

Guidelines for research on women of childbearing potential

The committee recognises the importance of undertaking research in diverse population groups including women of childbearing potential. However, it notes that there is a need for special care in this group because of the possible hazard to the potential foetus. In order to minimise any risk, the committee requires that the following 8 questions be considered before it will give permission to perform any study involving women of childbearing potential.

CHECKLIST

1. Have you included a copy of the Participant Information Leaflet and consent form to be given to each participant? Your application will **NOT** be considered unless these are included
2. Does the nature of the study justify involving women of childbearing potential?
3. Has toxicological and pharmacological testing in animals or humans, performed to date, failed to produce any evidence that the study drug may be teratogenic?
4. Is there a clear warning in the patient information sheet that the effects of the study drug on a foetus are unknown but that they may be damaging?
5. Is a pregnancy test to be performed immediately before the study begins?
6. Are the forms of contraception allowed (and those forms which are unacceptable) specifically stated in the research protocol?
7. Is there a clear indication in the patient information sheet that effective contraception must be practised during and for a time (corresponding to drug elimination kinetics) after the trial?
8. Does the study exclude any participant whom the investigators feel is unlikely or unable to follow contraceptive advice?
9. Is there a statement that if the patient becomes pregnant, or thinks she may be pregnant, that she should contact the study doctor immediately?

Where appropriate the following paragraph should be included:

If you are a woman of childbearing age, you may participate in this study only if you are surgically sterilised or are using the contraceptive pill. You must not be pregnant or lactating and you must have a negative pregnancy test before the study begins. The effects of... on the foetus or child are unknown and may be harmful. If you should become pregnant, in spite of all the precautions, please notify your doctor immediately.