

Evaluation of Gender -Neutral Language in IRB Guidance and Consent Templates



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INTRODUCTION

The use of gender-neutral language helps ensure all individuals are represented and respected. This survey evaluated the use of and attitudes towards gender-neutral language in consent forms and IRB guidance to pinpoint areas for improvement to foster meaningful informed consent, representation, respect, and inclusivity for all gender identities and expression.

MATERIALS / METHODS

This research was conducted via an electronic Qualtrics survey instrument. Email invitations were sent to contacts obtained from Health and Human Services, Office of Human Research Protections' FWA and IRB Registration database. Respondents included IRB Members, HRPP Administrators, IRB Chairs, IRB Staff, Institutional Officials, Research Coordinators, and Investigators. Participants answered a series of up to 26 questions, including research questions on the status of gender-neutral language in their IRB and their attitudes towards it, and demographic questions.

RESPONSE RATE

The overall response rate to the survey was low, with 642 validated and analyzed responses out of 11,748 delivered surveys (5.5% response rate); representativeness of respondents remains uncertain.

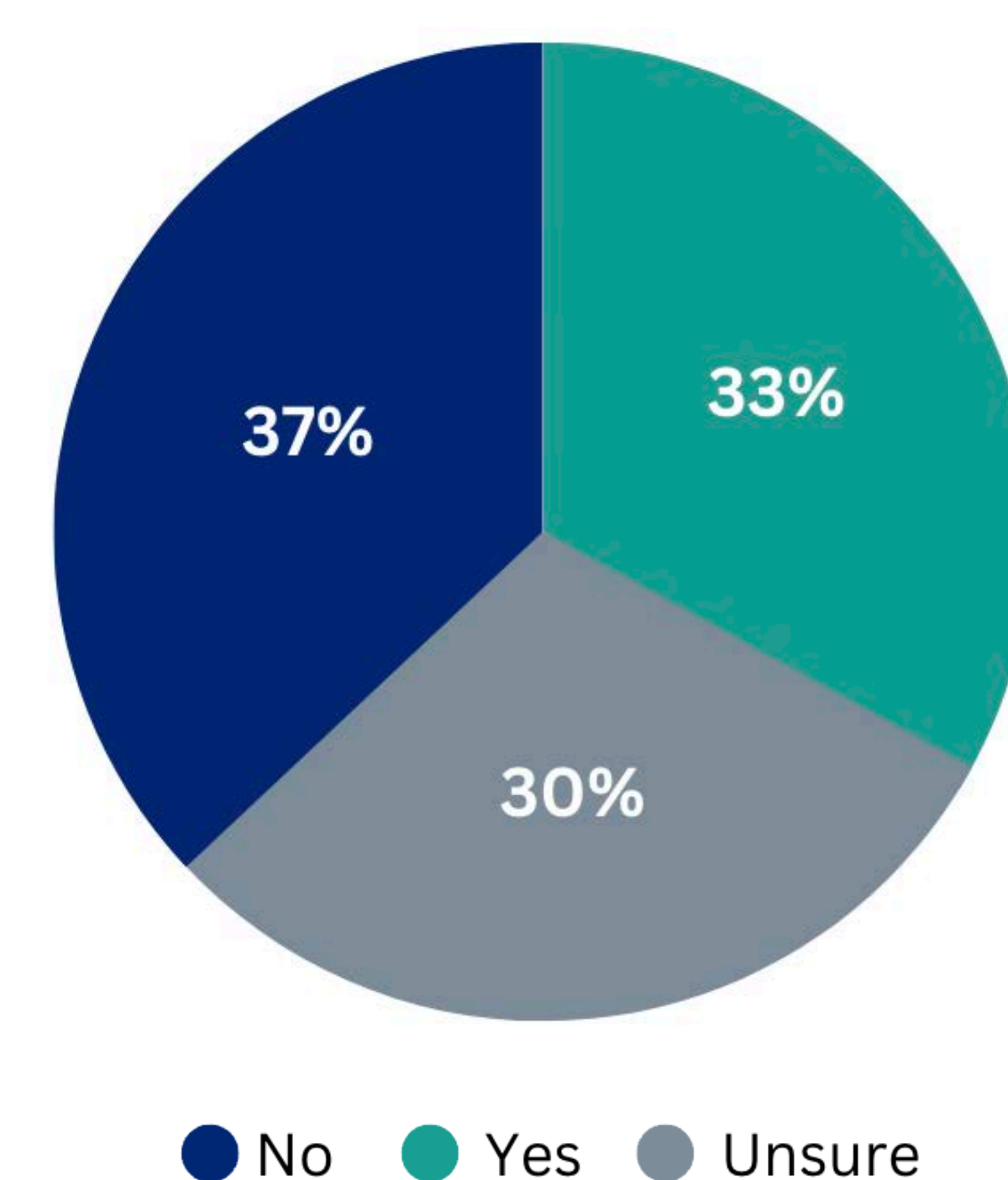
POPULATION CHARACTERISTICS

Respondents were predominantly non-Hispanic white (80%). Most indicated they were women (42%) or cisgender women (23%) with a smaller percentage indicating they were men (31%) or cisgender men (13%). Less than 2% indicated they were non-binary, gender-nonconforming, or genderqueer. Thirty-six percent of respondents worked only in social behavioral research, 18% only in biomedical research, and 46% in both.

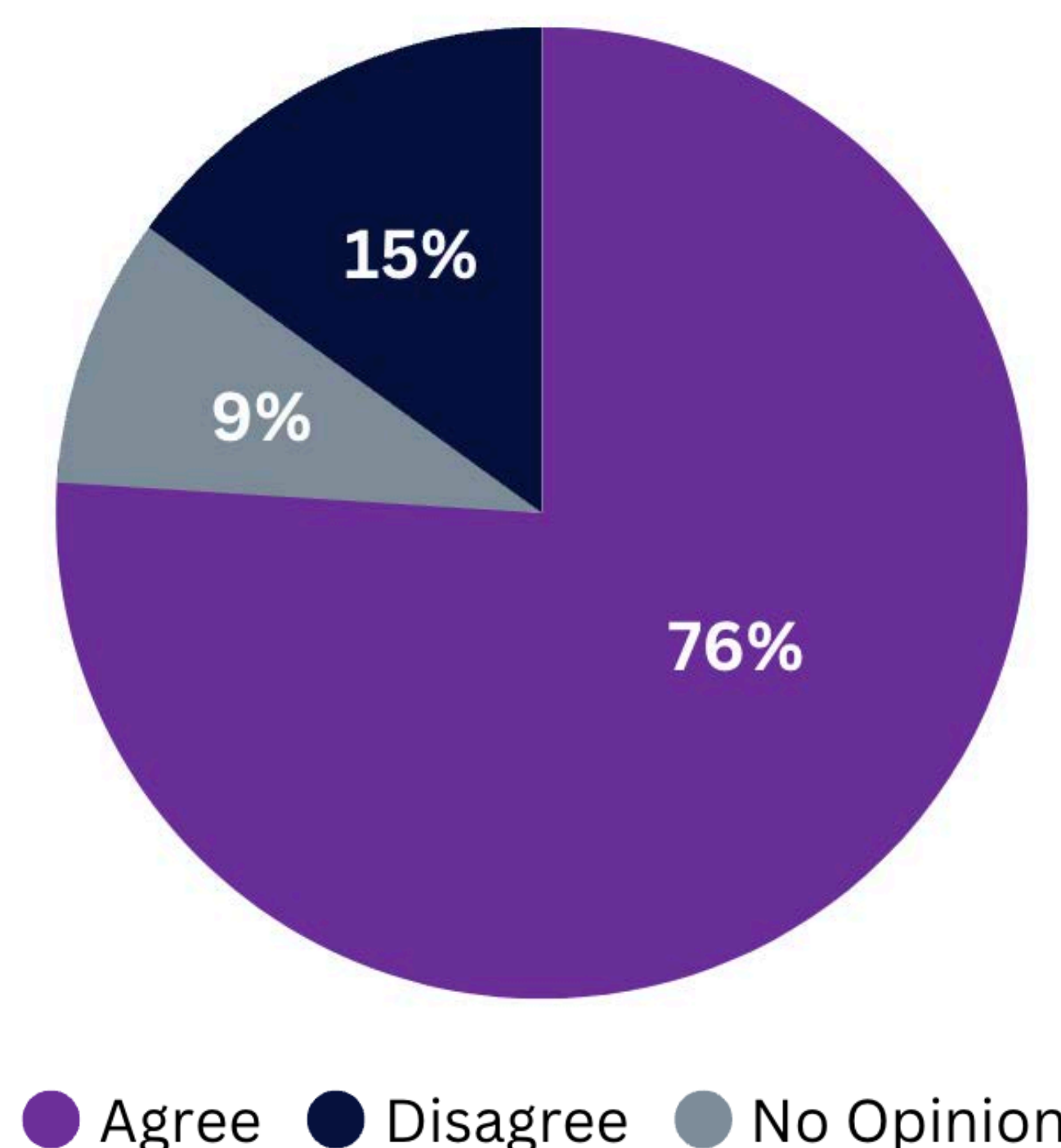
RESULTS

Most respondents (76%) felt that use of gender-neutral language in IRB guidance, templates, and forms is appropriate. Thirty-three percent reported that their IRBs use gender-neutral language in consent forms, 37% didn't, 30% unsure.

Current use of gender -neutral language in IRB guidance and consent templates:



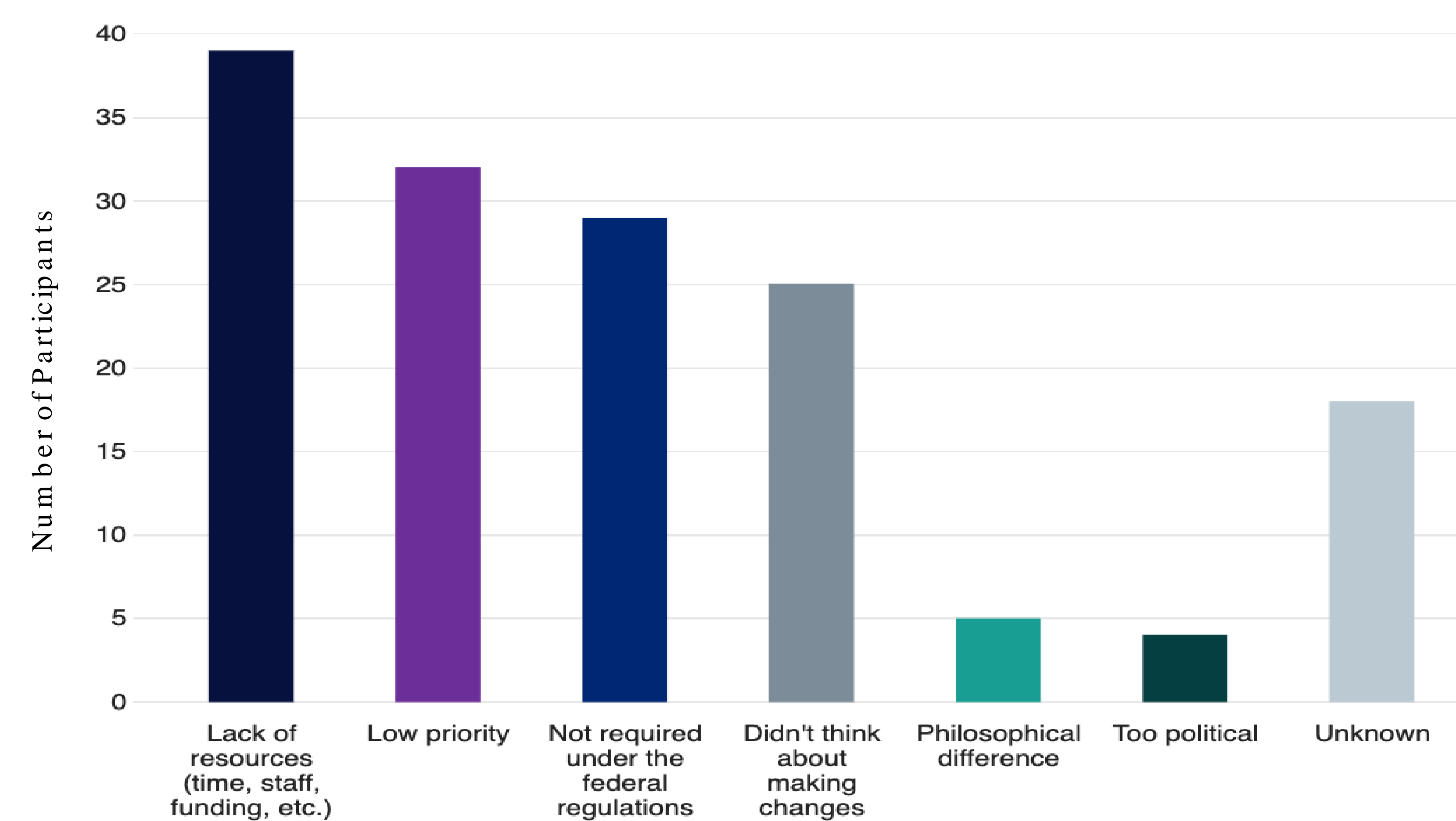
Agreement with use of gender neutral language in IRB guidance and consent templates:



Among responses about specific terminology, 65% agreed that the pronoun "they" is appropriate for an individual. Fifty-four percent agreed that, for pregnancy, the term "pregnant person," was appropriate instead of "pregnant woman." Forty-five percent agreed that "pregnant woman or pregnant person" was appropriate. Forty-six percent disagreed with use of "pregnant woman" without a gender-neutral term.

Among respondents who indicated their IRBs don't use gender-neutral language, the top four reasons (17%-26%) were as follows: lack of resources; low priority; is not required under federal regulations; didn't think about making changes. In comparison, only 3% of participants chose philosophical differences and too political as reasons.

Breakdown for lack of gender -neutral language inclusion:



Most respondents (65%) indicated that the FDA and OHRP should provide guidance for IRBs and investigators regarding use of gender-neutral language; 20% had no opinion and 15% said it is not necessary.

CONCLUSION

The responses to the question about appropriateness of gender-neutral language indicated an overwhelming majority support this. However, respondents reported that a minority of IRBs are currently using this language in consent forms, although almost an equal number are not sure, showing discrepancy between support and implementation. Reasons for lack of implementation indicate they are largely not due to philosophical or political disagreements. There is also majority agreement with gender-neutral terminology presented in the survey showing support for language revision. Future research includes subgroup analysis based on age, gender, type of research, IRB role, and IRB accreditation.