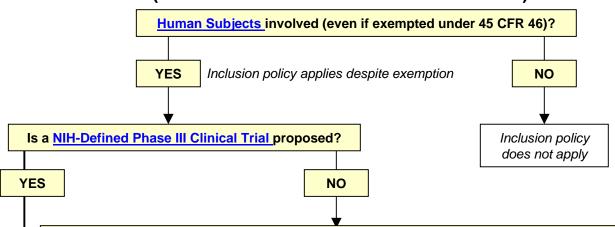


Decision Tree for Inclusion of Minorities in Clinical Research (not an NIH-Defined Phase III Clinical Trial)



What is the actual minority representation? Is minority representation acceptable?

- 1. U.S. minority individuals ARE included in scientifically appropriate numbers (non-minorities may or may not be included)? (Code M1: both U.S. minorities and non-minorities, or Code M2: U.S. minorities only) or
- 2. Some or all U.S. minority groups are excluded or poorly represented because any of the following applies?
 - inclusion is inappropriate with respect to their health

scientifically acceptable.

- research guestion is relevant to only one racial/ethnic group
- prior evidence strongly suggests no racial/ethnic difference in outcome variables
- proposal is for a single minority group study to fill a research gap
- data exists for excluded minority group(s); duplicative studies are unnecessary
- geographical location has too few eligible minorities and exclusion has been well justified (e.g., based on study size, disease characteristics, unfeasibility of collaboration)
- purpose of research constrains subject selection in regard to race/ethnicity

(Code M3: U.S. non-minorities only; or Code M2: U.S. minorities only; or Code M1: both included) or

- 3. Racial or ethnic origin of specimens/datasets cannot be accurately determined and this does not compromise scientific objectives? (Code M4: minority representation unknown)
- 4. 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) **ABSENT** YES NO No Information **ACCEPTABLE** UNACCEPTABLE M1A, M2A, M3A, M4A, M5A M1U, M2U, M3U, M4U, M5U **UNACCEPTABLE** Negative impact on score, Describe: inclusion plan, any Describe: inclusion plan, any Contact exclusions of minority groups, exclusions of minority groups, plans for analysis and plans for analysis and Scientific Review Administrator outreach. State why this is outreach. State why this is

Go To: Decision Tree for Inclusion of Minorities Plan in NIH- Defined Phase III Clinical Trials

scientifically unacceptable.