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EFFECTIVE: February 15, 2005	RESEARCH PROTOCOLS THAT MAY POSE A RISK TO A FOETUS AND/OR SUBSEQUENT CHILD		

1. In cases where there is

- a) a request to exclude pregnant women or women of childbearing potential
- or
- b) impose mandatory birth control, the REB gives consideration to the following questions and issues:

- a) Is there enough of a prospect of genuine benefit to the subject that justice issues are raised in arbitrary exclusions?
- b) What is the risk posed to a foetus or subsequent child?
- c) Is the information to be gained of such importance for the greater common good that justice issues are raised in arbitrary exclusions?
- d) What is the evidence with respect to reproductive risk?

The researchers must address the issues as follows:

- a) If there are justice concerns raised in arbitrary exclusions the investigator must defend the exclusion of pregnant women or women of childbearing potential.
- b) If the exclusion seems to be warranted the investigator must defend the position that it is important enough to usurp the woman's ordinary position as the arbiter of foetal risk. (I.e. the REB's position is that one that prefers an exclusion by warning the subject of the risk, rather than by issuing a dictum.)
- c) If it is warranted to exclude rather than just warn, the REB expects that the exclusion would be effected in a respectful manner. If the decision to exclude pregnant women or women of childbearing potential is appropriate and urgent enough that the woman shouldn't be the decision maker (generally a case of serious potential for foetal harm with only modest benefit for the woman):
- d) The Letter of Information should explain the issue rather than just demand compliance
- e) The contraceptive requirement should only be extended to heterosexually active pre-menopausal women
- f) There should be an explanation for specific contraceptive choices
- g) Contraceptive use must be considered a research risk and factored into the risk/benefit calculation

Case Scenario:

A sponsor insisted on oral contraceptives even for sexually abstinent women or lesbians. Asked if they would still make that requirement if a nun were the subject, they said "Yes". The REB felt there was also the issue that oral contraceptives might be a religious concern for nuns. But more seriously it was easy to calculate that the contraceptive use would create a risk of death (from thrombosis) that was far greater than would have been the risk of pregnancy without oral contraceptives.

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2. Monitoring and Follow up of pregnancies occurring during a clinical trial

In many instances if a woman becomes pregnant or a man fathers a child while in a study the pregnancy should be monitored to ascertain the health of the mother and child. In some cases it may be necessary/prudent to monitor the child once it has been born. In all cases, the request to monitor the pregnancy and/or the child should be made in a respectful manner.

When applicable, the Information / Consent documentation should:

- include a statement that the treatment or procedure may involve risks, which are currently unforeseeable, to the participant or to the foetus or child, if the participant is or may become pregnant or is breastfeeding.
- it may also be necessary to warn male participants or partners about the danger of fathering a child while involved with the study

3.0 Examples of wording for the Information / Consent Documentation

(These should be adapted to meet the needs of the particular study)

- We know that the treatment involved in this study poses significant risks to a foetus and/or a child that is being breast fed by a woman taking the drug. Therefore it is extremely important that you not become pregnant nor breastfeed while taking part in this trial. To ensure that you are not pregnant at the start of the study you will be asked to have a pregnancy test before undergoing any treatment. You will also be asked to use an approved method of birth control for the course of the study and have periodic pregnancy tests.
- If you are or become pregnant during the course of this study, the treatment or procedure may involve risks, which are currently unforeseeable, to you or to the foetus.
- Because we do not yet know very much about the safety of this drug in pregnancy, we want to know what happens if any of the participants become pregnant (father a child) while taking the drug. If you get pregnant (father a child) during this study you must inform your study doctor right away. We would then appreciate it if you'd allow us to record information about the outcome of the pregnancy (the child's health etc.) This will also involve asking you to permit us to contact you annually for the next five years to ask about the health of your child.