Decision Tree for Inclusion of Women in Clinical Research
(not an NIH-Defined Phase III Clinical Trial)

**Human Subjects** involved (even if exempted under 45 CFR 46)?

**YES**
Inclusion policy applies despite exemption

**NO**

**Is a NIH-Defined Phase III Clinical Trial proposed?**

**YES**

**NO**
Inclusion policy does not apply

**Is gender representation acceptable?**

1. Both genders are included in scientifically appropriate numbers? *(Code G1)* or
2. One gender is excluded because one of the following applies *(Code G2: females only, G3: males only)*
   - Inclusion is inappropriate with respect to their health
   - Research question is relevant to only one gender
   - Prior evidence strongly suggests no gender difference
   - Data exists for excluded gender; duplicative studies are unnecessary; or
3. One gender excluded or limited because subject selection is constrained due to purpose of research? *(Code G2: females only, G3: males only)* or
4. Gender representation of specimens or datasets cannot be accurately determined and this does not compromise the scientific objectives? *(Code G4: gender representation unknown)*

**YES**

**ACCEPTABLE G1A, G2A, G3A, or G4A**
Describe: inclusion plan, any gender exclusions, plans for analysis and outreach. State why this is scientifically acceptable.

**NO**

**ABSENT No Information**

**UNACCEPTABLE G1U, G2U, G3U, or G4U**
Negative impact on score.
Describe: inclusion plan, any gender exclusions, plans for analysis and outreach. State why this is scientifically unacceptable.

**GO TO: Decision Tree for Inclusion of Women in NIH-Defined Phase III Clinical Trials**

NIH/OER April 26, 2001