

**University of Minnesota Department of Obstetrics, Gynecology and Women's Health**  
**Department Protocol Review Committee**  
**\*\*human subjects protocols only\*\***

Date Submitted: \_\_\_\_\_

Type of Submission / Review:      renewal/new

Title of Project: \_\_\_\_\_

Name of Principal Investigator(s): \_\_\_\_\_

Name of Primary Faculty Mentor(s): \_\_\_\_\_

Division: \_\_\_\_\_ Funding Source: \_\_\_\_\_

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Date received by Department: \_\_\_\_\_ Date assigned to Department Committee: \_\_\_\_\_

Date due: \_\_\_\_\_ Date forwarded to Institutional IRB: \_\_\_\_\_

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Please indicate if the following criteria have been met by the above IRB:

	Yes	No
1. The rationale for the study is clearly stated and the rationale is scientifically sound.	<input type="checkbox"/>	<input type="checkbox"/>
2. The aims and corresponding hypothesis are clearly stated.	<input type="checkbox"/>	<input type="checkbox"/>
3. The primary outcome (and secondary outcomes, as appropriate) is clearly defined.	<input type="checkbox"/>	<input type="checkbox"/>
4. There are adequate preliminary data in the literature (or from the investigator) to justify the proposed research.	<input type="checkbox"/>	<input type="checkbox"/>
5. An adequate literature review has been done to support this study.	<input type="checkbox"/>	<input type="checkbox"/>
6. The question or hypothesis being tested is providing important knowledge to the field.	<input type="checkbox"/>	<input type="checkbox"/>
7. The design of the study is appropriate for the questions posed.	<input type="checkbox"/>	<input type="checkbox"/>
8. The validity and reliability of measures have been established or there are methods proposed for establishing validity and reliability.	<input type="checkbox"/>	<input type="checkbox"/>
9. The proposed subject population is appropriate.	<input type="checkbox"/>	<input type="checkbox"/>

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|--|--------------------------|--------------------------|
| 10. Statistical considerations, including sample size and justification, estimated accrual and duration, and statistical analysis are clearly described and adequate to meet the study objectives. | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. All the proposed tests or measurements requested are necessary to answer the scientific question.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. The principal and any other investigators are well qualified to conduct this study.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. The resources necessary to conduct this study are adequate.  | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. These criteria have been addressed sufficiently such that the human subject research described is scientifically valid.  | <input type="checkbox"/> | <input type="checkbox"/> |
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Reviewer name: \_\_\_\_\_

Date: \_\_\_\_\_