MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Representation in Research
LGBTQIA+

Tool 2: LGBTQIA+ Inclusive Language Checklist

Introduction

In the checklist below, the MRCT Center provides thinking prompts (note especially those prompts in bold) for the use of language that is respectful to and inclusive of LGBTQIA+ populations. The checklist can be used by stakeholders across the clinical research spectrum, from sponsors to patient navigators, when creating participant-facing documents (e.g., recruitment materials, informed consent forms), drafting study protocol eligibility criteria, and speaking with participants face-to-face. It is our shared responsibility to listen to participants' and communities' choice of wording and address, continually learn from each other, and ensure that all people are encouraged to participate by the language that we use.

Checklist

- ☐ **Use gender-neutral language whenever possible (e.g., they/their, the participant**, person/individual, adolescent/adult participant of childbearing potential, human) (see Box 1 below).[1, 2, 3, 4, a] If the study is focused on people of a particular gender(s), that terminology can be used.[5] In describing biological sex, use sex-related terminology (e.g., male, female, intersex).

- ☐ **Use language that is inclusive of all families (e.g., the parent/s, the caregiver/s,** the guardian/s, the partner/spouse, the sibling/s, the child/children, the chosen family).

- ☐ Avoid outdated and inappropriate language.[6, 7]

[a] Please note that US Government documents listed as weblinks in this tool may not be available. Please see Tool 7, "Exit Survey Inclusive of the LGBTQIA+ Perspective" for sample sexual orientation and gender identity (SOGI) questions and response options.

- ☐ Translate the text and concepts in participant-facing materials into the language/s used by participants locally, when possible.[b]
- ☐ Use the name and titles associated with or indicated by the individual. For example, use non-gendered professional titles (e.g., Dr., Rev., Captain, Mx. if the person uses this term). If a person states that they use Miss, Mrs., Ms., Lady, Ma'am, etc., use the specified terms. If a person's professional title is not known, use their full name or refer to your specific relationship with the person (e.g., the applicant, the participant).
- ☐ Offer your pronouns (e.g., in direct conversation, email signatures, Zoom handles, name badges) if you feel comfortable doing so. Ask about, and then use, the pronouns stated by the participant.[8,9] Confirm with the participant that the pronouns in their medical chart are correct. For privacy and safety reasons, and particularly for children and adolescents, some participants may prefer to use different pronouns depending upon whom they are speaking with. Respect that some people may elect not to disclose their pronouns or only do so in certain settings. Share with the participant how collected information, like pronouns, will be documented, used, and shared.

[b] Please note that LGBTQIA+ terminology may not translate directly from English to other languages, and determination of which terms are most respectful and commonly used can vary across locations that speak the same language (e.g., Mexico and Argentina may not use the same wording). Cited here are three resources in Spanish and one in French, with the caveat that these are general guides.

i. Counsel of the European Union Secretary General. 2018. *Comunicacíon Inclusiva en la Secretaría General Del Consejo.* Available from: https://www.consilium.europa.eu/media /35447/es_brochure-inclusive-communication-in-the-gsc.pdf

ii. Consejo Nacional para Prevenir la Discriminación. (2015). *Recomendaciones para el Uso Incluyente y No Sexista del Lenguaje.* Available from: https://www.gob.mx/conavim /documentos/recomendaciones-para-el-uso-incluyente-y-no-sexista-del-lenguaje

iii. Ibero Torreón. *Guía para Utilizar el Lenguaje Incluyente en la Universidad.* Available from: https://www.iberotorreon.mx/publico/asuntos-genero.php

iv. Counsel of the European Union Secretary General. (2018). *La Communication Inclusive au SGC*. Available from: https://op.europa.eu/fr/publication-detail/-/publication/cef4a4cd-91cb-11eb-b85c-01aa75ed71a1

- ☐ Use a gender-neutral body outline/chart for patients to mark pain points or other conditions (for one example, see here) unless more specific imagery of body parts is necessary (e.g., for a mammography intake form or reporting on sexual violence).
- ☐ **In study protocols, clearly justify the safety/ethical reasons for any exclusions in study eligibility criteria that, in effect, exclude LGBTQIA+ populations (e.g., participants who take PrEP, have HIV, or have HBV/HCV**). Where possible, provide more specific thresholds for inclusion/exclusion (e.g., undetectable HIV, CD4 count) that are based on the investigational product safety profile, the condition under study, and the risk to participants with that condition.[10,11] Please note, while the aim is to be non-discriminatory and as inclusive as possible, there are certainly cases where exclusion is necessary. For example, if the investigational product were to suppress the immune system, that may be a safety concern for immunocompromised individuals, and thus exclusion of immunocompromised individuals would be justified.
- ☐ Know that everyone makes mistakes! If you do, acknowledge it each time it happens, apologize, and move on by continuing to try to use respectful language (including the individual's pronouns and terms). The most important thing is to consistently try.

Example Language

Box 1: Examples of LGBTQIA+ inclusive study protocol eligibility criteria language

- To prevent becoming pregnant or causing a pregnancy during the study, the participant agrees to refrain from vaginal intercourse OR uses one barrier method (external or internal condoms), preferably in combination with a hormonal method (e.g., contraceptive pills or implants), intrauterine device, or permanent method (sterilization). The participant also agrees to no fertility treatment or sperm donation.
- Patients known to be positive for HIV are excluded if they meet any of the following criteria: 1) CD4+ T-cell count of <200 cells/mL if the experimental therapy is not known to have a negative impact on CD4+ T-cells, 2) Detectable HIV viral load, 3) History of an opportunistic infection in the last 12 months.
- Patients with a histologically documented adenocarcinoma of the prostate with Gleason score of 7 or lower.

References

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2. National Institutes of Health. (2024). *NIH style guide: Inclusive and gender-neutral language*. U.S. Department of Health and Human Services. Available from: https://www.nih.gov/nih-style-guide/inclusive-gender-neutral-language
3. National Institutes of Health. (2024). *Culturally Competent Gender-Related Communications (C3) Training Resource.* U.S. Department of Health and Human Services. Available from: https://dpcpsi.nih.gov/sgmro/c3training
4. Krempasky, C., Harris, M., Abern, L., & Grimstad, F. (2020). Contraception across the transmasculine spectrum. *American Journal of Obstetrics and Gynecology, 222*(2), 134–143. Available from: https://www.ajog.org/article/S0002-9378(19)30955-X/abstract
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6. University of Maryland LGBTQ+ Equity Center. *Good Practices: Inclusive Language*. University of Maryland. Available from: https://lgbtq.umd.edu/good-practices-inclusive-language
7. GLAAD. (2024). *Glossary of Terms: LGBTQ*. Available from: https://glaad.org/reference/terms/
8. Human Rights Campaign. (2024). *We Ask Each Other Pronouns*. Available from: https://www.hrc.org/resources/why-we-ask-each-other-our-pronouns; *Talking about Pronouns in the Workplace*. Available from: https://www.thehrcfoundation.org/professional-resources/talking-about-pronouns-in-the-workplace

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11. U.S. Food and Drug Administration. (2020). *Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections*. U.S. Department of Health and Human Services. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cancer-clinical-trial-eligibility-criteria-patients-hiv-hepatitis-b-virus-or-hepatitis-c-virus