

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. *Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.*

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 **Study title:**

1.2 **Company or agency sponsoring the study:**

1.3 **Names, degrees, and affiliations of the researchers conducting the study:**

2. PURPOSE OF THIS STUDY

2.1 **Study purpose:**

Comment [IRBMED1]: For studies that use the same informed consent document for both adult and pediatric subjects, the following text may be substituted for the first paragraph:

You, or your child, may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. Parents or legal guardians who are giving permission for a child, please note: in the sections that follow the word 'you' refers to 'your child.'

While this alternate text has been endorsed by Meriter IRB, it may not be appropriate for all studies. As appropriate, on an individual basis, Meriter IRB may require a different approach. Investigators may also propose a different approach, subject to Meriter IRB approval.

Comment [IRBMED2]: The study title must match on all documents (application, protocol, consent document, etc.). NOTE: The investigator may designate a subtitle for each consent document used in the study. The Consent Subtitle uniquely identifies a consent document when a study uses multiple consents (e.g., Main, Genetic, Screening, Treatment Group, etc.) iRIS will automatically generate a version number and page numbers.

Comment [IRBMED3]: Provide the name(s) of the sponsor(s) of the study. If the study is not sponsored, state or otherwise explain that there is no sponsor.

Comment [IRBMED4]: List the names and degrees of the PI and Co-PIs and their respective affiliations (i.e., department and institution). For example, Ima Researcher, M.D., Ph.D., Department of Internal Medicine, University of Michigan.

Comment [IRBMED5]: Briefly (one paragraph) explain in lay-terms the scientific reason for doing this study. Do not describe the details of the protocol here – that will be done in Section 4 on Study Procedures (below). For example: "Disease Z is known to be caused by increased levels of a particular protein, called Y, in the bloodstream. Research in animals has shown that a new drug, called X, can lower the levels of the Y protein. We do not know, however, whether Drug X is safe for use in humans, and if so whether it will lower levels of Y protein in people as well as it has in animals. This research study is being done to learn what effect 3 months of treatment with Drug X will have on the levels of Protein Y in the bloodstream of patients with Disease Z."

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

3.2 How many people (subjects) are expected to take part in this study?

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid them. In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator,

Comment [IRBMED6]: If applicable, investigators should consider using this section to reassure subjects that their standard medical treatment does not depend on their participation in this study.

Comment [IRBMED7]: List important eligibility criteria in lay terms. Also include a discussion of important exclusion criteria, if applicable. For some studies, investigators may wish to remind potential subjects of the importance of providing complete and accurate information about their health condition/history in order to ensure that they are safe and appropriate candidates for participation.

Comment [IRBMED8]: Insert the total number of subjects you expect to enroll. If this is a multi-site study, include the total number over all sites as well as the local number of subjects. For example: 300 subjects are expected to participate, 25 at Meriter (or between Meriter and University of Wisconsin) and 275 at other sites around the United States. If the study includes different subject pools (control group/affected group), note that also. For example: 100 total subjects (25 subjects with Alzheimer's disease and 75 healthy subjects).

Comment [IRBMED9]: Explain in lay terms, usually in chronological order, the experimental/investigational procedures/treatments. To provide context for these procedures/treatments, it may be helpful to include a brief description of medical care or other procedures that would be performed whether or not the subject participated in the study, but these procedures must be clearly distinguished from the ... [1]

Comment [IRBMED10]: Explain as needed, describing time in hours, number of visits, amount of time each visit will entail, etc. Include expectations for long-term follow-up, if applicable. For example: Each subject will receive Drug X for 3 months, then have at least 3 follow-up visits to the researcher over the next 3 months. Each visit is expected ... [2]

Comment [IRBMED11]: Explain the risks and discomforts in clear, simple, concise terms (consider using bulleted format). Please note that none or not applicable are not considered appropriate for this section, since even studies involving minimal risks do have foreseeable risks, such as discomfort or inconvenience. ... [3]

Comment [IRBMED12]: Explain how risks are monitored and reduced. For example, explain that the subject will receive a physical examination and blood test once a week after beginning treatment with the new drug or device. Also explain what types of steps will be taken if adverse effects are detected (e.g., the drug dose will be lowered or stopped) ... [4]

(name) at (phone number) if you are injured or for further information. The cost of this first aid or emergency care may be billed to your insurance company. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Please note: It is important that you tell the researchers about any injuries, side effects, or other problems that you experience during this study. You may also need to tell your regular doctors.

NOTE: If you are a *UW researcher and this is an industry sponsored study* and the sponsor has specific compensation language that they are requiring to be included in the consent form, there are additional language requirements, and these can be found here: <http://www.grad.wisc.edu/hrpp/10147.doc>

Comment [I13]: UW REQUIRED LANGUAGE for greater than Minimal Risk Research. **DO NOT REMOVE** if you are a UW researcher.

Comment [IRBMED14]: If the study sponsor(s) will pay for treatment of study-related injuries or illness, replace these sentences with language that informs subjects that the sponsors will pay and any limitations on the payments.

Comment [IRBMED15]: Delete this sentence if it does not apply to your study.

Comment [IRBMED16]: If applicable, follow this sentence with a description of any relevant potential risks associated with participation in multiple studies (e.g., drug interactions, excessive radiation exposure, etc.).

Comment [IRBMED17]: This should always be the first sentence. If applicable, it can be followed with language that describes possible benefits to subjects or to society. For example: "However, some subjects may [describe potential benefit to subjects]" and/or "Possible benefits of the research for society (or for future patients with this disease) include [describe potential benefit to society]." Do not describe payments or other compensations to subjects here. That information belongs in Section 8 on Financial Information (below).

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

Comment [IRBMED18]: If new information might affect the eligibility of subjects to continue to participate in the study, address that possibility here and also in answer to Question 7.3. For studies in which a subject's participation is limited to a single experimental session (e.g., a single survey study, or study that collects all data at a single time point), investigators may choose to delete this question from the template.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

Comment [IRBMED19]: Describe alternatives to participation (e.g., what is usually done to treat the condition or disease). If appropriate, consider informing subjects of alternative studies, either specifically or by reference to a central source (e.g., www.clinicaltrials.gov). For non-therapeutic studies, in which there is no "alternative" or standard treatment, reiterate the voluntary nature of participation and state that the alternative is to not participate, in which case there will be no penalty. A suitable last sentence for this section is: Ask the researchers or your doctors about (... [5])

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 "Contact Information" (below).

Comment [IRBMED20]: If applicable, investigators should consider using this section to reassure subjects that their standard medical treatment does not depend on their continued participation in this study. If the study involves special procedures for termination of treatment (e.g., orderly withdrawal from dru ... [6])

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Comment [IRBMED21]: Let the subject know about any termination procedures that might exist for this study (e.g., exit interviews, tests, etc.), and any dangers of terminating treatment abruptly or completely, particularly without consulting with the researchers or another doctor, etc.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

Comment [IRBMED22]: If participation will be at no cost to the subject, so state. This is also the place to describe any reimbursement for participation-related expenses (e.g., mileage, parking, etc.). For studies involving treatment intervention(s), clearly explain which costs will be billed to the subject's insurance company, and who (the subject? the study sponsor?) will be responsible for payment of any costs not covered by the insurance. For example: You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as [list]. It is important to understand that some insurance companies do not cover some cost ... [7]

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? If so, which costs? What happens if my insurance does not cover these costs?

Comment [IRBMED23]: Delete these three sentences if not applicable for this study.

Comment [IRBMED24]: Provide clear, concise information. For example: "No. You will not be paid for taking part in this study," or "You will receive \$20 for completing the study questionnaire." Include the amounts and conditions of payment. Investigators are advised that payments to subjects should be pr ... [8]

8.2 Will I be paid or given anything for taking part in this study?

Comment [IRBMED25]: Delete any of the sub-headings under this question that are not applicable to this study. If no person or organization has a financial interest in the outcome of the study, so state in answer to this question and delete all sub-headings. If a person or organization involve ... [9]

8.3 Who could profit or financially benefit from the study results?

The company whose product is being studied:

Comment [IRBMED26]: Disclose under this sub-heading if a company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study, particularly if the company/organization is also the ... [10]

The researchers conducting the study:

The University of Wisconsin:

9. CONFIDENTIALITY OF SUBJECT RECORDS

Meriter policies require that private information about you be protected. This is especially true for your personal information.

Comment [IRBMED27]: If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here in accordance with the management plan approved by the Conflict of Interest Committee (visit: www.med.umich.edu/medschool) ... [11]

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

Comment [IRBMED28]: If the University of Wisconsin owns the investigational technology (for example if there is a technology transfer agreement), so disclose under this sub-heading. Delete this sub-heading if it does not apply.

9.1 How will the researchers protect my privacy?

Comment [IRBMED29]: Describe procedures that will be followed to keep subject information, specimens, and tissues secure and confidential. For example: "Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record. Or: "Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you." This would be the place to mention a Certificate of Confidentiality, if applicable.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- Meriter IRB, Food and Drug Administration [FDA], and other government officials may need the information to make sure that the study is done properly.
- Organizations that are funding the study may need the information to make sure that the study is done properly.
- Safety monitors or committees may need the information to make sure that the study is safe.
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- UW Madison Research Oversight Offices

Comment [IRBMED30]: This paragraph should apply to all studies and should not be deleted.

Comment [I31]: MERITER REQUIRED LANGUAGE, DO NOT REMOVE.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

Comment [I32]: If applicable.

Comment [IRBMED33]: Alternate language for use when identifying information will be used in publications or presentations: The results of this study may be published or presented at a scientific meeting. If your name or other information that might identify you will be used in the publications or presentations, the researchers will ask for your separate written permission. Likewise, if video or audio recordings or photographs of the subject will be used: If your name and pictures will be used in any publications or presentations, the researchers will ask for your separate written permission.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:

Mailing Address:
Telephone:

Study Coordinator:
Mailing Address:
Telephone:

You may also express a concern about a study by contacting the Meriter Patient Representative at:

417-6462
Meriter Hospital
202 South Park Street
Madison, WI 53715

Comment [IRBMED34]: Insert PI and study coordinator names, addresses, and phone numbers. Duplicate and/or edit the contact information headings as necessary to include all appropriate contact personnel.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher and details about the problem. This will help Meriter officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

This Consent to be Part of a Research Study document. *(Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your medical record.)*

Other (specify):

Comment [IRBMED35]: A copy of the signed consent form should be placed in the medical record of subjects, particularly when the research intervention may affect other treatment or care. **However**, doing so may **not** be appropriate in all cases (for example if identification of the subject as a study participant might put the subject at risk of criminal prosecution or harm to reputation). If that is the case, replace ...and may... with ...but will **not**... If more appropriate for this study, the portion of the sentence after ...separate research file... may be deleted altogether.

Comment [IRBMED36]: If you provide the subject with other information, such as a Notice of Privacy Practices or information about advance directives for research, list the documents here. Otherwise, you may delete this bullet.

12. SIGNATURES

Research Subject:

I have discussed this study, its risks and potential benefits, and my other choices with. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Date of Birth: _____

Person Explaining Consent: _____ Date: _____

Signature of Person Explaining Consent: _____

Comment [IRBMED37]: This signature block may also be used to document the assent of minors or others unable to fully give their own consent. If used for assent, the following signature block should be used to document the consent of the person serving as the legal representative of the assenting subject.

Comment [IRBMED38]: This is where the subject signs to consent or assent (in the case of minors or others unable to fully consent for themselves) to participate in the study. For assenting subjects, investigators may choose to insert the word Assenting before the word Subject in the signature line label for clarity (although this is not required). Investigators are reminded that the consent of the Legally Authorized Representative (see the next signature block) is always required for assenting subjects.

Comment [IRBMED39]: Delete Date of Birth for Adults.

Legal Representative (if applicable):

Signature of Person Legally Authorized to Give Consent _____ Date: _____

Name (Print legal name): _____ Phone: _____

Address: _____

Check Relationship to Subject:

Parent Spouse Child Sibling Legal Guardian Other: _____

Comment [IRBMED40]: If the study will enroll minors or others unable to fully consent for themselves, this signature block should be used to document the consent of the minor's parent(s) or other person serving as the legal representative of the assenting subject. **Special note** for studies involving minor subjects: If there is **no direct benefit** to the minor subject, and the risks are assessed by the IRB to be **more than minimal**, the consent of **both** parents (or of the legal guardian) will be required.

Explain in **lay terms**, usually in chronological order, the experimental/investigational procedures/treatments. To provide context for these procedures/treatments, it may be helpful to include a brief description of medical care or other procedures that would be performed whether or not the subject participated in the study, but these procedures must be clearly distinguished from the experimental procedures. Be sure to list **ALL** research-related procedures and treatments, including eligibility testing (e.g., blood tests, imaging, biopsies, etc.), additional blood-drawing, and research uses of approved drugs. Also be sure to describe any wash-out periods or other deviations from the subjects' regular regimen.

Explain as needed, describing time in hours, number of visits, amount of time each visit will entail, etc. Include expectations for long-term follow-up, if applicable. For example: Each subject will receive Drug X for **3 months**, then have at least **3 follow-up visits** to the researcher over the next **3 months**. Each visit is expected to last about **1 hour**. Most subjects will complete their part in the study within about **6 months**. The entire study is expected to last about **3 years**.

Explain the risks and discomforts in clear, simple, concise terms (consider using bulleted format). Please note that none or not applicable are not considered appropriate for this section, since even studies involving minimal risks do have foreseeable risks, such as discomfort or inconvenience.

Note that federal regulations require that research consent documents list **ALL** reasonably foreseeable risks, stresses, and discomforts of **ALL** aspects of participation in a study, not just the most serious or common side effects of a research intervention or procedure (e.g., study drug or device). Avoid statements like The main risks are... or Side effects include... as these statements would not comply with the federal requirement to list all foreseeable risks. However, investigators **are** encouraged to stratify the risks by categories such as

- The most common side effects (occurring in more than 10% of patients) are:...
- Less common side effects (1% - 10% of patients) are:...
- Rare side effects (less than 1% of patients) are:...

Remember to include the risks of any research-related monitoring procedures such as biopsies, blood draws, or radiological tests, as well as the risks of allergic reactions and adverse drug-drug interactions, as applicable. Include risks to a fetus if women of child-bearing potential may participate

in the study. It is **not** necessary to list risks associated with non-research procedures.

Page 2: [4] Comment [IRBMED12] IRBMED 4/2/2007 2:57:00 PM

Explain how risks are monitored and reduced. For example, explain that the subject will receive a physical examination and blood test once a week after beginning treatment with the new drug or device. Also explain what types of steps will be taken if adverse effects are detected (e.g., the drug dose will be lowered or stopped altogether).

Page 3: [5] Comment [IRBMED19] IRBMED 15/23/2286 11:28:00 AM

Describe alternatives to participation (e.g., what is usually done to treat the condition or disease). If appropriate, consider informing subjects of alternative studies, either specifically or by reference to a central source (e.g., www.clinicaltrials.gov). For non-therapeutic studies, in which there is no “alternative” or standard treatment, reiterate the voluntary nature of participation and state that the alternative is to not participate, in which case there will be no penalty. A suitable last sentence for this section is: Ask the researchers or your doctors about other options you may have. (...or your doctors... should be deleted if it is not applicable for this study.)

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If applicable, investigators should consider using this section to reassure subjects that their standard medical treatment does not depend on their continued participation in this study. If the study involves special procedures for termination of treatment (e.g., orderly withdrawal from drug treatment) or potential dangers of terminating treatment (e.g., on implanted device studies), investigators should edit the boilerplate text under Question 7.1 as appropriate, and be sure to describe the termination risks and procedures under Question 7.2. Please note that subjects always have the right to end their participation in research for any reason, so be careful not to imply that subjects should remain in the study against their will or should stop participating only for certain reasons.

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If participation will be at no cost to the subject, so state. This is also the place to describe any reimbursement for participation-related expenses (e.g., mileage, parking, etc.). For studies involving treatment intervention(s), clearly explain which costs will be billed to the subject's insurance company, and who (the subject? the study sponsor?) will be responsible for payment of any costs not covered by the insurance. For example: You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study,

such as [list]. It is important to understand that some insurance companies do not cover some costs (for example, approved drugs used in a way different from the package instructions). If your insurance company does not cover these treatments or procedures, you will be required to pay for them. Remember that study subjects often don't know what specific procedures would have been charged to their insurance companies in non-research settings, so specifics and clarity are important here. For example, are X-rays or scans that determine eligibility being paid for by the study or charged to the subject or their insurance? A suitable way to end this section is Ask the researchers if you have any questions about bills, fees, or other costs related to this study.

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IRBMED

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Provide clear, concise information. For example: “No. You will not be paid for taking part in this study.” or “You will receive \$20 for completing the study questionnaire.” Include the amounts and conditions of payment. Investigators are advised that payments to subjects should be prorated, and the amount earned to date should be paid even when subjects withdraw from the study prematurely. Incentive payments for completing the study, or disproportionately high levels of payments, might constitute enticement and should not be offered.

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IRBMED

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Delete any of the sub-headings under this question that are not applicable to this study.

If no person or organization has a financial interest in the outcome of the study, so state in answer to this question and delete all sub-headings.

If a person or organization involved in the conduct of this study may have a conflict of interest, consider addressing under this question any of the following issues that may apply:

- How is the research supported or financed?
- Where and by whom was the study designed (i.e., industry-sponsored versus investigator-initiated)?
- Do individuals or the institution receive any compensation that is affected by the study outcome?
- Do individuals or the institution
 - (1) have any proprietary interests in the product (including patents and licensing agreements);
 - (2) have an equity interest in the sponsor;
 - (3) receive significant payments of other sorts (e.g., grants or consultant retainers); and/or

(4) receive payment per participant or incentive payments?
If applicable to this study, include the following language under this heading: You will not receive any proceeds, profits, or other benefits from any commercial product that may result from this study.

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Disclose under this sub-heading if a company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study, particularly if the company/organization is also the sponsor of the study or has a financial relationship with the investigators (as described under the next sub-heading). Delete this sub-heading if it does not apply.

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If any of the investigators on the study have an ownership, consulting, or similar financial relationship with the sponsor, they should disclose it here in accordance with the management plan approved by the Conflict of Interest Committee (visit: www.med.umich.edu/medschool/orgs/ResearchPolicies/ConflictofInterest.html). Delete this sub-heading if it does not apply.