APPENDIX B: Evaluation of Gender-Neutral Language in IRB Guidance and Informed Consent Templates

Recruitment Email

You are being invited to participate in the study titled Evaluation of Gender-Neutral Language in IRB Guidance and Informed Consent Templates. This study aims to assess the use of gender-neutral and inclusive language in IRB guidance and consent templates nationwide. There are no anticipated risks to you because the data we collect will be anonymous. You may not directly benefit from participating in the research; however, you may learn more about gender diversity and the use of gender-neutral language. We hope to use this survey to assess the current status of IRB language and inform IRBs on potential changes to guidance and consent templates. The survey takes approximately 15 minutes.

This research has been approved by the SUNY Downstate Health Sciences University IRB and Privacy Board.

Survey

Standard: Contact Info and Consent (1 Question)
Block: Question Block (29 Questions)

Page Break

You are being invited to participate in the study titled Evaluation of Gender-Neutral Language in IRB Guidance and Informed Consent Templates. This study is being conducted by an interprofessional team from SUNY Downstate Health Sciences University. You were selected to participate in this study because of your association with the IRB and your email address was obtained through the Office of Human Research Protections. This study aims to assess the use of gender-neutral and inclusive language in IRB guidance and consent templates nationwide. There are no anticipated risks to you because the data we collect will be anonymous. You may not directly benefit from participating in the research; however, you may learn more about gender diversity and the use of gender-neutral language. We hope to use this survey to assess the current status of IRB language and inform IRBs on potential changes to guidance and consent templates. We plan to present and/or publish our findings using aggregate data.

You will be receiving reminders for a few weeks if you haven't answered the survey. Be assured that these come automatically via Qualtrics, and the researchers do not know to whom they are sent. We will not link survey responses to any individual respondent. Your participation in this study is completely voluntary and you can withdraw at any time by simply exiting the survey.

If you have questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Ronnie Lichtman CNM, LM, Ph.D., FACNM at (718) 270-7740 or send an encrypted (secure) email to Ronnie.Lichtman@downstate.edu.

This research is reviewed and approved by an Institutional Review Board (IRB). An IRB is a committee that provides ethical and regulatory oversight of human research. If you have any questions or concerns regarding this survey that cannot be answered by the research team, you may talk to the SUNY Downstate Health Sciences University IRB & Privacy Board by calling (718) 613-8480 or sending an encrypted (secure) e-mail to IRB@downstate.edu.

By clicking the **NEXT** button and completing the survey you indicate that you are at least 18 years old and agree to participate in this study. Any question you do not wish to answer you may choose to leave unanswered.

End of Block: Contact Info and Consent

Start of Block: Question Block

*

Select your role(s) at your institution *(select all that apply):*

- ☐ IRB Member
- ☐ Human Research Protections Program (HRPP) Administrator (including the contact person for OHRP registration)
- ☐ IRB Staff
- ☐ IRB Chair
- ☐ Institutional Official (Signatory Official, Senior Officer, Head Official)
- ☐ Investigator
- ☐ Research Coordinator
- ☐ Other (specify): _____

What type of human subjects research does your IRB review?

- ○ Biomedical (e.g., research on drugs, biologics, devices, medical techniques/technology, medicine, biomedicine, healthcare)
- ○ Social Behavioral (e.g., research that explores how and why individuals or groups behave the way they do)
- ○ Both of the above

Is your institution or IRB accredited by the Association for Accreditation of Human Research Protections Program (AAHRPP)?

- ○ Yes
- ○ No
- ○ Unsure

To your knowledge, does your IRB membership include gender diverse individuals (e.g., transgender, non-binary, gender non-conforming, intersex)?

- ○ Yes
- ○ No
- ○ Unsure
- ○ Unfamiliar with the terminology

VALIDATION 1 For validation purposes, select answer choice "A":

- ○ A
- ○ B
- ○ C

Page Break

What written IRB guidance is available at your institution? (select all that apply):

- ☐ Enrollment or exclusion of potential research participants due to pregnancy
- ☐ Enrollment or exclusion of potential research participants due to lactation
- ☐ Contraception for research participants
- ☐ Pregnancy testing for research participants
- ☐ Outcomes of the participants who are or who become pregnant
- ☐ Enrollment or exclusion of participants based on their partners' pregnancy or potential to become pregnant
- ☐ Outcomes of the partners of research participants who become pregnant or are pregnant
- ☐ Minor rights to consent
- ☐ Waiver of parental permission for research consent on individuals who become pregnant under the age of majority for your state
- ☐ Other related guidance (specify): _____
- ☐ None of the above
- ☐ Unsure

Display This Question:

If What written IRB guidance is available at your institution? (select all that apply): = None of the above

What are some of the reasons for not having written guidance on these topics? *(select all that apply)*

- ☐ Didn't think about making changes
- ☐ Low priority
- ☐ Haven't gotten to making changes yet
- ☐ Lack of resources (time, staff, funding, etc.)
- ☐ Not required under the federal regulations
- ☐ Philosophical difference
- ☐ Institutional culture would not be supportive
- ☐ Too political
- ☐ IRB member objections
- ☐ Researcher objections
- ☐ Too difficult for researchers
- ☐ The research participants we serve would not understand this language
- ☐ The research participants we serve would be discouraged by this language from participating in studies
- ☐ Unknown
- ☐ Other (specify): _____

Display This Question:

If What written IRB guidance is available at your institution? (select all that apply): = None of the above

Should your IRB develop written IRB guidance on these topics?

- Yes
- No
- Unsure

Display This Question:

If What written IRB guidance is available at your institution? (select all that apply): = None of the above

Should your IRB include gender-neutral/diverse/inclusive language in their written guidance?

- Yes
- No
- Unsure

Should guidance for IRBs and investigators from the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP) use gender-neutral/diverse/inclusive language?

- Yes
- No
- No opinion

Indicate your agreement or disagreement with the following statements used in IRB GUIDANCE, TEMPLATES, and FORMS:

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
Gender-neutral language is appropriate.	○	○	○	○	○
The use of the terms ***"pregnant person"*** is appropriate instead of ***"pregnant woman"***.	○	○	○	○	○
The use of terms ***"pregnant woman or pregnant person"*** is appropriate instead of ***"pregnant woman"***.	○	○	○	○	○
The use of the terms ***"pregnant woman or pregnant individual"*** is appropriate instead of ***"pregnant woman"***.	○	○	○	○	○
Only using the term ***"pregnant woman"*** is appropriate without adding a gender-neutral term.	○	○	○	○	○

The use of the pronoun ***"they"*** is appropriate to refer to an individual.	○	○	○	○	○

Indicate your agreement or disagreement with the hypothetical revised language statements used in an INFORMED CONSENT TEMPLATE:

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
PRIOR language: pregnant woman **REVISED language:** pregnant individual	○	○	○	○	○
PRIOR language: pregnant woman **REVISED language:** pregnant person	○	○	○	○	○
PRIOR language: pregnant woman **REVISED language:** pregnant woman or pregnant individual	○	○	○	○	○
PRIOR language: pregnant woman **REVISED language:** pregnant woman or pregnant person	○	○	○	○	○
PRIOR language: women of childbearing potential **REVISED language:** individuals of childbearing potential	○	○	○	○	○
PRIOR language: women of childbearing potential **REVISED language:** people of childbearing potential	○	○	○	○	○
PRIOR language: women of childbearing potential **REVISED language:** women or individuals of childbearing potential	○	○	○	○	○

PRIOR language: If you are a woman who becomes pregnant... **REVISED language:** If you become pregnant...	○	○	○	○	○
PRIOR language: Women who can get pregnant... **REVISED language:** Individuals who can get pregnant...	○	○	○	○	○
PRIOR language: Women should not become pregnant... **REVISED language:** You should not become pregnant...	○	○	○	○	○
PRIOR language: Men should not get a woman pregnant if they join this study. **REVISED language:** You should not get someone pregnant if you join this study.	○	○	○	○	○
PRIOR language: Women who join the study and have a positive pregnancy test will be told about the test results and will be withdrawn from the research. **REVISED language:** If you join the study and have a positive pregnancy test, we will tell you about the test results and you will be withdrawn from the research.	○	○	○	○	○

PRIOR language: If you are a girl under 18, you must give your permission before we can share the pregnancy test results with a parent or guardian or anyone else. Girls who have a positive pregnancy test will be asked to leave the study. **REVISED language:** If you are under eighteen (18), you must give your permission before we can share the pregnancy test results with a parent or guardian or anyone else. If you have a positive pregnancy test, we will ask you to leave the study.	○	○	○	○	○
PRIOR language: …regardless of whether he/she was participating in the study… **REVISED language:** …regardless of whether you participate in the study…	○	○	○	○	○

PRIOR language: When your child reaches age 18, we will try to contact him or her to ask whether he or she wants to continue to participate in research. **REVISED language:** When your child reaches age 18, we will try to contact them to ask whether they want to continue to participate in research.	○	○	○	○	○
PRIOR language: Your child can request additional information when he or she is 18. **REVISED language:** Your child can request additional information when they turn 18.	○	○	○	○	○
PRIOR language: We will obtain her/his consent if (s)he becomes able to decide later. **REVISED language:** We will obtain their consent if they become able to decide later.	○	○	○	○	○
PRIOR language: …a description of his or her authority to act for the individual… **REVISED language:** … a description of their authority to act for the individual…	○	○	○	○	○

PRIOR language: The researchers and his/her staff approved by the IRB **REVISED language:** The researchers and their staff approved by the IRB	○	○	○	○	○
PRIOR language: Collection of urine will be done to test for pregnancy if you are a woman who is able to become pregnant. **REVISED language:** Urine samples will be collected for a pregnancy test for anyone who can become pregnant.	○	○	○	○	○

PRIOR language: The effect of the study drug on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of the unknown risks, if you are a woman capable of giving birth or a man capable of fathering a child, you and your sexual partner must use adequate birth control measures while you are in this study. **REVISED language:** The impact of the study drug on an embryo or fetus (developing baby still in the womb) or on a baby fed with milk released from lactation is unknown and may be harmful. Because of these potential risks, if you can become pregnant or get someone pregnant, you and your sexual partner must use effective birth control measures while participating in this study.	○	○	○	○	○

Indicate your agreement or disagreement with the general hypothetical definitions, listed alphabetically, used in IRB GUIDANCE:

	Strongly Agree	Agree	No Opinion	Disagree	Strongly Disagree
A ***boy*** is a child or young adult who identifies as male, regardless of sex assigned at birth.	○	○	○	○	○
Breast feeding is feeding a baby milk from the breast.	○	○	○	○	○
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.	○	○	○	○	○
Cis-gender describes a person whose gender identity corresponds with the sex the person was assigned at birth. A person who is not Transgender.	○	○	○	○	○
Embryo means the product of conception from implantation to 9 actual weeks or 11 weeks from the last menstrual period.	○	○	○	○	○

Gender-affirming hormone therapy is a hormone treatment (or treatments) by which a transgender person may alter their physical secondary sex 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.	○	○	○	○	○
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.	○	○	○	○	○

Gender expression is how a person communicates their gender through behavior, clothing, hairstyle, voice, etc. Gender expression may vary regardless of how someone identifies.	○	○	○	○	○
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.	○	○	○	○	○
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.	○	○	○	○	○

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 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.	○	○	○	○	○

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.	○	○	○	○	○
Lactating describes the process of producing and releasing milk from the mammary glands.	○	○	○	○	○

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.	○	○	○	○	○
A ***man*** is an adult who identifies as male, regardless of sex assigned at birth.	○	○	○	○	○
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, 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.	○	○	○	○	○

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.	○	○	○	○	○
Post menarche means a time in an individual's life following the beginning of menstruation.	○	○	○	○	○
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.	○	○	○	○	○

Sex is a socially constructed category within a spectrum of natural biological variation, often simplified as a male or female, and sometimes intersex.	○	○	○	○	○
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.	○	○	○	○	○
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.	○	○	○	○	○

A ***woman*** is an adult who identifies as female, regardless of sex assigned at birth.	○	○	○	○	○

VALIDATION 2 For validation purposes, select answer choice "B":

- ○ A
- ○ B
- ○ C

Should guidance from the Food and Drug Administration's (FDA) and Office for Human Research Protections' (OHRP) provide definitions for the terms above?

- ○ Yes
- ○ No
- ○ No opinion

Does your IRB-approved Informed Consent template include gender-neutral/diverse/inclusive language?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If Does your IRB-approved Informed Consent template include gender-neutral/diverse/inclusive language? = Yes

How does your IRB prefer to use gender-neutral/diverse/inclusive language within the Informed Consent template? *(select all that apply):*

- ☐ Uses the term “pregnant women” or “women” as applicable to the context.
- ☐ Uses gender neutral/diverse/inclusive language (as an example, “pregnant persons”) rather than “pregnant women”.
- ☐ Adds gender-neutral/diverse/inclusive language to the term “pregnant women” (as an example, “pregnant women or pregnant persons”).
- ☐ Generally, avoids the use of gender specific terms (as an example, “if you become pregnant”).
- ☐ Other (specify): _____
- ☐ Unsure

Display This Question:

If Does your IRB-approved Informed Consent template include gender-neutral/diverse/inclusive language? = No

What are some of the reasons for not using gender-neutral/diverse/inclusive language in the consent template? *(select all that apply):*

- ☐ Didn't think about making changes
- ☐ Low priority
- ☐ Haven't gotten to making changes yet
- ☐ Lack of resources (time, staff, funding, etc.)
- ☐ Not required under the federal regulations
- ☐ Philosophical difference
- ☐ Institutional culture would not be supportive
- ☐ Too political
- ☐ IRB member objections
- ☐ Researcher objections
- ☐ Too difficult for researchers
- ☐ The research participants we serve would not understand this language
- ☐ The research participants we serve would be discouraged from participating in studies
- ☐ Unknown
- ☐ Other (specify):

Display This Question:

If Does your IRB-approved Informed Consent template include gender-neutral/diverse/inclusive language? = No

Should your IRB modify the IRB informed consent template to include gender-neutral/diverse/inclusive language?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If Does your IRB-approved Informed Consent template include gender-neutral/diverse/inclusive language? = Unsure

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?

- ○ Yes
- ○ No
- ○ Unsure

Should gender neutral/diverse/inclusive language be used throughout all consent templates regardless of the type of research being conducted, e.g., they, for him/her?

- ○ Yes
- ○ No
- ○ Unsure
- ○ No Opinion
- ○ Other (specify): _____

VALIDATION 3 For validation purposes, select answer choice "C":

- ○ A
- ○ B
- ○ C

Page Break

What is your age?

- ○ 18-19
- ○ 20-19
- ○ 30-39
- ○ 40-49
- ○ 50-59
- ○ 60-69
- ○ 70 or above
- ○ Prefer not to answer

What is your gender? *(select all that apply):*

- ☐ Man
- ☐ Woman
- ☐ Cisgender Man
- ☐ Cisgender Woman
- ☐ Transgender Man
- ☐ Transgender Woman
- ☐ Non-binary
- ☐ Gender Non-conforming
- ☐ Gender Fluid
- ☐ Genderqueer
- ☐ Intersex
- ☐ Other (specify): _____
- ☐ Prefer not to answer

What are your pronouns? *(select all that apply)*

- ☐ He/Him/His
- ☐ She/Her/Hers
- ☐ They/Them/Theirs
- ☐ Other (specify): _____
- ☐ Prefer not to answer

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16 What is your race? *(select all that apply):*

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ Other (specify): _____
- ☐ Prefer not to answer

What is your ethnicity? *(select all that apply):*

- ☐ Hispanic or Latino
- ☐ Not Hispanic nor Latino
- ☐ Other (specify): _____
- ☐ Prefer not to answer

What is the highest level of education you have completed?

- ○ Less than high school degree
- ○ High school diploma (or GED)
- ○ Post-high school trade school
- ○ Associate's degree
- ○ Bachelor's degree
- ○ Master's degree
- ○ MD or equivalent Doctoral degree
- ○ Ph.D. or equivalent Doctoral degree
- ○ Prefer not to answer

Page Break

OPTIONAL: If your IRB has guidance related to the topics on this survey that are posted on a public website, please provide the link to the website, if you are willing to share:

We will not link this answer to any response in order to maintain anonymity.

_____

End of Block: Question Block