Justice, Equity, Diversity, and Inclusion Considerations when Reviewing Research

Ben Mooso

Outline

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- Historical Perspective
- Modern Perspective
- Kuali Application
- References

Regulatory and Ethical Basis

- 21 CFR 56.111(a)(3)/45 CFR 46.111(a)(3):
  - Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, pregnant individuals, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

- Belmont Report - Justice
  - Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research.
  - Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.
  - Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

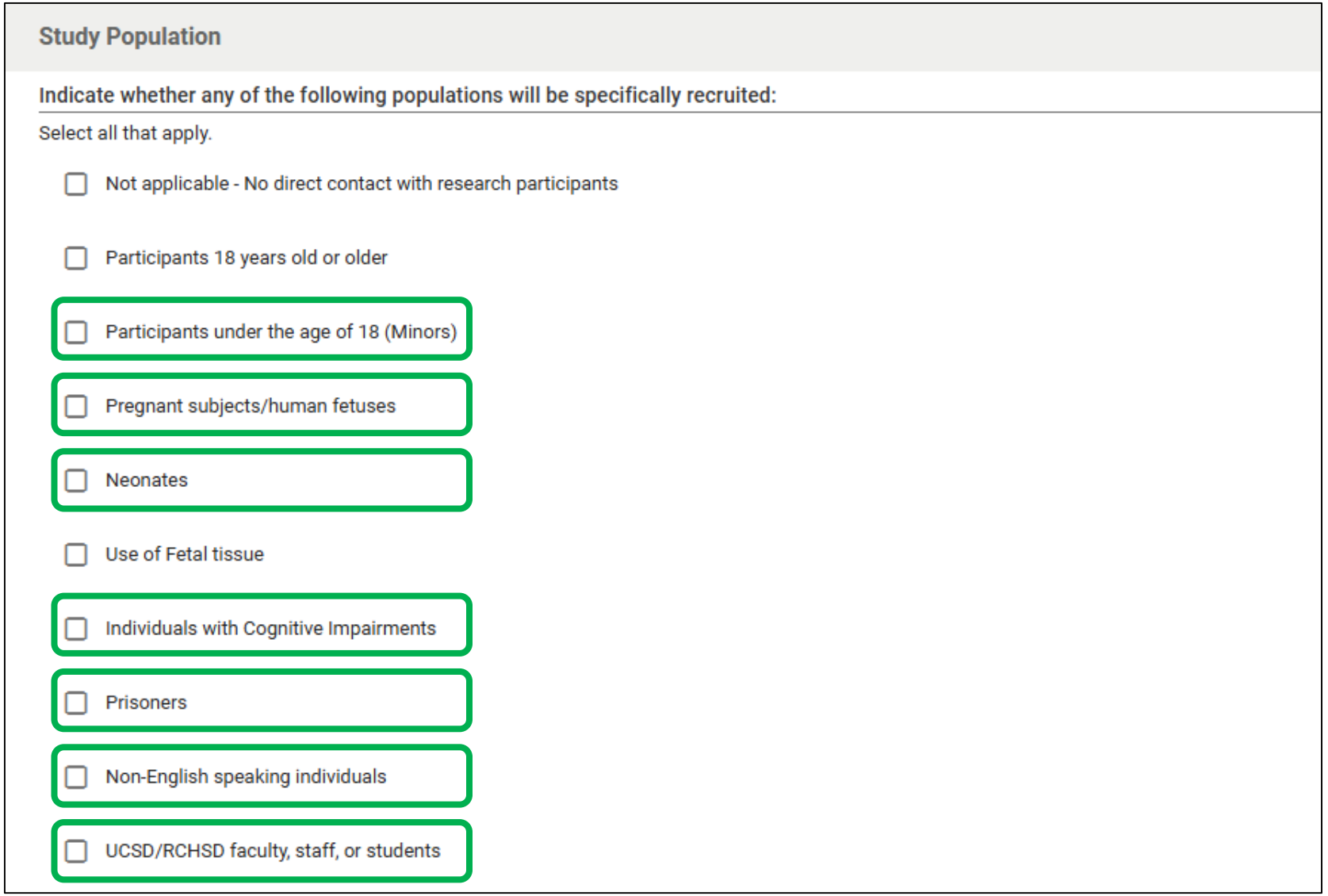
Historical Perspective

- Historically, the role of the IRB has been one of protector, not includer
- Ethical abuses led to public distrust in research, especially in minority communities
- IRBs set high bars for inclusion of populations deemed "vulnerable"
  - Explicit justifications required for including vulnerable populations
  - Explicit inclusion/exclusion criteria to specify whether or not they'd be enrolled
- In 1977, the FDA recommended excluding women of childbearing potential (even those using contraception, were single, or who had sterile husbands) from Phase 1 and 2 drug trials
- Resulted in many studies being solely on Caucasian men

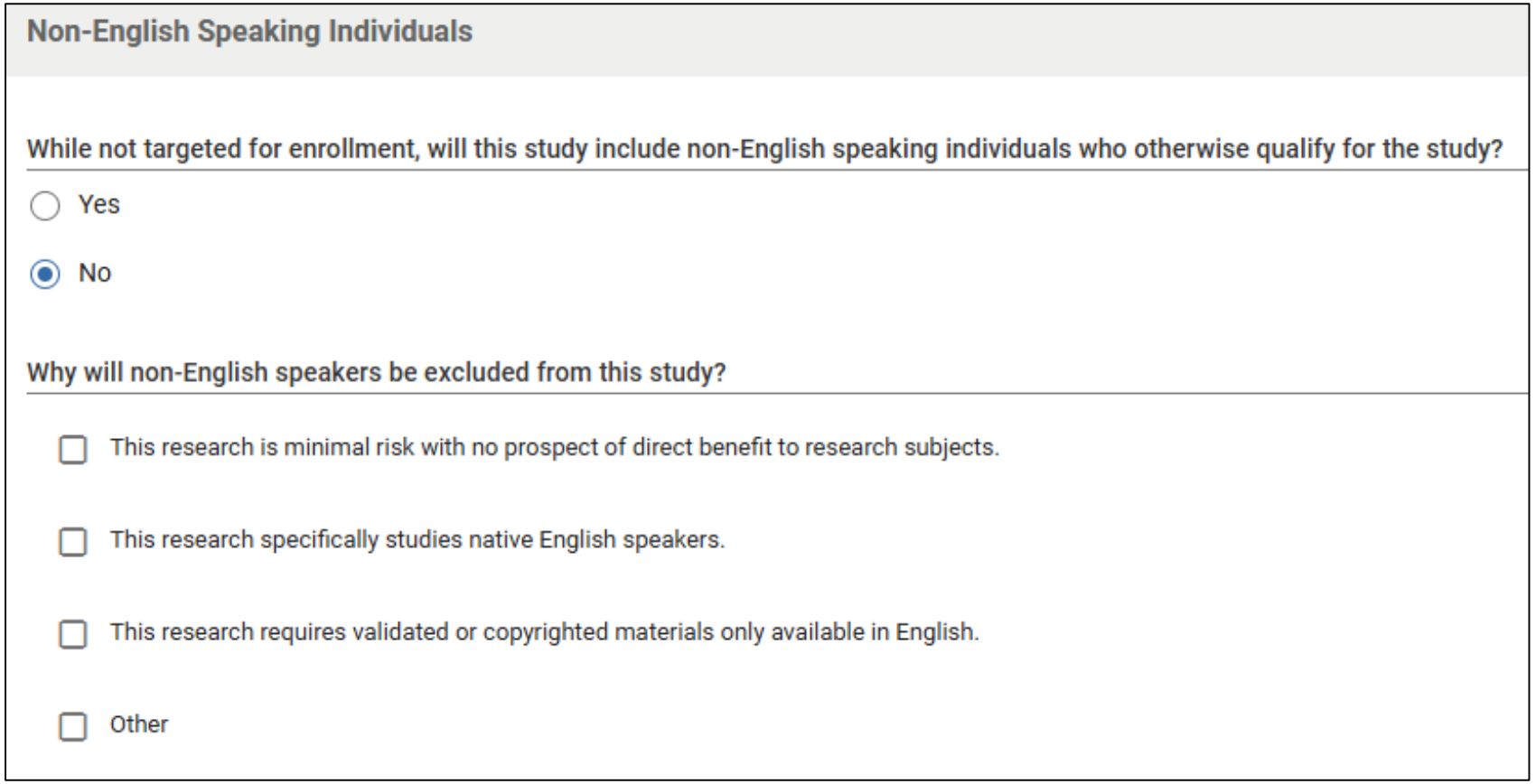
Modern Perspective

- In 1986, NIH established a policy that encouraged researchers to include women in studies
- In July 1989, NIH extended the policy to include minorities
- In 1993, Congress wrote the NIH inclusion policy into Federal law
- In July 1993, the FDA published the "Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs"
- In March 1994, NIH issued revised guidelines on the inclusion of women and minorities
- Topic of national debate in the IRB community
- IRBs generally more interested in inclusion/exclusion for safety

Kuali Application



Kuali Application



References

- 21 CFR 56.111
- 45 CFR 46.111
- Belmont Report
- NIH Guidelines on Inclusion of Women and Minorities
- NIH Office of Research on Women's Health