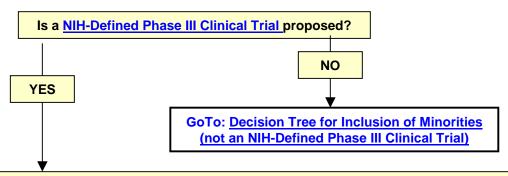
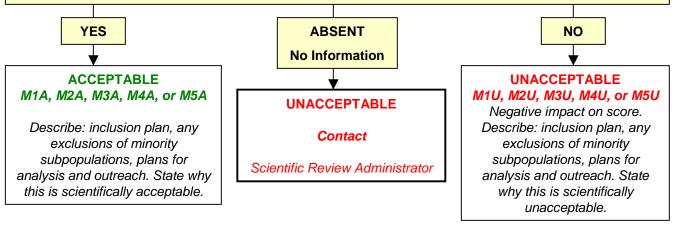


Decision Tree for Inclusion of Minorities In NIH-Defined Phase III Clinical Trials



Is minority representation acceptable?

- Strong evidence exists for significant racial or ethnic differences in intervention effect and study design or analysis can answer primary question(s) separately for each relevant subgroup and the analysis plan can detect significant differences in intervention effect? (Code M1: both U.S. minorities and non-minorities included) or
- 2. Strong evidence exists for NO significant racial or ethnic differences in intervention effect? (Code M1: both U.S. minorities and non-minorities, or Code M2: U.S. minorities only, or Code M3: U.S. non-minorities only) or
- 3. No clear evidence exists for or against significant racial or ethnic differences in intervention effect **and** study design and analysis plans will permit <u>valid analysis</u> of a differential intervention effect? (Code M1: both U.S. minorities and non-minorities) or
- 4. Some or all minority groups or subgroups are excluded because inclusion is inappropriate with respect to their health or because the research question is not relevant to them? (Code M1: both U.S. minorities and non-minorities, or Code M2: U.S. minorities only, or Code M3: U.S. non-minorities only) or
- 5. ONLY foreign (non-U.S.) subjects are involved **and** study design addresses any known scientific reasons for examining in-country minority group or subgroup differences (Code M5: no U.S. subjects involved)



Summary of Codes Minority Representation Both minorities and non-minorities included Minorities only Non-minorities only Max Mepresentation is scientifically... Acceptable M1A M1U M2A M2U M3A M3U

Unknown (cannot be known)

ONLY foreign (non-U.S.) subjects in study

M5A

M5A

M4U

M5U