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 require 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.