Flowchart to determine whether study involves pregnant women

Does the study **enroll** pregnant women? (no exclusion of pregnant women)

**NO**

Do you **anticipate at least one pregnancy** among study subjects during the trial?

**NO**

Are female subjects **counseled to avoid pregnancy** or **required to use contraception** during the study?

**YES**

If a female subject becomes pregnant while enrolled, will **all research interventions and procedures cease**?

**NO**

Will information about the pregnancy, the pregnancy outcome, and/or the child be collected?

**YES**

**Category A Pregnancy study**
See Section A of Pregnant Women in Research Policy

**NO**

**Category B Pregnancy study**
See Section B of Pregnant Women in Research Policy

**YES**

If a female subject becomes pregnant while enrolled, will all research interventions and procedures cease?

**NO**

Study does not involve Pregnant Women

**YES**

Will information about the pregnancy, the pregnancy outcome, and/or the child be collected?

**NO**

Study does not involve Pregnant Women

**YES**

**Category C Pregnancy study**
See Section C of Pregnant Women in Research Policy