Reproductive Risk in Clinical Research

Purpose

The purpose is to describe the policies and procedure related to reproductive risk in clinical research.

Policies

No reference to contraception may be used in the informed consent form or any other materials shared with human subjects participating in research.

If reproductive risks have been identified in a proposed study, the following language is required in the informed consent form:

Avoidance of Pregnancy: *The medicines and procedures used in this study may be unsafe for an unborn baby, an infant, sperm, and eggs. If you, a woman of child bearing potential, are a study/trial participant, you must agree to avoid pregnancy during your participation in this study and for _____ months after the completion of the study (include protocol time frame as appropriate); if you, as a participant are a man, you must agree to not conceive a child during your participation in this study and for _____ months after the completion of the study (include protocol timeframe as appropriate). If you do become pregnant during the study or if you father a child during the study, you should immediately notify Dr. _____ (name of contact) at _____ (contact information). In addition, if you are already pregnant or are breast feeding, you cannot participate in this study.*

Procedure

Whenever reproductive risks are identified in a proposed study, the investigator includes the above language in the informed consent form's risk section.

History

11/24/2020: Updated format and added procedures