Research Compliance Office

Additional Protections for Pregnant Women, Fetuses and Neonates in Research

45 CFR 46 Subpart B

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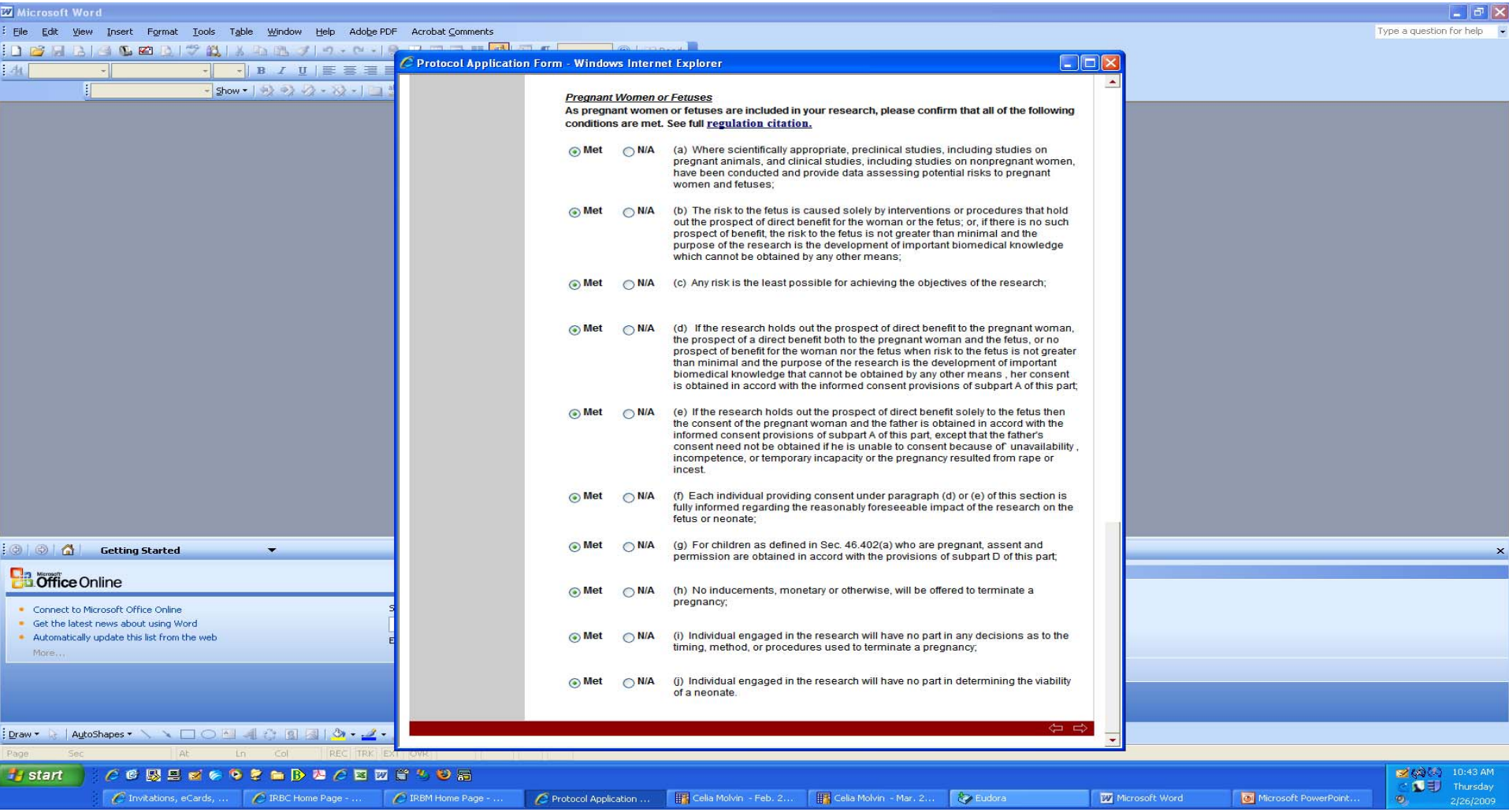
Pink Laminate

- 46.204 Research with pregnant women or fetuses

- 46.205 Research with neonates

Text Change in eProtocol from True/False to Met/NA



For Pregnant Women or fetuses the following conditions must be met:

a. **Where scientifically appropriate, preclinical studies**, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, **have been conducted** and provide data for assessing potential risks to pregnant women and fetuses;

Not scientifically appropriate (surveys)= NA

Assessment of Risk to Fetus

b. **The risk to the fetus** is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

Least Possible Risk; Consent of Pregnant Women

c. **Any risk is the least possible** for achieving the objectives of the research;

d. If the research holds out the **prospect of direct benefit** to the pregnant woman, the prospect of a direct benefit 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** and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means, **her consent is obtained** in accord with the informed consent provisions of subpart A of this part;

Consent of Pregnant Woman and Father

e. If the research holds out the prospect of **direct benefit solely to the fetus** then the **consent of the pregnant woman and the father is obtained** in accord with the informed consent provisions of subpart A of this part, 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;

Benefit not solely to the fetus = NA

Impact of Research on Fetus Made Known

f. **E**ach individual providing consent under paragraph (d) or (e) of this section is **fully informed** regarding the **reasonably foreseeable impact of the research on the fetus or neonate**;

Pregnant Children; Inducements to Terminate Pregnancy

g. **For children** as defined in Sec 46.402(a) **who are pregnant**, assent and permission are obtained in accord with the provisions of subpart D of this part;

If no pregnant children = NA

h. **No inducements**, monetary or otherwise, will be offered **to terminate the pregnancy**;

Decisions about Termination Viability of a Neonate

i. Individuals engaged in the research will have **no part in any decisions** as to timing, method, or procedures used **to terminate a pregnancy**; and

j. Individuals engaged in the research will have **no part in determining the viability of a neonate.**