because [explain how subject was identified].

The purpose of this research study is [insert study purpose].

This study is being done by [insert principal investigator's name and earned degrees]. This person is called the principal investigator in this study. Other health care personnel may assist [insert principal investigator's name] in conducting this study.

**Where is this study being done?**

[insert all local sites of this study.]

**How many people will take part in this study?**

About [indicate the number of subjects to be recruited] people will take part in this study at [insert name of institution].

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**Comment:** The study title listed here should match the protocol and submission application titles. Do NOT include sponsor information (name, address, etc.) below the study title. Sponsor information should be listed in the "Who is sponsoring this study?" section.

**Comment:** Explain research question and purpose in lay language. State why the drug/device is being studied. Indicate whether the drug or device being tested in the study or used in the study is experimental or whether any procedures are experimental. Consent documents for studies of investigational articles should include a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that the test articles are safe, or statements that the safety has been established in other studies. (... [1])

**Comment:** State the department, institution, and/or practice with which the investigator(s) is affiliated. If the investigator is a student, include the name of the person supervising the research. If applicable, state that an investigator is a member of (... [2])

**Comment:** Page: 1  
When using the terms "study doctor" or "investigator" be mindful of what is being done for research purposes. For registry studies, the IRB generally prefers the use of "investigator" or "researcher" in the consent. (... [3])

**Comment:** Indicate the specific location of the research study. If it is being conducted at a site other than an Aurora hospital or medical center, give the name of the clinic or facility followed by "of Aurora Health Care," if applicable.

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< OR if applicable >

The study is being conducted by others and will involve [indicate the number of subjects to be recruited] people at several medical centers in the [United States or world] including [indicate the number of subjects at this institution] at [institution where subject is being enrolled].

**Who is sponsoring this study?**

[Insert Sponsor's name] the company that makes the [drug or device] being studied, sponsors this study. [Include, if applicable] The principal investigator has a financial interest in that [she/he] is paid by the company to perform this study. You should ask the investigator, or [his/her] representatives, if you want to know more.

Aurora Health Care, Inc. has a financial interest in the study and is being paid by the company to perform this study and provide health care professionals to conduct this study. You should contact Aurora's Patient-Centered Research at 414.219.7817 if you want to know more.

**What is involved in the study?**

Screening procedures: To see if you are eligible to be in this study, you will be asked to answer questions about your health. If your answers tell us that you are eligible, you will be asked to take part in the testing portion of this study. If you are not eligible, your answers will be shredded so they cannot be seen or used again <OR> your answers will be kept in a locked file in the investigator's office until the study is over and then shredded so they cannot be seen or used again.

If you agree to be in this study, you are an active participant and need to follow the directions of the principal investigator and other members of the research team. If you decide to participate in this study, the investigators will ask you to do the following things:

You will be "randomized" into one of the study groups. This means that you will be assigned to a group by chance, like flipping a coin. This is done by a computer program – neither you nor the investigator will know which group you will be in. This approach, called "blinded," is needed to make a fair evaluation of the study treatment methods. [include if applicable] In cases of emergency, the principal investigator can be informed of the study treatment you are receiving.

This study uses questionnaires. Some of the questions are about personal and sensitive things such as [give details and examples]. Your answers to the questions will be kept with your research records <OR> destroyed.

You will have responsibilities as a research subject, which include:

- following study directions
- attending study visits
- telling the research team if you are feeling bad or worse than before
- [Insert subject responsibilities specific to this study]

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**Comment:** In this section, state the sponsoring organization and whether the principal investigator receives financial support from the organization. If Aurora has a financial interest in conducting this study, that should be stated also.

**Comment:** Only studies managed by Clinical Research should include this paragraph. If you are unsure if this applies to your study, contact Clinical Research.

**Comment:** The template language in this section may not be applicable to all studies. Customize this section to your specific protocol.

**Comment:** If a screening procedure is used to determine eligibility to participate, include a description of the screening. State whether information obtained from those who are ineligible will be maintained or destroyed. If screening procedures are not used, [4]

**Comment:** If this study includes testing for HIV/AIDS, contact the RSPP office (414-219-7744) for template language.

**Comment:** Explain all procedures, interventions, and tests the subject will undergo as part of this study. A distinction must be made between procedures that are not used, [5]

**Comment:** For randomized studies, include this paragraph. If randomization is 1:1, 1:2, 1:3, etc., explain this in this paragraph. If the randomization process is not used, [6]

**Comment:** If the subject will be asked to complete a questionnaire or interview, describe the types of questions that she/he will be asked to answer, [7]

**Comment:** Describe the questions that subjects will be expected to answer. For example, explain that questions will ask about illicit drug or alcohol abuse, sexual history, [8]

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**How long will you be in this study?**

If you choose to participate in this study, your participation is going to last [insert description]. The whole study, outside of the time you will directly participate, is expected to last for [insert duration].

**Comment:** State how long the subject will be in the study, i.e. the duration of the study, and include the duration of long-term follow-up procedures. The time frame given to the subject should be measured from the time of enrollment to the last follow-up visit.

The investigator or sponsor may take you off the study at any time if she/he feels that continuing would hurt you, or if any of the following things happen:

<AND/OR>

The sponsor could end your participation in this study at any time. The possible reasons are 1) if safety concerns are found in the analysis of the research data; 2) if the research question(s) of the trial have been answered, proved or disproved earlier than expected; or 3) if the sponsor decides to stop development of this product. There may be other reasons that are not foreseen.

**Comment:** This is the amount of time that the study sponsor has estimated it will take to enroll all subjects and analyze the data. [9]

**What are the risks to you from participating in this study?**

[Use a risks template to communicate the potential risks of this study]

While you're in this study, you may have side effects. Side effects are unwanted problems from a drug, procedure or device. The side effects we know about are listed [below or in the attached Risks Chart]. Most side effects go away when you stop taking the drug.

**Comment:** List the circumstances or events that would necessitate the removal of the subject from the study without his/her consent. [10]

The [insert drug or device] may involve risks or side effects that we don't know about right now. If the investigator learns about new risks or side effects, the investigator or health care personnel assisting [him/her] will tell you about them as soon as possible.

**Comment:** In this section, address if the sponsor intends to make the study drug available after subject participation has ended. If [11]

[Include risks of blood draws, CT, X-Ray as relevant to this study. Insert the following paragraphs if applicable:]

**Comment:** Risks templates are available on the RSP web site.

The study drug(s) may have side effects because of other medications you are taking. Please tell the investigator about any medications, including over-the-counter drugs and herbal supplements, that you are taking.

**Comment:** Page: 3  
For oncology studies, assess whether the likelihood of experiencing side effects is [12]

**Questionnaire Risks**

You may experience unpleasant memories while responding to the questionnaire or interview. You don't have to answer any questions that you don't want to answer. You may also choose not to complete certain questions or even the entire questionnaire.

**Comment:** If the available templates are not appropriate for your study, please list the physical and non-physical study risks [13]

**MRI Risks**

- MRI poses almost no risk to the average subject when appropriate safety guidelines are followed.
- If sedation is used there are risks of excessive sedation. Technologists will monitor your vital signs to minimize this risk.
- Although the strong magnetic field is not harmful in itself, implanted medical devices that contain metal may malfunction or cause problems during an MRI exam.

**Comment:** Modify this statement as appropriate for the study. If the sponsor has information regarding long-lasting or permanent side effects [14]

**Comment:** Include this paragraph if your study involves drugs or devices. If not, then list the risks specific to your study (genetics) [15]

**Comment:** For studies involving drugs, a statement should be included, if applicable, that the study drug(s) may have [16]

**Comment:** For studies that involve only questionnaires or interviews, DO NOT state that there are no risks associated with the study [17]

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- There is a very slight risk of an allergic reaction if contrast material is injected. Such reactions usually are mild and easily controlled by medication. If you experience allergic symptoms, a radiologist or other physician will be available for immediate assistance.
- Nephrogenic systemic fibrosis is currently a recognized, but rare, complication of MRI believed to be caused by the injection of high doses of MRI contrast material in patients with very poor kidney function.

**X-Rays and Procedures involving radiation**

*[If this study involves extra radiation beyond what would be received as standard medical care, include a description of how much additional radiation, using lay terms. For example: "You will have two extra x-rays which is the equivalent of the radiation you are exposed to on a flight across the United States." Please consult a radiologist or the IRB office to draft appropriate language.]*

**Reproductive risks:**

We know that the [insert drug or device] being studied is dangerous to an unborn child. If you are a woman, you may only take part in this study if you can't have children (are post-menopausal or if you are surgically sterile). <AND if applicable> If you are a man, you may only take part in this study if you agree to use [insert acceptable birth control methods].

<OR>

If you are a woman who can still have children (that is, premenopausal and not surgically sterile), a [blood or urine] sample will be taken from you before you start the study so we can be as sure as possible that you are not pregnant. **Because the use of [insert drug or device being studied] being studied could hurt an unborn child, to be eligible to participate in this study, you have to use effective birth control methods [bold text and list acceptable birth control methods] to keep you from getting pregnant [insert time frame or endpoint].** If you do get pregnant, tell the principal investigator right away so that you can get medical treatment or counseling if medically necessary. You may have to be taken off this study if you get pregnant. Nursing mothers can't be in this study because of the following risks or nursing inconveniences.

**Are there benefits to you from participating in this study?**

The benefits that you may get from being in this study are [insert potential benefits] <OR>

You [choose one: may/will not] benefit by being in this study. We do think we'll get new information about [disease, medical condition, etc.], and this information may help patients in the future.

**What are your options if you don't take part in this study?**

You may choose to not participate in this study. Other options if you choose not to take part in this study include: [Delete this sentence and chart if the only option is to not participate in this study.]

Option/Alternative Treatment	Risks	Benefits

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**Comment:** The following statements are examples of language that should be included to address reproductive risks, if applicable to the study. If there are risks of fathering a child, that must be addressed in this section.

**Comment:** List the risks or inconveniences to the embryo or fetus.

**Comment:** Specify how long subjects should use birth control methods. For example, if subjects should use birth control until completion of a specific study visit or for a certain number of weeks following participation, then state that here.

**Comment:** Include this sentence if applicable to this study.

**Comment:** Take care not to misrepresent experimental therapy of unknown efficacy as beneficial therapy of established efficacy. If the patient will not benefit personally, state so clearly. Payment to subjects (including study drug or procedures at no cost) is not considered a benefit and will be addressed in the Costs section.

**Comment:** Insert the potential risks and benefits of alternative modes of treatment, procedures, courses of treatment that may be available, and the ramifications if no treatment is provided. The person(s) obtaining the subjects' consent must be able to discuss available alternatives and answer questions that the subject may raise about them. As with other required elements, the consent document should contain sufficient information to ensure an informed decision. This information should parallel conversations in the clinical [18]

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**[You may add more rows if necessary]**

\*Note: Alternative treatment risks and benefits listed above have been abbreviated and cannot substitute for detailed discussion with your physician.

**What are the costs to you for participating in this study?**

You will have to pay for tests/procedures that are normally done for the diagnosis and treatment of your condition.

If you have health insurance, the costs of your usual medical care while in the study will be billed to your insurance company. We don't ask your health insurance company if they will pay, so it is recommended that you contact the company to see what they will and will not pay for on your behalf. Your investigator or research team can provide you with information about how to do this.

The study sponsor will pay for the cost of tests, procedures, and/or medications that are required for the study, and would not normally have been done by standard of care. This includes costs associated with the following:

**[insert the research costs the sponsor will be responsible for].**

Anything not paid by either the study sponsor or your health insurance company will be billed directly to you for payment.

You will <OR> will not be paid for being in this research study. **[If subjects will be paid, include the rest of this paragraph.]** You will receive **[insert amount]** for each office visit. If you complete all study visits and procedures, you will receive a total of **[insert total payment amount]**. **[If there is payment for this study, include the following statement: Since there is payment in this study, we may be required to report your payment to the IRS. You will be responsible for paying any state, federal, or social security taxes.]** This payment is for your time and travel and you will be paid after each visit. If you decide to stop taking part in the study or if you are withdrawn from this study, you will be paid for the visits or procedures that you completed. Please contact your study coordinator at **[insert phone number]** with questions.

**For registry studies, delete the preceding section and insert the following:**

All costs associated with your standard medical care **[insert list of examples]** will be billed to you or your insurance company.

Since the research-related activities in this study are data collection, there will be no charge to you for the research.

You will <OR> will not be paid for being in this research study. **[If subjects will be paid, include the rest of this paragraph.]** You will receive **[insert amount]** for each office visit. If you complete all study visits and procedures, you will receive a total of **[insert total payment amount]**. **[If there is payment for this study, include the following statement: Since there is payment in this study, we may be required to report your payment to the IRS. You will be responsible for paying any state, federal, or social security taxes.]** This payment is for your time and travel and you will be paid after each visit. If you decide to stop taking part in

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**Comment:** If costs associated with the study are being reimbursed by the sponsor or other entity, the informed consent form must clearly state the circumstances under which funds will be made available, the process for obtaining such funds, and provide the name and telephone number of a contact person who will be available to answer subjects' questions and arrange for disbursement of the funds. Indicate who pays for the research (i.e. study materials, medicines, procedures, etc.) and non-research costs (i.e. regular care), and who pays for monitoring. Inform the subject, when pertinent, that they may undergo testing or procedures that would not necessarily be performed if they received treatment outside of the study. Inform the insured subject that his/her insurance company may or may not cover these costs. ... [19]

**Comment:** Address the issue of payment to research subjects in this section. Explain when disbursement will occur and conditions of payment. Note: FDA guidelines state that any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. However, payment of a small proportion as an incentive for completion of the study is ... [20]

**Comment:** Address the issue of payment to research subjects in this section. Explain when disbursement will occur and conditions of payment. Note: FDA guidelines state that any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. However, payment of a small proportion as an incentive for completion of the study is ... [21]

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the study or if you are withdrawn from this study, you will be paid for the visits or procedures that you completed. Please contact your study coordinator at [insert phone number] with questions.

**What if you get hurt or ill from your participation in this study?**

If you get hurt or ill from your participation in this study, you should seek medical treatment as soon as possible.

- You will not have to pay for the costs of this medical treatment if the [UNEXPECTED] illness or injury is caused by your participation in this research study.
- Aside from the costs of medical treatment, there is no plan to provide you with other payments (such as lost wages, reimbursement for time and travel).
- The costs associated with medical treatment that is not related to your participation in the research will be billed at the usual charge to your health insurance, if you have health insurance. You are responsible for any co-pays or deductibles of your health insurance. If you do not have health insurance, or if your health insurance does not pay the costs associated with your medical treatment that is not related to your participation in the research, these costs will be billed to you.
- You do not give up your legal rights by signing this form.

If you think that you've been hurt because you were in this research study, you can call the principal investigator, [insert name], at [insert phone number] anytime or Patient-Centered Research at 414-219-7817 during normal business hours to find out what you should do next.

**[IRB office note: At the time of initial submission, we are assuming that the contract will be negotiated so that the sponsor pays for research related injury. IRB deliberation is based on this assumption. This language is consistent with Aurora's policy and is expected to be acceptable to the sponsor. Sponsors should be made aware that it is highly unlikely that the Aurora IRB will renegotiate this language.]**

**The following language should be used for FEDERALLY-FUNDED studies that are sponsored by the government or for studies for which, as verified by Aurora Sponsored Programs, there are insufficient resources to cover research-related injury treatment costs.**

**What if you get hurt or ill from your participation in this study?**

If you get hurt or ill from your participation in this study, you should seek medical treatment as soon as possible.

- The costs associated with this medical treatment will be billed at the usual charge to your health insurance, if you have health insurance.
- You are responsible for any co-pays or deductibles of your health insurance. If you do not have health insurance, or if your health insurance does not pay the costs associated with your medical treatment that is not related to your participation in the research, these costs will be billed to you.

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**Comment:** For minimal risk studies, only include the last paragraph.

**Comment:**  
INSTRUCTIONS: At the time of submission, unless your study is federally funded or you know definitively otherwise, the contract will be negotiated so that the sponsor will cover the costs of a research related injury. This template language is expected to be acceptable to the sponsor. Once the contract is signed and after the IRB approval letter is issued, if changes need to be made, submit as a modification that will be taken back to a fully-convened IRB meeting. However, sponsors should be made aware that the Aurora IRB is unlikely to approve changes to this language. Call the RSPP manager if there are specific questions.

**Comment:** Page: 6  
Insertion of the word "UNEXPECTED" would be acceptable to the IRB if this is consistent with the contract language – study coordinators will need to confirm this as the RSPP office will not have this information.

**Comment:** Page: 6  
From a legal perspective, using "caused by" is tighter and cleaner than "related to" or "directly related to". Here's an example – subject arrives at the site for visit 2 of her diabetes drug study, and just prior to receiving an injection of the investigational agent, the building blows up and she is injured. She could say that her injuries are "related to" her trial participation, but certainly not "caused by" the investigational agent or any trial procedure. In contrast, there may be a n[...] [22]

**Comment:** Page: 6  
Depending on the study, this could be physical or mental.

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- There is no plan to provide you with other payments for or related to your injury or illness.
- You do not give up your legal rights by signing this form.

If you have Medicare health insurance and if you become hurt or ill because you were in this research study, information that identifies you may be sent to Medicare.

If you think that you've been hurt because you were in this research study, you can call the principal investigator, [insert name], at [insert phone number] at anytime or Patient-Centered Research at 414.219.7817 during normal business hours to let you know what you should do next.

**Comment:** Page: 7  
Depending on the study, this could be physical or mental.

**What are your rights if you take part in this study?**

This study has been reviewed and approved by an Aurora Health Care Institutional Review Board (Aurora IRB). An IRB is made up of a group of people (both scientists and lay persons) who review and approve research studies. The IRB checks that the research being done follows federal regulations for human subject research. IRB approval of a research study only means that everything is okay according to the federal regulations and Aurora policies to start the study. The IRB wants you to know that **only you can decide** if being in this study is the right decision.

Being in this study is your choice. Because you volunteer to be in this study, you may also choose to leave this study at any time. Before you leave this study, talk with the investigator who will help you stop in the safest way. There may be procedures or exams that are needed to ensure your safety.

**Comment:** Specify the procedures or exams required for this study.

If you leave this study early, the study sponsor and investigator will continue to use and disclose any information about you that was gathered before you dropped out. This is necessary to preserve the integrity of the research study. If you do not want to participate, or if you later leave this study, you will not be treated differently, your health care will not be affected in a negative way, and you will not lose any benefits you would normally receive.

If we learn new things during the study that may affect your health or your willingness to continue in the study, we will tell you as soon as possible.

For general questions, concerns, or complaints about the study, contact the principal investigator, [insert name], at telephone number [insert telephone number]. If the principal investigator or research staff cannot be reached, contact the Human Protections Administrator in the Aurora Research Subject Protection Program office at 414.219.7744 or toll-free at 1.877.219.7744 (outside the Milwaukee area).

**Comment:** This telephone number should connect the subject with someone who is knowledgeable about the study. Also, if the number changes after the subject is enrolled, submit a modification to update the consent form.

If you want to talk to someone not part of this study about your rights as a human subject, or to address concerns, complaints, or input about the study, contact the Human Protections Administrator in the Aurora Research Subject Protection Program office at 414.219.7744 or toll-free at 1.877.219.7744 (outside the Milwaukee area).

For general information regarding Aurora Health Care's Research Subject Protection Program, go to: [www.aurora.org/irb](http://www.aurora.org/irb) . For general information regarding human subject research at Aurora Health Care, go to: <http://www.aurorahealthcare.org/yourhealth/clinicalresearch/index.asp>.

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**Information about Confidentiality and HIPAA Authorization**

The federal Health Insurance Portability & Accountability Act (HIPAA) sets standards for the privacy and security of health information records. HIPAA limits how health insurance plans, pharmacies, hospitals and others can use and disclose your personal health information. HIPAA provides certain protections for medical records and other health information, whether on paper, in computers, or communicated orally.

**Why is access to my health information being requested?**

We are asking you to allow others to access your health information, for purposes related to this research study. If you do not want your information to be used in connection with this study as explained below, and do not want to participate, you will not be treated differently, your health care will not be affected in a negative way, and you will not lose any benefits you normally receive.

**What protected health information is going to be collected and used as part of the research study?**

During your participation in the study, we will be collecting and/or creating personal health information about you (for example, results of tests and procedures you undergo while in the study) and recording it on study documents. The study doctor will keep this personal health information in your study-related records (which we will refer to as your "study records"). In addition, the study doctor may obtain, and include in your study records, information regarding your past, present and/or future medical conditions. Your study records may include personal identifying information such as your social security number, date of birth, medical record numbers, etc., that could be used to identify you ("Protected Health Information" or "PHI"). Under HIPAA, your PHI that is created or obtained during this research study cannot be used or disclosed as needed for research-related purposes without your permission ("Authorization"). Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI (as described below) by signing this Authorization.

**What protected health information will be disclosed as part of the research study?**

If you agree to be in this research study and sign this Consent/Authorization, protected health information collected and/or created for the research study may be disclosed to others. By signing this Authorization, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study and to disclose your PHI as described below:

- To the sponsor of the study and anyone working on behalf of the sponsor (referred to as "the sponsor") to conduct the study. The sponsor also may analyze and use the PHI to develop new tests, procedures and commercial products. Also, in overseeing the way the study is being conducted and making sure the information is correct, the sponsor may look at your complete study records that identify you, and the sponsor may visit the study site and review your PHI during these visits. This means that the sponsor may have direct access to your original medical records at Aurora Health Care.
- To members of the Aurora Health Care Institutional Review Board (IRB), consultants, and staff of Aurora Health Care. The purpose is to ensure adequate protection of research subjects.
- To organizations involved in the regulation of research (e.g., the FDA, the Department of Health and Human Services, OCR, government agencies in other countries) and in accreditation of research

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programs or hospitals. The purpose of this disclosure is for research compliance and to obtain and maintain accreditation.

**What about the confidentiality of my research information?**

Any protected health information collected or created during this research study will be kept in your medical and research records at Aurora Health Care and will be kept as confidential as possible in accordance with Aurora Health Care health information privacy policies. **[If this study will collect HIV/AIDS test results or status, contact the RSPP office (414-219-7744) for template language.]** Except for disclosure described above, your PHI will not be shared with others unless required or permitted by law. The sponsor's key individuals have agreed to keep confidential information they are authorized to receive, which will minimize the risk that your information will be released to others without your permission. However, once your information leaves Aurora Health Care, Aurora will not be able to control how it is used by those who receive it, and the information is no longer protected from further disclosure by the federal HIPAA privacy law.

In any written material about results of this research study that might be published, no information will be included that will make it possible to identify you.

A description of this research study will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. law or in other appropriate circumstances. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. The description requirement only applies to clinical trials. If this research study is not a clinical trial, information about this research study may not be available on this web site.

**During what period of time will the entities listed above have access to your protected health information?**

Access to your protected health information related to this study will begin as soon as you sign this consent/Authorization. This Authorization expires when the study is finished, all data analysis has been completed, and the study records have been destroyed.

**Comment:** If you know an event or date, you may enter that instead.

**What if you change your mind about allowing access to your protected health information?**

You may withdraw your Authorization for us to use and disclose your protected health information as explained above, but you must do so in writing to the investigator. If you need help with this, call the Aurora Research Subject Protection Program office at 414.219.7744 or toll-free at 1.877.219.7744 (outside the Milwaukee area). If you withdraw this Authorization, you will no longer be able to take part in this research study. If you drop out of this study, the study sponsor and investigator will continue to use and disclose any information about you that was gathered before you dropped out in order to preserve the integrity of the research study.

**Your right to see your protected health information.**

**Add one of the following statements regarding the subject's access to research records, as applicable:**

You can't have access to your research related records during the research study, but once you've completed the study or have left, you can have access to your research related records. **<OR>** You can

Subject Initials \_\_\_\_\_

Page 9 of 12

**Aurora IRB Stamp of Review**

Aurora IRB Protocol #: \_\_\_\_\_  
IRB approved consent final version date: 3-30-2012  
Use of this consent form expires on: \_\_\_\_\_  
(subject's consent/authorization is not affected by this date)

**Deleted:** 12/15/2011

Subject Medical Record Number: \_\_\_\_\_

have access to your research records at any time during this research study or upon its completion. **<OR>**  
Describe any restrictions on the subject's access to the research study records.

**This study has a Certificate of Confidentiality.**

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**Comment:** For studies that have a negotiated Certificate of Confidentiality, the use of this section is suggested. Otherwise, it should be deleted.

**Deleted:** To further help us protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services. With this certificate, the investigators cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative or other proceedings.¶

¶ You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research; and if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.¶

¶ Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others, and the Certificate does not prevent the review of your research information under some circumstances (for example, under the Federal Food, Drug and Cosmetic Act or during the course of an internal program audit or evaluation).¶

Subject Initials \_\_\_\_\_





**Aurora IRB Stamp of Review**

Aurora IRB Protocol #: \_\_\_\_\_

IRB approved consent final version date: 3-30-2012

Use of this consent form expires on: \_\_\_\_\_  
(subject's consent/authorization is not affected by this date)

Deleted: 12/15/2011

Subject Medical Record Number: \_\_\_\_\_

**RISK/BENEFIT/ALTERNATIVES DISCUSSION:** An investigator in the research study 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 investigator's direct supervision. However, if the research study involves a medical treatment or intervention in which consent is normally obtained in the clinical setting, and the medical records will be maintained at an Aurora facility, state law requires documentation that a physician [who is the principal investigator or a sub-investigator in the study] has informed the patient [subject] about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. It is the Aurora RSP's and IRB's position such discussion should take place prior to the initiation of any research related activity, and any attempt to delegate this responsibility to another individual (e.g., a non-physician study coordinator) would constitute a breach of the physician's duty to provide informed consent under state law. However it is ultimately the principal investigator's decision.

This is to verify that I, (print name) \_\_\_\_\_ have explained to and discussed with the subject, or the subject's Legally Authorized Representative, Legal Guardian, Health Care Agent, or Parent ("LAR"), as appropriate, the following items related to the above procedure(s) before the initiation of the research-related intervention:

- The nature of the research
- Potential risks, benefits, drawbacks
- Potential problems related to recuperation (if applicable)
- Possible results of research
- Known side effects or complications of the research
- The availability of all alternate viable modes of treatment and the benefits and risks of such treatments, if applicable).

\_\_\_\_\_  
SIGNATURE and TITLE of individual providing this information

\_\_\_\_\_  
DATE

**DOCUMENTATION OF INFORMED CONSENT:**

- The study and all elements contained within this informed consent document were discussed with the subject/LAR, after which the subject/LAR verbalized understanding.
- The subject/LAR was given the opportunity to ask questions, and all questions were answered.
- Written informed consent was obtained prior to initiating any research-related procedures.
- A copy of the signed/dated consent form was given to the subject/LAR.

COMMENTS:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**A SIGNED COPY OF THIS FORM MUST BE FILED IN THE INSTITUTION'S PATIENT MEDICAL RECORD (if applicable). The original must be kept in the investigator's research records.**

Form IC 701Av3-30-2012

Deleted: 12-15-2011

**Page 1: [1] Comment****RSPP Staff**

Explain research question and purpose in lay language. State why the drug/device is being studied. Indicate whether the drug or device being tested in the study or used in the study is experimental or whether any procedures are experimental. Consent documents for studies of investigational articles should include a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that the test articles are safe, or statements that the safety has been established in other studies, or that the articles are effective are not appropriate when the purpose of the study includes determination of safety.

**Page 1: [2] Comment****RSPP Staff**

State the department, institution, and/or practice with which the investigator(s) is affiliated. If the investigator is a student, include the name of the person supervising the research. If applicable, state that an investigator is a member of the full-time faculty of the University of Wisconsin Medical School's Milwaukee Clinical Campus. The RSPP office will allow all investigators to be listed here however only including the PI's name is preferred. If all investigators are listed, a modification to the informed consent document will be required each time an investigator is added or removed. If modifications are not submitted, and investigators change, this will be considered a protocol violation.

**Page 1: [3] Comment****RSPP Staff**

Page: 1

When using the terms "study doctor" or "investigator" be mindful of what is being done for research purposes. For registry studies, the IRB generally prefers the use of "investigator" or "researcher" in the consent. For clinical trials, the IRB generally prefers the use of "study doctor" in the consent. Be consistent in the use of a term and if necessary, change the template terms to be consistent.

**Page 2: [4] Comment****RSPP Staff**

If a screening procedure is used to determine eligibility to participate, include a description of the screening. State whether information obtained from those who are ineligible will be maintained or destroyed. If screening procedures are not used in this study, then delete this paragraph.

**Page 2: [5] Comment****RSPP Staff**

Explain all procedures, interventions, and tests the subject will undergo as part of this study. A distinction must be made between procedures that are part of standard medical care for the disorder in question, those that are not required as standard medical care but are required by the study design, and those that are experimental. You may provide a simplified schema/calendar. When procedures are repeated, list the frequency and intervals concerned.

Describe the assignment to study groups, anticipated length of time for an individual subject's participation, and any other pertinent information.

Reminder: quantities, such as blood drawn, should be listed in lay term equivalents, such as teaspoons.

If this is a Phase I, II, III, or IV study, please explain what that means in lay terms. In this section, define what follow-up consists of, i.e. how many clinic visits, x-rays, visits for special exams, etc. and what will be expected of the subject during follow-up.

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**Page 2: [6] Comment**

**RSPP Staff**

For randomized studies, include this paragraph. If randomization is 1:1, 1:2, 1:3, etc., explain this in this paragraph. If the randomization process involves stratification, this should be explained and should be consistent with the content of the protocol. The study design should also be explained, i.e., blinded, double-blind, open label, cross over, placebo-controlled, descriptive, etc.

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**Page 2: [7] Comment**

**RSPP Staff**

If the subject will be asked to complete a questionnaire or interview, describe the types of questions that she/he will be asked to answer along with an estimate of the amount of time it will take to complete. A copy of the questionnaire or script of the interview must be included for IRB review.

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**Page 2: [8] Comment**

**RSPP Staff**

Describe the questions that subjects will be expected to answer. For example, explain that questions will ask about illicit drug or alcohol abuse, sexual orientation or history, etc.

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**Page 3: [9] Comment**

**RSPP Staff**

This is the amount of time that the study sponsor has estimated it will take to enroll all subjects and analyze the data collected.

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**Page 3: [10] Comment**

**RSPP Staff**

List the circumstances or events that would necessitate the removal of the subject from the study without his/her consent. Statements that the subject may be withdrawn if the subject violates study plan, or for administrative reasons, are not appropriate since the subjects may not know all of the violations contained in the study plan or the administrative reasons that would constitute disenrollment and those statements do not adequately inform the subjects of anticipated circumstances for such withdrawal.

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**Page 3: [11] Comment**

**RSPP Staff**

In this section, address if the sponsor intends to make the study drug available after subject participation has ended. If the study drug will not be available following subject participation, that should be stated as well.

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**Page 3: [12] Comment**

**RSPP Staff**

Page: 3

For oncology studies, assess whether the likelihood of experiencing side effects is “very likely” and state that here. Delete “you may have side effects” and insert “it is very likely that you will have side effects.”

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**Page 3: [13] Comment**

**RSPP Staff**

If the available templates are not appropriate for your study, please list the physical and non-physical study risks according to “most likely,” “less likely,” or “least likely.” You should also note whether the risks are “most serious,” “less serious,” and “least serious” in this section. Specifically note those risks that are relating solely to research. Also, risks of the tests required in the study protocol should be explained, especially for tests that carry significant risk of morbidity/mortality themselves. The explanation of risks should be reasonable and should not minimize reported adverse effects. The explanation of risks of the test article should be based upon information presented in documents such as the protocol and/or investigator’s brochure, package labeling, and previous research study reports.

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**Page 3: [14] Comment**

**RSPP Staff**

Modify this statement as appropriate for the study. If the sponsor has information regarding long-lasting or permanent side effects, please specify those here. If there are none, then delete statement.

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**Page 3: [15] Comment**

**RSPP Staff**

Include this paragraph if your study involves drugs or devices. If not, then list the risks specific to your study (genetics, tissue banking, etc.).

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**Page 3: [16] Comment**

**RSPP Staff**

For studies involving drugs, a statement should be included, if applicable, that the study drug(s) may have interactive side effects and that the subject should report any medications, including over-the-counter drugs and herbal supplements being taken, to the investigator and to all physicians treating the subject.

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**Page 3: [17] Comment**

**RSPP Staff**

For studies that involve only questionnaires or interviews, DO NOT state that there are no risks associated with the study. For example, because of the personal nature of the questions asked, a subject may reflect on unpleasant memories while responding to the questionnaire or interview. The subject should be informed of the potential for discomfort and told that if she/he begins to feel uncomfortable, she/he may discontinue participation, either temporarily or permanently, and may decline to answer any questions that cause the subject to feel uncomfortable.

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**Page 4: [18] Comment**

**RSPP Staff**

Insert the potential risks and benefits of alternative modes of treatment, procedures, courses of treatment that may be available, and the ramifications if no treatment is provided. The person(s) obtaining the subjects' consent must be able to discuss available alternatives and answer questions that the subject may raise about them. As with other required elements, the consent document should contain sufficient information to ensure an informed decision. This information should parallel conversations in the clinical setting.

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**Page 5: [19] Comment**

**RSPP Staff**

If costs associated with the study are being reimbursed by the sponsor or other entity, the informed consent form must clearly state the circumstances under which funds will be made available, the process for obtaining such funds, and provide the name and telephone number of a contact person who will be available to answer subjects' questions and arrange for disbursement of the funds. Indicate who pays for the research (i.e. study materials, medicines, procedures, etc.) and non-research costs (i.e. regular care), and who pays for monitoring. Inform the subject, when pertinent, that they may undergo testing or procedures that would not necessarily be performed if they received treatment outside of the study. Inform the insured subject that his/her insurance company may or may not cover these costs. Advise the subject that their insurance company is not contacted prospectively to determine what investigational services may be a covered benefit for the subject. Whenever possible, suggest the insured subject contact his/her insurance company to determine whether their individual policy would cover the charges not paid by the sponsor or whether the subject him/herself would be responsible for the cost. Inform the uninsured subject that s/he will be responsible for services not paid by the sponsor. Itemize the costs to be billed to the uninsured subject (those not paid by the sponsor.). Also, inform subjects that they will be responsible for health insurance co-pays and deductibles.

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**Page 5: [20] Comment**

**RSPP Staff**

Address the issue of payment to research subjects in this section. Explain when disbursement will occur and conditions of payment. Note: FDA guidelines state that any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. However, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. All information concerning payment, including the amount and schedule of payment(s) should be set forth in the informed consent document [FDA Information Sheets 1998 Update – Payment to Research Subjects].

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**Page 5: [21] Comment**

**RSPP Staff**

Address the issue of payment to research subjects in this section. Explain when disbursement will occur and conditions of payment. Note: FDA guidelines state that any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. However, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. All information concerning payment, including the amount and schedule of payment(s) should be set forth in the informed consent document [FDA Information Sheets 1998 Update – Payment to Research Subjects].

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**Page 6: [22] Comment**

**RSPP Staff**

Page: 6

From a legal perspective, using "caused by" is tighter and cleaner than "related to" or "directly related to". Here's an example – subject arrives at the site for visit 2 of her diabetes drug study, and just prior to receiving an injection of the investigational agent, the building blows up and she is injured. She could say that her injuries are "related to" her trial participation, but certainly not "caused by" the investigational agent or any trial

procedure. In contrast, there may be a number of individuals who participated in the Vioxx trials and who can legitimately claim that their heart problems were "caused by" the investigational drug.