# Subpart B: Pregnant Women, Human Fetuses and Neonates Involved in Research

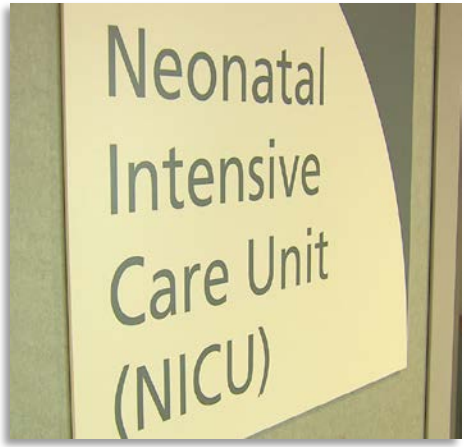
https://www.hrpo.pitt.edu/policies-and-procedures/research-involving-pregnant-women-neonates-and-fetuses

University of Pittsburgh

# Application

All research involving:

- Pregnant women
- Human fetuses
- Neonates of uncertain viability
- Nonviable neonates



# Pregnant Women, Fetuses and Neonates

§46.202

| | |
|---|---|
| **Pregnancy** | The period of time from implantation to delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery. |
| **Fetus** | product of conception from implantation to delivery |
| **Non-viable neonate** | [newborn] after delivery that, although living, is not viable |
| **Viable** | being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration…If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part. |

# PREGNANT WOMEN AND FETUSES

45 CFR 46.204

CONDITIONS A-J MUST BE MET

# Pregnant Women and Fetuses: Conditions to Meet

When possible, confirm / ensure the following conditions are met:

- When scientifically appropriate, preclinical studies have been done and data has been assessed for the potential risks to pregnant women & fetuses
- Risk is least possible to achieve the research objectives
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy
- Researchers have no part in decisions related to timing, method or procedures for pregnancy termination
- Researchers will have no part in determining the viability of a neonate

**Make a risk determination:**

Risk to fetus is caused by procedures that have potential benefit to the fetus or the woman

or

No prospect of benefit, fetal risk is minimal & knowledge cannot be obtained in a different way

# Consenting in a Nutshell

(§46.204 d,e,f,h)

- **Direct benefit to the pregnant woman or fetus**:

  Pregnant woman consents

- **No benefit, minimal risk to fetus**:

  Pregnant woman consents

- **Greater than minimal risk, direct benefit to only the fetus**:

  Pregnant woman and father* consent

*Unless father is unable to consent due to unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest

# RESEARCH INVOLVING NEONATES

45 CFR 46.205

# Viable Neonates

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of Subpart D

# Non-Viable and Uncertain Neonates: Conditions to Meet §46.205

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate
3. Individuals engaged in the research will have no part in determining the viability of a neonate

# Risk Considerations with Neonates 45 CFR 46.205(B)(C)

**Uncertain Viability:**

Holds out prospect of enhancing survival
(Least possible risks to reach the goal);
or
Develop important knowledge that cannot be obtained by other means
(No added risk)

**Non-Viable:**

- Vital functions not artificially maintained
- Can't terminate heartbeat or respiration
- No added risk
- Develop important biomedical knowledge that cannot be obtained by other means

# Consent Issues with Neonates

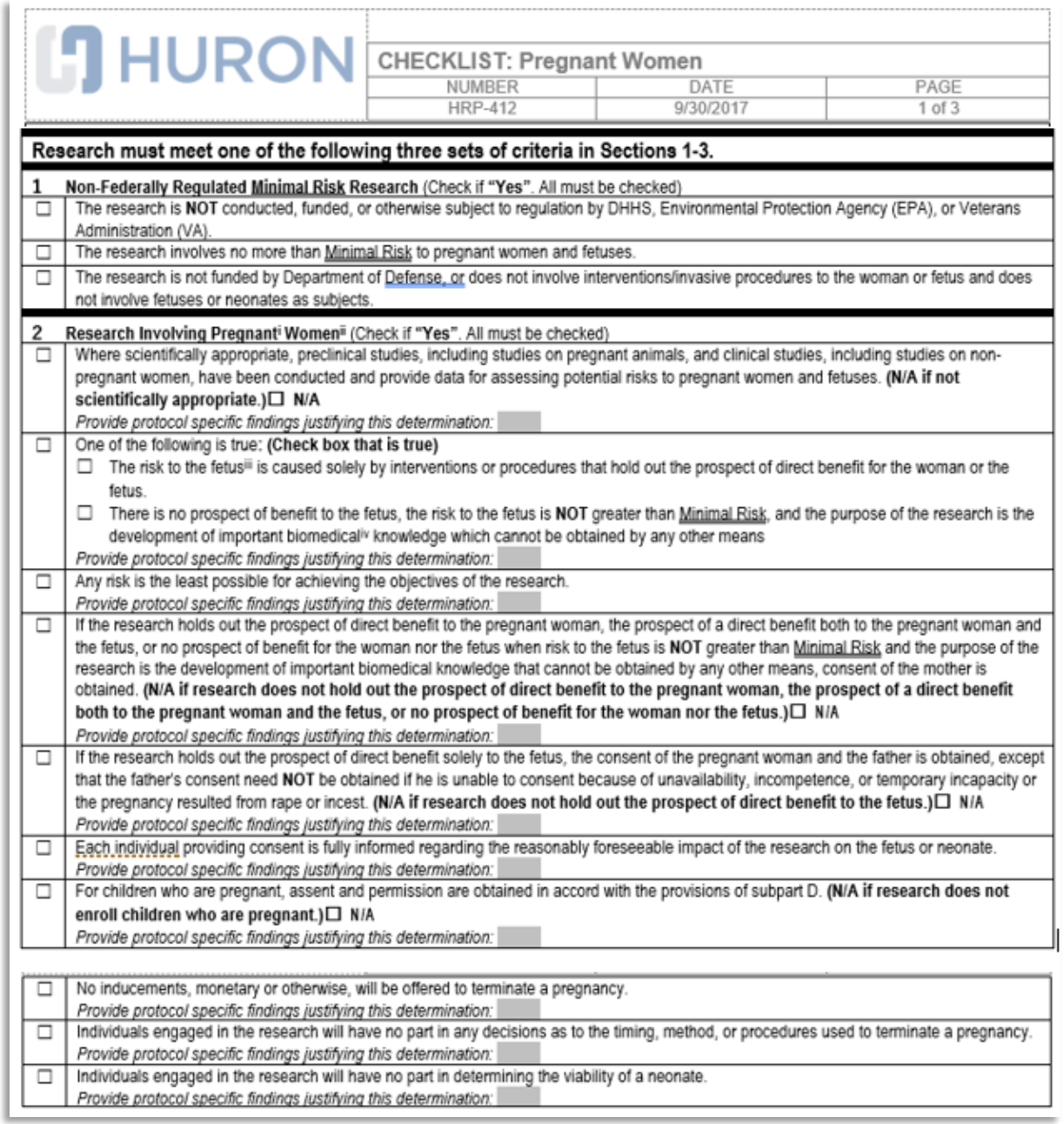
The legally effective informed consent of **either parent** of the neonate

Consider the legally effective informed consent of **both parents** of the neonate

**Uncertain Viability**

**Non-Viable**

# Tools for Review:
## Checklists Available in PittPRO Library



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**CHECKLIST: Pregnant Women**

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**Research must meet one of the following three sets of criteria in Sections 1-3.**

**1 Non-Federally Regulated Minimal Risk Research** (Check if **"Yes"**. All must be checked)

| | |
|---|---|
| ☐ | The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS, Environmental Protection Agency (EPA), or Veterans Administration (VA). |
| ☐ | The research involves no more than Minimal Risk to pregnant women and fetuses. |
| ☐ | The research is not funded by Department of Defense, or does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects. |

**2 Research Involving Pregnant[i] Women[ii]** (Check if **"Yes"**. All must be checked)

| | |
|---|---|
| ☐ | Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. **(N/A if not scientifically appropriate.)**☐ **N/A**<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | One of the following is true: **(Check box that is true)**<br>☐ The risk to the fetus[iii] is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.<br>☐ There is no prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than Minimal Risk, and the purpose of the research is the development of important biomedical[iv] knowledge which cannot be obtained by any other means<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | Any risk is the least possible for achieving the objectives of the research.<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | If the research holds out the prospect of direct benefit to the pregnant woman, 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 when risk to the fetus is **NOT** greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained. **(N/A if research does not hold out the prospect of direct benefit to the pregnant woman, 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.)**☐ **N/A**<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, except that the father's consent need **NOT** be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. **(N/A if research does not hold out the prospect of direct benefit to the fetus.)**☐ **N/A**<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(N/A if research does not enroll children who are pregnant.)**☐ **N/A**<br>*Provide protocol specific findings justifying this determination:* |

| | |
|---|---|
| ☐ | No inducements, monetary or otherwise, will be offered to terminate a pregnancy.<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.<br>*Provide protocol specific findings justifying this determination:* |
| ☐ | Individuals engaged in the research will have no part in determining the viability of a neonate.<br>*Provide protocol specific findings justifying this determination:* |

# Pregnant Women Checklist:

Available in the PittPRO Library

# Uncertain and Non-Viable Checklists

## Available in the PittPRO Library

HURON

**CHECKLIST: Non-Viable Neonates**

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**The research must meet one of the following two sets of criteria**

**1 Research Involving Non-Viable[i] Neonates[ii]** (Check if **"Yes"**. All must be checked)

- ☐ Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
  *Provide protocol specific findings justifying this determination:*
- ☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
  *Provide protocol specific findings justifying this determination:*
- ☐ Individuals engaged in the research will have no part in determining the viability of a neonate.
  *Provide protocol specific findings justifying this determination:*
- ☐ Vital functions of the neonate will not be artificially maintained.
  *Provide protocol specific findings justifying this determination:*
- ☐ The research will not terminate the heartbeat or respiration of the neonate.
  *Provide protocol specific findings justifying this determination:*
- ☐ There will be no added risk to the neonate resulting from the research.
  *Provide protocol specific findings justifying this determination:*
- ☐ The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.
  *Provide protocol specific findings justifying this determination:*
- ☐ The legally effective informed consent of both parents of the neonate is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
  *Provide protocol specific findings justifying this determination:*
- ☐ The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not be obtained.
  *Provide protocol specific findings justifying this determination:*

**2 Research Involving Neonates that is Not Otherwise Approvable[iii]** (Check if **"Yes"**. All must be checked)

- ☐ The research does **NOT** meet the requirements of §46.205.
  *Provide protocol specific findings justifying this determination:*
- ☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.
  *Provide protocol specific findings justifying this determination:*

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**CHECKLIST: Neonates of Uncertain Viability**

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**The research must meet one of the following two sets of criteria**

**1 Research Involving Neonates[i] of Uncertain Viability[ii]** (Check if **"Yes"**. All must be checked)

- ☐ Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
  *Provide protocol specific findings justifying this determination:*
- ☐ Individuals engaged in the research will have no part in determining the viability of a neonate.
  *Provide protocol specific findings justifying this determination:*
- ☐ One of the following is true: **(Check box that is true)**
  - ☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.
  - ☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

  *Provide protocol specific findings justifying this determination:*
- ☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. **("N/A" if the consent process is waived)**
  *Provide protocol specific findings justifying this determination:*
- ☐ The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the regulations, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. **("N/A" if the consent process is waived)**
  *Provide protocol specific findings justifying this determination:*

**2 Research Involving Neonates of Uncertain Viability that is Not Otherwise Approvable[iii]** (Check if **"Yes"**. All must be checked)

- ☐ The research does **NOT** meet the requirements of §46.205.
  *Provide protocol specific findings justifying this determination:*
- ☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.
  *Provide protocol specific findings justifying this determination:*

Pitt Research

# In Summary…

- Ethical and regulatory concerns should be carefully considered
  - Determinations should follow the regulatory points
- Pregnant women need to be included in research when possible
- Under the 2018 Common Rule, pregnant women are no longer labeled “vulnerable” but Subpart B regulations still apply as written

# QUESTIONS?

*Contact askirb@pitt.edu*