Suggested language for IRB protocols for Women of Childbearing Potential

The following is standard language for the inclusion of women of childbearing age in research studies which was reviewed and approved by the IRB. However, investigators may choose to use different language if they desire.

Women of Childbearing Potential

If you are pregnant you should be aware that the effect of *[insert study drug name]* on the development of fetus is unknown. Therefore, participation in this study could possibly have an adverse effect on your developing fetus.

As part of the screening process and before you take the first dose of study drug, a serum pregnancy test will be done if you are in one of the following categories: 1) woman less than two years post-menopausal, 2) women of reproductive potential who may have had a tubal ligation or are currently using another form of birth control. If you have had a hysterectomy, then a pregnancy test will not be required.

While you are participating in this study, you must continue to use an effective method of birth control. Acceptable methods of birth control include the birth control pill, intrauterine device, injection of Depo-Provera, Norplant, tubal ligation and barrier methods such as condoms or the diaphragm.

Should you become pregnant despite using an acceptable method of birth control, you must stop the study medication immediately and inform your study doctor. Your doctor will then give you more information on the possible risks on the fetus and the options that are available to you.