APPENDIX H

# RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES

When a proposed research project involves pregnant women and human fetuses, the DU IRB must take into consideration the regulatory requirements that provide additional protection for the subjects who would be involved in the research (45 CFR 46 – Subpart B “Additional Protections for Pregnant Women and Human Fetuses Involved in Research”). Only research that fulfills all of the conditions outlined in Subpart B may be approved by the IRB.

For additional guidance on Research Involving Pregnant Women, please refer to the following links:

* [Ethical Considerations for Including Women as Research Participants - American Congress of Obstetricians and Gynecologists](http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Ethical-Considerations-for-Including-Women-as-Research-Participants)
* [Enrolling Pregnant Women: Issues in Clinical Research - Office of Research on Women’s Health/National Institute of Health](https://orwh.od.nih.gov/sites/orwh/files/docs/ORWH-EPW-Report-2010.pdf)

## 1: Subject Participation

Will any persons under the age of 18 be enrolled in this study?

Yes

No

If yes, please provide the age range of the minor participants:

Click here to enter text.

Is it possible that any research subjects could include wards (custody) of the State, or any other agency, institution or entity other than the parents?

Yes

No

If yes, please explain what measures are taken to obtain permission for their participation:

Click here to enter text.

Is it possible the research subject, if minors, are homeless or are emancipated?

Yes

No

If yes, please explain what safeguards have been established to protect these subjects:

Click here to enter text.

Where will the study subjects participate in the study?

Home

Elementary, secondary or high school (submit [Appendix M: Research in Schools](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_appendix_m.docx))

List the names of the school(s): Click here to enter text.

DU campus

International location (please specify): Click here to enter text.

(If checked, please submit [Appendix G: International Research](https://www.du.edu/orsp/media/documents/new_irb_forms/irb-appendixg.docx))

Denver or Colorado community (please specify): Click here to enter text.

Other (please specify): Click here to enter text.

Describe the details of the setting for this research:

Click here to enter text.

Describe the potential benefits to the mother and fetus participating in this research:

Click here to enter text.

Describe the potential risks to the mother and fetus participating in this research:

Click here to enter text.

## 2: Consent Signature Requirements

The mother’s consent is required when the research holds:

* the prospect of direct benefit to the pregnant woman, or
* the prospect of a direct benefit both to the pregnant woman and the fetus, or
* no prospect of benefit for the woman nor the fetus but risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means;

**Consent from the mother \*and\* father** is required (unless the father is absent, incompetent, unknown, or the pregnancy resulted from rape/incest) when the research holds out the prospect of **direct benefit solely to the fetus.**

### Table 2.A Consent Decision Chart for Pregnant Women and Fetuses

|  | DIRECT BENEFIT TO MOTHER ONLY | DIRECT BENEFIT TO MOTHER AND FETUS | DIRECT BENEFIT TO FETUS ONLY | NO DIRECT BENEFIT OR SOCIETAL BENEFITS ONLY |
| --- | --- | --- | --- | --- |
| RISK IS MORE THAN MINIMAL RISK | Mothers consent | Mothers consent | Mother and Father’s consent | NOT APPROVEABLE BY THE IRB |
| RISK IS NO MORE THAN MINIMAL RISK | Mothers consent | Mothers consent | Mother and Father’s consent | Mother’s consent |

### Informed Consent

Informed consent will be obtained by:

Permission from mother only

Permission will be obtained from both mother and father (unless father is absent, incompetent, unknown, or the pregnancy resulted from rape/incest)

A waiver of informed consent/ waiver of documentation of informed consent

**NOTE:** If a waiver is requested, please explain the reasons for this waiver.

Click here to enter text.