



# NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research



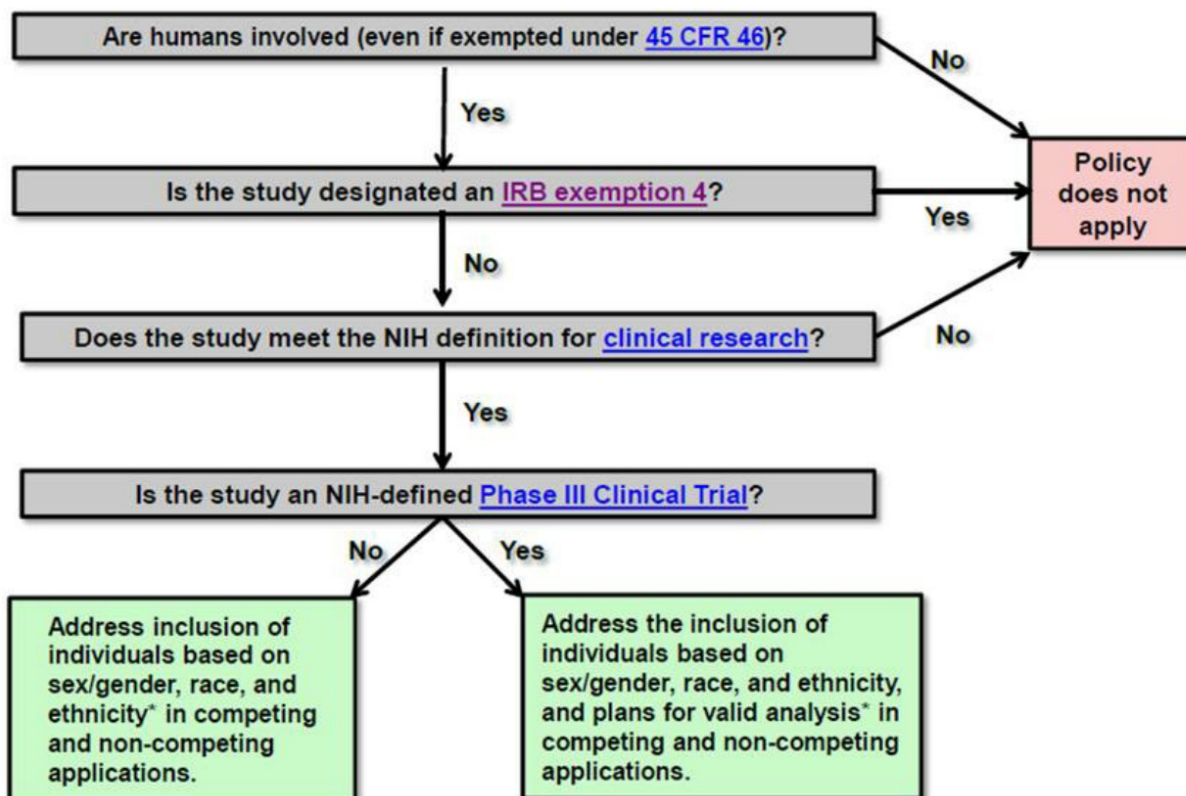
## Policy Summary

- Women and Minority groups must be included in NIH-funded clinical research studies

- Women and Minority groups must be included in Phase III clinical trials & the trial must be designed to document valid analysis

- The NIH supports appropriate outreach programs to recruit and retain women and minority groups in clinical trials

### Decision Tree for Monitoring Inclusion Based on Sex/Gender, Race, and Ethnicity in Research



\*Refer to [application instructions](#), the relevant Funding Opportunity Announcement, and the [inclusion policy page](#) for additional guidance.

## PRE PHASE III CONSIDERATIONS

"Did prior studies indicate significant differences between subgroups?"

- Have a plan to conduct valid analyses to distinguish the significant differences between genders and/or racial/ethnic subgroups."

"Did prior studies not support significant differences between subgroups?"

- Representation as subject selection standard is not required; however, inclusion and analyses is encouraged."

"Finally, if the prior studies neither supported nor negated significant differences in intervention effects between subgroups, the researcher should have a plan on how to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups."

## POLICY DEFINITIONS

### Human Subjects

"A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or if identifiable private information is being used"

### Valid Analysis

"A valid analysis is an unbiased assessment. In order to do a valid analysis the researcher must have a diverse participation population"

### Significant Difference

"Significant difference is of clinical or public health importance, based on substantial scientific data"

## RESOURCES

1. [http://grants1.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants1.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

2. [http://grants.nih.gov/grants/funding/women\\_min/women\\_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm)



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