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|  |  |  |
| ***Subject Name*** | ***Date*** |

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***Title of Study***

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***Principal Investigator***

**FWA00004459**

**KEY INFORMATION**

**INVITATION TO PARTICIPATE**

**PURPOSE**

**DESCRIPTION OF THE PROCEDURES**

**DISCOMFORTS AND RISKS**

**CONFIDENTIALITY**

**RISKS DURING PREGNANCY**

**EXPECTED BENEFITS**

**WITHDRAWAL FROM THE STUDY**

**COSTS AND PAYMENTS**

**FUTURE USE OF DATA STATEMENT**

**CONTACTS**

**RESEARCH SUBJECT RIGHTS:**  I have read or have had read to me all of the above.

*has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study.*

*I understand that I do not have to ta*k*e part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of benefits to which I am entitled*.

*I understand that any information obtained as a result of my participation in this research study will be kept as confidential as legally possible.*

The results of this study may be published, but my records will not be revealed unless required by law.

**NOTE:**

If I have any questions about the conduct of this study or my rights as a subject in this study, I have been told I can call **The Catholic University of America,** **Office of Sponsored Programs 202-319-5218**

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

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| ***Signature of Subject Date*** |  |
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| ***Signature of Subject’s Representative\* Date*** |  | ***Subject’s Representative (Print)*** |
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| ***Signature of Witness Date*** |  | ***Witness (Print)*** |
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|  |  |  |
| **Signature of person obtaining consent\*\* *Date*** |  | ***Signature of Principal Investigator*** |

**\*Only required if subject is not competent.**

**\*\*Only required if not investigator.**