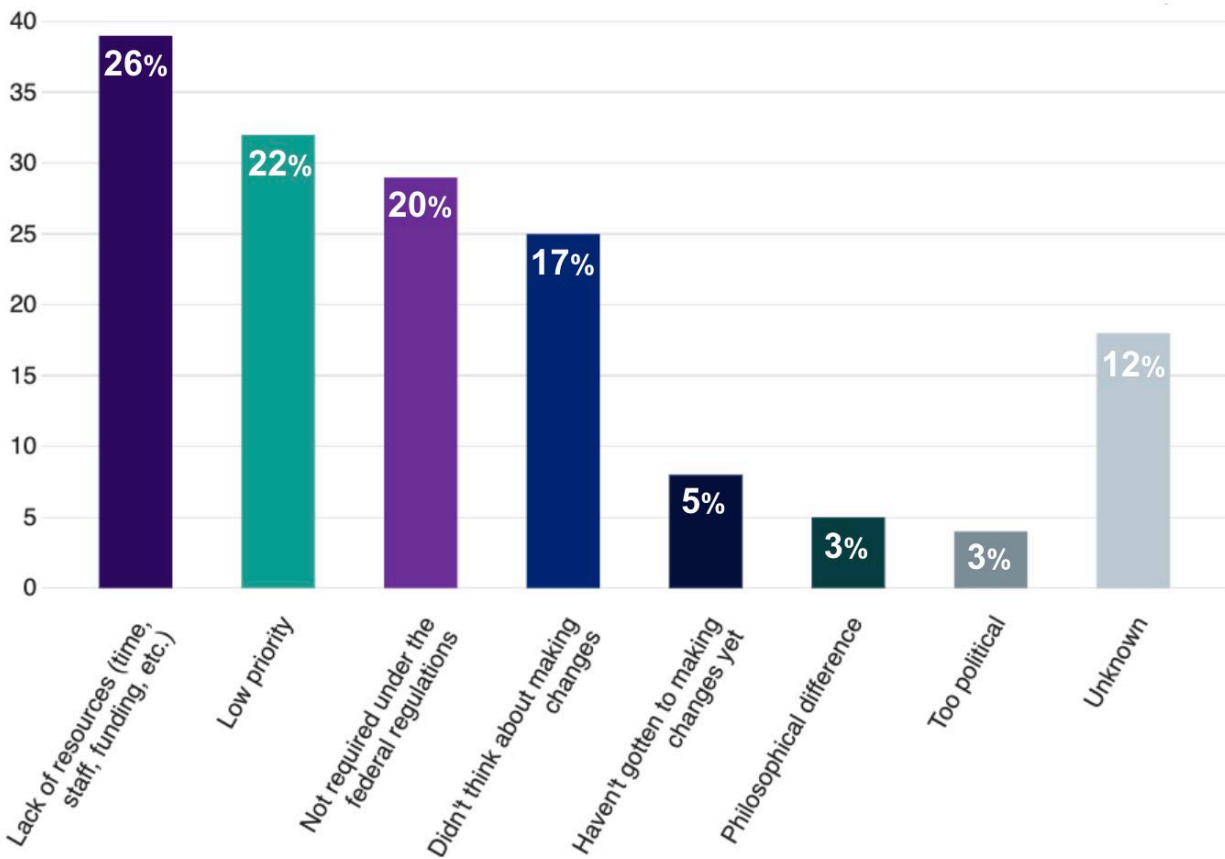




Figure 1. Reasons for Not Having Written Guidance on the Topics Listed in Table A



Additional reasons included in the “other” category were:

- Generally not related to the types of research we are doing (plus 2 responses that were “not applicable”)
- It is included in the CITI training we provide
- Not relevant in our high school student projects (plus another response—we are a HS IRB)



- We use central IRB
- We do not have an IRB. We work with research organizations so we are not required to have these
- Does not apply to the types of research studies we do (I.e., very low risk studies with non-vulnerable populations) (Four other responses were that this does not apply to the type of research they do or populations included in their research studies)
- We follow the federal studies guideline, exclusion and inclusion criteria .
- Our institution does not conduct research with pregnant women.
- Our IRB mostly reviews observational studies and quality improvement projects.
- These proposed changes are contrary to scientific knowledge and are based on political agendas
- Research participants are under the age of 8
- To date, no one here has done research on these topics. We are in NYS, and it is politically liberal, so guidelines regarding these topics don't need any more attention than do other topics.
- Not a common concern for our researchers

Figure 2: Should Your IRB Develop Written Guidance on Topics as Listed in Table A

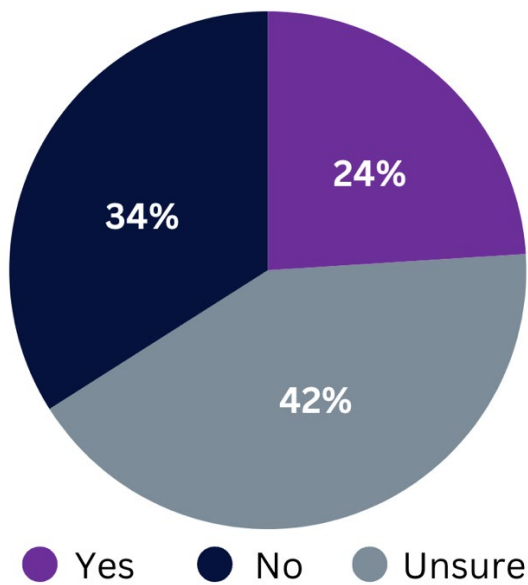


Figure 3: Should Your IRB Use Gender-Neutral Language in IRB Written Guidance; Subset of Respondents Who Did Not Have Guidance as Listed in Table A

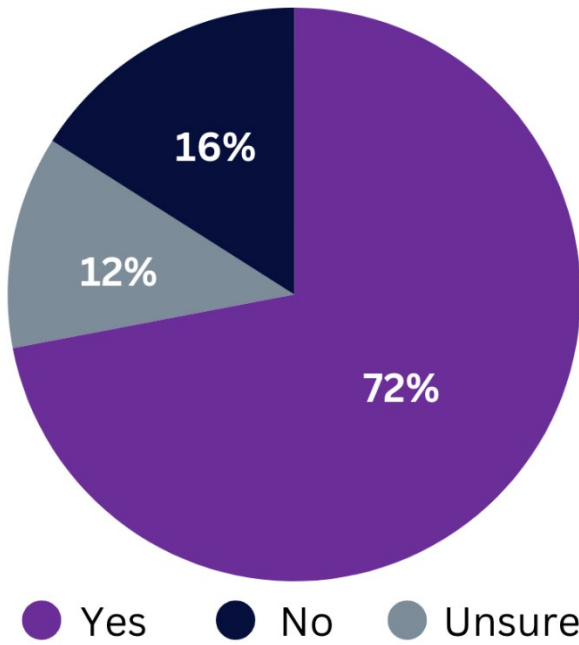




Figure 4: Use of Gender-Neutral Language in IRB Consent Templates

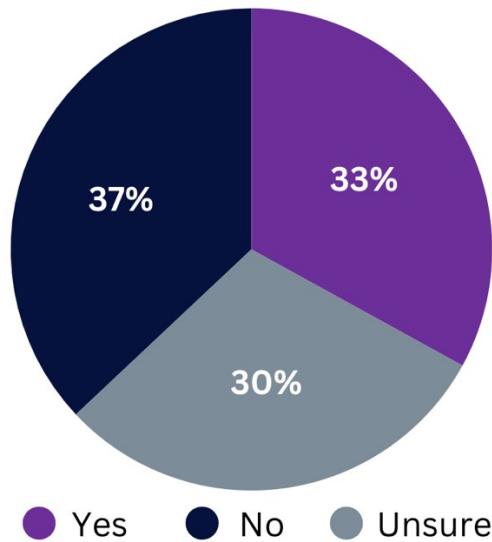
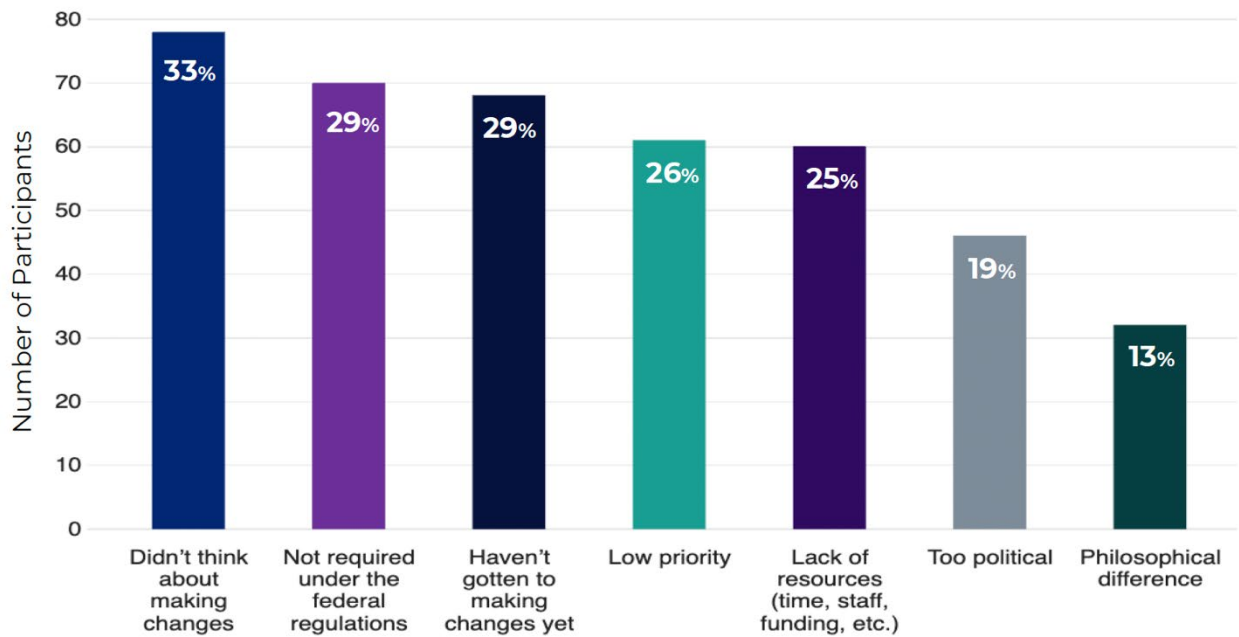


Figure 5: Reasons for Non-use of Gender-Neutral Language in IRB Consent Templates





There was a wide variety of responses to the “other” category. These included:

- Older generations have trouble seeing they as a singular pronoun. If possible, avoid pronouns in the ICF. If not possible, use "they" but make it align with the plural use.
- Given that the gender diverse language suggested applies to a very small percentage of the population, my suggestion would be not to supersede the language of mother/father, woman/man, boy/girl, etc., but to provide options in addition.
- Depends on the population and research questions
- This is really a no, but wanted to explain. Where gender is germane to the research at hand, or may impact safety or analysis of results, it's important to recognize birth gender, even in the face of current gender fluidity. For example, spirometry results are always going to be normalized to people of the same birth gender, regardless of changes in sexual identity after birth.
- Inclusive language appropriate to the aims of the study.
- Using "they" or "them" to refer to one person can be confusing
- Yes, but academic freedom suggests a spectrum of thought. We can suggest gender neutral language but not mandate it



- Most of our templates/samples are gender neutral but not all. We have not had resources available to do a more thorough edit of all our materials but this is planned.
- This language is confusing and would complicate the informed consent process. In addition, the language would be offensive to most of the participants that we serve.
- This could offend other people and they could back down on the research, Leave things as they are and just provide language translations as usual.
- They for him/her is acceptable, but not neutral language when biological differences matter
- I believe it is more appropriate to tailor the language to the community it is targeted for
- It depends on the culture and language of the population to be engaged in the research. Gender appropriate terms cannot assume that there are direct equivalents in other languages or that all communities share the same orientation as the dominating colonial language.
- If the chromosomal sex of an individual is key to the performance of the study, then it may be important to use language that specifies the genetic sex of the subject.
- Gender neutral/diverse/inclusive language should be used where appropriate. This would mean having a separate consent for those individuals.



- What are the implications then for translated consents where these new concepts don't have equivalent translations?
- Too controversial
- Male or Female definition goes beyond what people identifies. Genders are genetic, not ways of feeling. situationally specific
- Yes- but it should be the researchers prerogative whether they choose to use this language, Use of this language may influence recruitment- and therefore- should be the researchers job (not the IRBs) to define.

Figure 6: Agreement with the Appropriateness of the Use of Gender-Neutral Language in Irb Guidance, Templates, and Forms

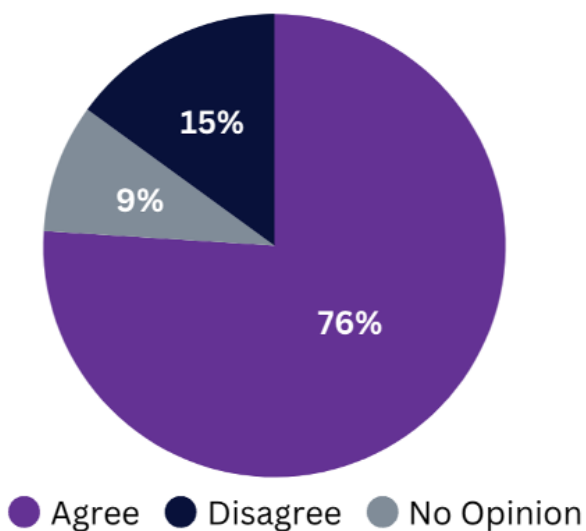






TABLE A: What Written Guidance Is Available at Your Institution

| Written IRB Guidance: | Number and percent of respondents selecting written IRB guidance as available at their institution: |
|--|--|
| Enrollment or exclusion of potential research participants due to pregnancy | 277 (54%) |
| Enrollment or exclusion of potential research participants due to lactation | 115 (22%) |
| Contraception for research participants | 141 (27%) |
| Pregnancy testing for research participants | 154 (30%) |
| Outcomes of the participants who are or who become pregnant | 139 (27%) |
| Enrollment or exclusion of participants based on their partners' pregnancy or potential to become pregnant | 122 (24%) |
| Outcomes of the partners of research participants who become pregnant or are pregnant | 106 (21%) |
| Minor rights to consent | 326 (64%) |
| Waiver of parental permission for research consent on individuals who become pregnant under the age of majority for your state | 106 (21%) |
| Other related guidance | 46 (9%) |
| Unsure | 124 (24%) |
| None of the above | 148 (28%) |

Totals equal more than 100% as participants were asked to choose all that apply.



TABLE B: Agreement with Hypothetical Definitions of Gender-Neutral Terms

| Hypothetical Definitions: | Mean | Median | SD | Number of Responses |
|--|-------------|---------------|-----------|----------------------------|
| A boy is a child or young adult who identifies as male, regardless of sex assigned at birth. | 2.64 | 2 | 1.33 | 634 |
| Breast feeding is feeding a baby milk from the breast. | 1.68 | 2 | 0.77 | 636 |
| Chest feeding is feeding a baby milk from the chest. Anyone can use this gender-neutral term and it is most commonly used by transmasculine people or nonbinary people. | 2.94 | 3 | 1.30 | 636 |
| Cis-gender describes a person whose gender identity corresponds with the sex the person was assigned at birth. A person who is not Transgender. | 2.08 | 2 | 1.14 | 637 |
| Embryo means the product of conception from implantation to 9 actual weeks or 11 weeks from the last menstrual period. | 1.94 | 2 | 0.89 | 636 |
| Gender-affirming hormone therapy is a hormone treatment (or treatments) by which a transgender person may alter their physical secondary sex | 2.01 | 2 | 1.03 | 637 |



| | | | | |
|---|------|---|------|-----|
| characteristics to resemble those socially associated with their identified gender. | | | | |
| Gender-affirming surgery (formerly sex reassignment surgery) is a surgical procedure (or procedures) by which a transgender individual’s physical appearance and function of their existing sexual characteristics are altered to resemble those socially associated with their identified gender. | 2.03 | 2 | 1.05 | 637 |
| Gender diverse is a term used to refer to persons whose gender identity/expression defies gender norms, including those who identify outside the binary of male/female. | 2.16 | 2 | 1.07 | 636 |
| Gender expression is how a person communicates their gender through behavior, clothing, hairstyle, voice, etc. Gender expression may vary regardless of how someone identifies. | 1.98 | 2 | 1.02 | 637 |
| Gender fluid is a term that describes someone whose experience of gender is not fixed. Someone who is gender fluid may identify with having two or more genders that may shift over time. | 2.14 | 2 | 1.13 | 637 |
| Gender identity is a person's inner experience of self – for example, the knowledge or sense of being a man, a woman, another gender, or no gender. | 2.02 | 2 | 1.10 | 637 |
| Gender non-conforming is a term that describes people who do not conform with the gender norms; usually referring to gender expression, presentation, behavior, appearance or roles that | 2.14 | 2 | 1.09 | 637 |



| | | | | |
|--|------|---|------|-----|
| do not conform to prevailing cultural or social expectations regarding their gender. Being gender non-conforming does not necessarily mean the person is transgender or nonbinary although they could be both. | | | | |
| A girl is a child or young adult who identifies as female, regardless of sex assigned at birth. | 2.57 | 2 | 1.34 | 635 |
| Intersex is a general term used for a variety of conditions in which a person is born with reproductive or sexual anatomy that does not seem to fit the typical definitions of female or male, or a person is born with mosaic genetics with some cells that have XX chromosomes and others cells that have XY chromosomes. Intersex may or may not be adopted as an identity term by individuals whose sex, anatomy, or genetics defy binary categorization. | 2.03 | 2 | .99 | 634 |
| Lactating describes the process of producing and releasing milk from the mammary glands. | 1.58 | 2 | 0.67 | 635 |
| LGBTQIA+ is an abbreviation for lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual and more. These terms are used to describe a person’s sexual orientation or gender identity. | 1.89 | 2 | 0.93 | 635 |
| A man is an adult who identifies as male, regardless of sex assigned at birth. | 2.50 | 2 | 1.34 | 633 |
| A non-binary individual identifies with any gender that is not girl/woman or boy/man. Non-binary is an umbrella term that includes people who identify as non-binary, genderqueer, | 2.14 | 2 | 1.12 | 632 |



| | | | | |
|---|------|---|------|-----|
| <p>agender, or bigender, gender nonconforming, two-spirited, or other diverse gender identities. These individuals may use non-binary or gender-neutral pronouns such as they/them or ze/hir.</p> | | | | |
| <p>Non-nutritive sucking is offering the chest or breast to simply comfort or soothe their infant without milk, similar to a pacifier. This non-nutritive comfort can foster attachment, build security, increase warmth, help baby fall asleep, provide pain relief, or promote the baby’s sucking reflex. Also referred to as comfort nursing.</p> | 2.41 | 2 | 1.08 | 634 |
| <p>Post menarche means a time in an individual’s life following the beginning of menstruation.</p> | 1.90 | 2 | 0.92 | 633 |
| <p>Post menopause is the time in a menstruating person's life when menses ceases permanently and the person is no longer capable of childbearing; this can only be defined retroactively after the person has had 12 months without menses.</p> | 1.86 | 2 | 0.93 | 610 |
| <p>Sex is a socially constructed category within a spectrum of natural biological variation, often simplified as a male or female, and sometimes intersex.</p> | 2.6 | 2 | 1.32 | 634 |
| <p>Transgender is a broad term that can be used to describe people whose gender identity is different from the gender they were assigned at birth. Trans is often used as shorthand for transgender.</p> | 1.91 | 2 | 0.95 | 634 |



| | | | | |
|--|------|---|------|-----|
| Two Spirit is an umbrella and/or community organizing term that is meant to unify various gender identities, roles, expressions and/or diverse sexualities among Indigenous, Native American, Alaskan Native, First Nations People, or Peoples of Turtle Island. This may be viewed as a third gender or may involve taking on the identified roles of the opposite sex that was assigned at the time of birth. | 2.5 | 3 | 1.10 | 632 |
| A woman is an adult who identifies as female, regardless of sex assigned at birth. | 2.52 | 2 | 1.35 | 632 |



TABLE C: Agreement with Gender Neutral Language Usage Based on Participant Characteristics

| | Social Behavioral IRB | Social Behavioral & Biomedical IRB | Biomedical IRB | AAHRPP Accredited | Non-AAHRPP Accredited | All Men | All Women |
|---|-----------------------|------------------------------------|----------------|-------------------|-----------------------|---------|-----------|
| Should your IRB include gender-neutral/diverse/inclusive language in their written guidance? | 74.7 % | 76.6% | 43.8% | 68.3% | 73.7% | 55.9% | 69.1% |
| Should guidance for IRBs and investigators from the FDA and OHRP use gender-neutral/diverse/inclusive language? | 73.6% | 64% | 50.4% | 63.1% | 67.9% | 56.9% | 67.9% |



| | | | | | | | |
|---|-------|-------|-------|-------|-------|-------|-------|
| Level of agreement on whether gender-neutral language is appropriate in IRB guidance, templates, and forms | 83.5% | 78.2% | 55.6% | 39.1% | 52.9% | 33.3% | 48.1% |
| Should guidance from the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) provide definitions for gender inclusive terminology? | 66.1% | 62.1% | 57.3% | 62.4% | 63.7% | 56.4% | 66.5% |
| Should your IRB modify the IRB informed | 41.2% | 50.4% | 31.9% | 42.0% | 46.4% | 38.6% | 51.1% |



| | | | | | | | |
|---|-------|-------|-------|-------|-------|-------|-------|
| consent template to include gender-neutral/diverse/inclusive language? | | | | | | | |
| Should investigators always use gender-neutral/diverse/inclusive language in subject-facing materials (e.g., consent forms, information sheets, surveys, advertisements) that are submitted for IRB review? | 53.7% | 48.2% | 45.8% | 46.9% | 52.9% | 37.5% | 51.2% |
| Should gender neutral/diverse/inclusive language be used throughout all consent | 58.8% | 45.2% | 42.7% | 44.3% | 35.5% | 41.0% | 52.1% |



| | | | | | | | |
|--|--|--|--|--|--|--|--|
| templates regardless of the type of research being conducted, e.g., they, for him/her? | | | | | | | |
|--|--|--|--|--|--|--|--|

Table D: Relationship of Type of Research Reviewed to AAHRPP Accreditation Status

| | | Is your institution or IRB accredited by the Association for Accreditation of Human Research Protections Program (AAHRPP)? | | | |
|---|-------------------|---|-----------|----------|-------|
| | | Yes | No | Unsure | Total |
| Types of Human Subjects Research Reviewed by IRB | Biomedical | 63 (54%) | 20 (17%) | 34 (30%) | 117 |
| | Social Behavioral | 66 (29%) | 108 (48%) | 53 (23%) | 227 |
| | Both of the above | 161(55%) | 83 (28%) | 49 (17%) | 293 |