Non-Pregnant Women Research Policy

I. **General Rule:**
Women of reproductive potential should not be excluded from a research protocol unless there is a valid scientific rationale for such exclusion. In studies for which pregnancy is a criterion for exclusion, women must be told in advance that there will be periodic pregnancy tests and whether or not they will be removed from the study if they become pregnant.

All potential risks imposed by the protocol must be taken into consideration, such as, but not limited to radiation exposure, dietary manipulation, or drug intervention.

II. **FDA categories of research with women of reproductive potential:**
The policy is based upon the *FDA Current Categories of Drug Use in Pregnancy* (Categories A, B, C, D or X) defined in this policy.

1. **Category A**
   FDA Definition: “Adequate, well controlled studies in pregnant women have not shown an increased risk of fetal abnormalities.” (Scientific grounds for believing that the product does **not** have teratogenic, mutagenic or other toxic effects on the fetus.) All women are potentially eligible to participate.

2. **Category B**
   FDA Definition: “Animal studies have revealed no evidence of harm to the fetus, however, there are no adequate and well-controlled studies in pregnant women, OR, animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus.”

All non-pregnant women are potentially eligible to participate if they abide by the following policy:
   a. Pregnancy test prior to enrollment.
   b. Agreement by the study subject not to conceive during the course of the study.
   c. Agreement by the study subject to use an effective method of contraception as determined by a competent health provider trained in this area.
   d. The Investigator must ensure that the importance of contraceptive counseling is discussed with potential subjects. A counseling plan is required to be submitted to the CCI/IRB which may include counseling by
the woman’s own physician or counseling made available through the study program.
e. Agreement by the study subject to inform the investigator if she thinks she may be pregnant (i.e., a missed period) and to have pregnancy testing performed at that time

3. **Category C**
FDA Definition: “Animal studies have shown an adverse effect and there are no adequate and well-controlled studies in pregnant women, OR, no animal studies have been conducted and there are no adequate and well-controlled studies in pregnant women.”
   a. All the criteria listed above for Category B drugs **plus**, 
   b. The designated IRB will determine, on a case-by-case basis, additional appropriate intervals for pregnancy testing.

4. **Category D**
FDA Definition: “Adequate well-controlled or observational studies in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risk.”
All non-pregnant women are potentially eligible to participate if they abide by the following policy:
   a. All the criteria listed above for Category B and C drugs), **plus**
   b. Urine or serum pregnancy test every two months, or per a schedule determined by the designated IRB on a case-by-case basis.
   c. Agreement by the study subject to either abstain from intercourse, use two effective methods of contraception, or use one highly effective method of contraception, as determined by a competent health care provider trained in this area.
   d. The Investigator must ensure that the importance of contraceptive counseling is discussed with potential subjects. A counseling plan is required to be submitted to the CCI/IRB which may include counseling by the woman’s own physician or counseling made available through the study program.

5. **Category X**
FDA Definition: “Adequate well-controlled or observational studies in animals or pregnant women have demonstrated positive evidence of fetal abnormalities. The use of the product is contraindicated in women who are or may become pregnant.”
   a. All the criteria listed above for Category D.
   b. For drugs of exceptionally high risk to the fetus (i.e. thalidomide, accutane, etc.) the designated IRB may require that specific effective contraception be utilized.
6. **Drugs Not Yet Classified by the FDA**
   The Montefiore IRB/AECOM CCI reserve the authority to require that drugs not as yet classified by the FDA be handled as Category D and X listed above.

### III. Researchers’ obligations in designing and conducting Category B, C, D and X studies:

1. The Investigator must ensure that the importance of contraceptive counseling is discussed with potential subjects. A counseling plan is required to be submitted to the CCI/IRB, which may include counseling by the woman’s own physician or counseling made available through the study program.
2. The Investigator is responsible for ordering and financing all pregnancy tests and documenting the results.
3. If the woman becomes pregnant during the course of a Category B, C, D or X study, the Investigator must ensure appropriate referral to medical genetic services for the counseling and follow up of potential teratogenic exposure. Management and follow up will be directed by the medical service, completely independent of the research team. Individuals engaged in the research will have no part in such management or the study subject’s decision making.
4. When the sponsor proposes exclusion of women in Category B, C, D or X, the researcher will discuss this with the sponsor.

### IV. **Requirements for Informed Consent:**

The informed consent document should include the following:

1. Whether the study falls under category A, B, C, D or X.
2. Contraceptive counseling will be made available for categories B, C, D and X, either through the study subject’s own health provider or a competent provider who will be made available through the study program.
3. Whether there will be pregnancy tests, and how frequently they will be done.
4. That, in studies for which pregnancy is an exclusion criterion, there will be periodic pregnancy tests and that the subject may be removed from the study if she becomes pregnant.
5. Information of the results of any pre-clinical or clinical studies (on pregnant women and/or animals).
6. The possibility of birth defects to a child if a subject becomes pregnant during the study.
7. The possible effects on future fertility potential (such as premature menopause, if known or suspected based on similar drugs).

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