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

|  |
| --- |
|       |

 ***Title of Study***

|  |
| --- |
|       |

 ***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.

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

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

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