Contraception Requirements (HRPP 3.9)

Description:

This policy describes the contraception requirements for subjects participating in research.

Pregnancy and Lactation Labeling Available:

For drugs/biologics for which pregnancy and lactation labeling is available, the ICFs must include the appropriate standard contraception language based on the following categories:

- **Group 1 Drugs** (*no systemic absorption of the drug/biologic*)
  - The protocol may NOT require use of contraception. Exceptions must be approved by the IRB.
- **Group 2 Drugs** (*human data shows no evidence of adverse developmental outcomes*)
  - The protocol may requires ONE form of contraception with IRB approval.
- **Group 3 Drugs** (*animal studies show no evidence of adverse developmental outcomes*)
  - The protocol may require ONE form of contraception with IRB approval.
- **Group 4 Drugs** (*animal studies show evidence of adverse developmental outcomes, at dose levels higher than those to be used in the study*)
  - The protocol MUST require ONE or TWO form(s) of contraception with IRB approval.
- **Group 5 Drugs** (*animal or human studies show evidence of adverse developmental outcomes, or drug mechanism of action suggests the possibility of adverse developmental outcomes*)
  - The protocol MUST require TWO forms of concurrent contraception.

Pregnancy and Lactation Labeling NOT Available:

For drugs/biologics for which pregnancy and lactation labeling is not available, the ICFs must include the appropriate standard contraception language based upon the following categories:

- **Category A Drugs** (*controlled studies show no risk to fetus*)
  - The protocol may NOT require use of contraception. Exceptions must be approved by the IRB.
- **Category B Drugs** (*no evidence of risk to fetus in humans*)
  - The protocol may require the use of ONE form of contraception with IRB approval.
- **Category C Drugs** (*risk to fetus cannot be ruled out*)

    - The protocol MUST require use of ONE or TWO form(s) of concurrent contraception.
- **Category D Drugs** (*positive evidence of risk to fetus*)
    - The protocol MUST require TWO forms of concurrent contraception.
- **Category X Drugs** (*indicates should NOT be used if pregnant*)
    - The protocol MUST require TWO forms of concurrent contraception.

General Considerations:

The duration of contraception must be stated in the IRB application and ICF. If it's required for longer than the time the drug is being administered, justification must be provided.

CLICK HERE- Addendum #1 lists ICF standard language pregnancy risk statements.

The ICF must include standard contraception language except:

- Group 5 drugs
- Category D drugs
- Category X drugs

If a sponsor mandates specific contraception language, this may be used in lieu provided the IRB determines it's acceptable.