

Contraception & Pregnancy Issues in Research Protocols REB Guidelines

Context

Some research protocols mandate adequate contraception and pregnancy testing before recruitment e.g. drug trials, interventional radiology projects. This requirement can lead to the exclusion from the study of patients who are found to be pregnant, or who decline the use of adequate contraception. The circumstances around which this exclusion occurs could have the unintended consequence of constituting a significant breach of privacy and confidentiality.

Principles & Issues

1. There is no intention to exclude subjects of childbearing age. On the contrary, these guidelines are to facilitate their inclusion and avoid the creation of research orphans by protecting their rights.
2. In Ontario, there is no age of consent for testing, treatment or research. Determination of a person's capacity to give valid consent is based on ability to understand the information relevant to participation or non-participation, and ability to appreciate the consequences of that decision.
3. Cultural and religious views on contraception, pregnancy and sexuality can have a profound influence on research subjects and their families. In some cases, such information can result in a woman's safety, or even her life, being at risk. Accordingly, discussion of these subjects with research participants requires the strictest preservation of confidentiality.

THEREFORE THE FOLLOWING ARE SUGGESTED WITH REGARD TO PREGNANCY TESTING AND CONTRACEPTION:

Pregnancy Testing

1. Describe provisions for a private interview space to allow the child/adolescent to be able to refuse participation privately if she is, or could be, pregnant, without disclosing her pregnancy or sexual activities to her parents or partner.
2. If pregnancy is being tested for, ensure the inclusion of relevant clinical follow-up in the event of the diagnosis being confirmed e.g. social work involvement, counseling.
3. Describe provisions for the management of the patient if she refuses these services.
4. In long term studies involving young females, ensure that these methodological issues are addressed in a manner that reflects understanding of the changing behaviors of the maturing child.
5. Ensure that consent forms clearly state that the patient may be excluded from the study for reasons which the researcher will not be able to divulge to the parents eg., There can be a variety of reasons which lead to the exclusion of patients from studies. These reasons will be kept confidential. This is to ensure that the patient who is pregnant, or sexually active and not using appropriate contraception, can be excluded from the study without divulging the reason to the parents (and thereby breaching confidentiality).

Contraception

1. If contraception is being mandated in the study, discuss the acceptability of abstention or withdrawal.
2. Avoid mandating contraception for patients who are unable to become pregnant due to their individual circumstances e.g. extreme illness or young age.
3. Ensure that the cost implications of mandatory contraception are addressed in the study budget.

Consent Form Sample Language

Below are examples of the language which could be used when describing pregnancy and reproductive risks:

To the participant -

Reproductive Risks

Pregnant or nursing women are not eligible to participate in this study. If you are female and able to get pregnant, a urine pregnancy test will be done. If the test is positive, you will not be able to enter the study. The results of the pregnancy test are confidential and will be told to you by one of the study nurses or doctors in private. Every effort will be made to keep positive pregnancy test results private.

It is unknown what effect these treatments may have on an unborn child. For this reason if you are of childbearing age you will be asked to practice an effective method of birth control while participating in this study. If you become pregnant during this study, you should tell your doctor immediately.

The administration of chemotherapy and/or radiation may cause infertility (being less able to produce a viable egg or sperm) or sterility (being unable to produce a viable egg or sperm). We will talk to male patients who have reached puberty about sperm banking.

To the parent or legal guardian of the participant –

Reproductive Risks

Pregnant or nursing women are not eligible to participate in this study. If your child is female and able to get pregnant, a urine pregnancy test will be done. The results of the pregnancy test are confidential and a doctor or a nurse will explain the results of the test to your child in private.

There can be many reasons why potential research subjects do not qualify for this study, one of which is pregnancy. Privacy laws mandate that the pregnant woman be told in confidence that she is pregnant, and appropriate supportive counseling should be offered at the same time. It is the pregnant woman's choice to reveal the pregnancy to her family and the duty of the physician is to support her in any decision she makes. Therefore reasons why your child cannot participate or, if enrolled, why she can't continue to participate, may only be revealed to you as 'your child's screening reveals she cannot

continue with/be part of the study' or 'your child's condition no longer fulfils the criteria for the study'.

It is unknown what effect these treatments may have on an unborn child. For this reason if your child is of childbearing age, he/she will be asked to practice an effective method of birth control while participating in this study. If your child becomes pregnant during this study, you should tell your child's doctor immediately.

The administration of chemotherapy and/or radiation may cause infertility (being less able to produce a viable egg or sperm) or sterility (being unable to produce a viable egg or sperm). We will talk to male patients who have reached puberty about sperm banking. Unfortunately there is no way to bank eggs from females at the present time.