LGBTQIA+ Inclusion by Design in Clinical Research

Toolkit and Resources

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

Representation in Research
LGBTQIA+

Representation in Research LGBTQIA+

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Introduction

Background

People who are LGBTQIA+[a] are discriminated against in many areas of life. This has been documented in clinical care and likely this is true for clinical research. While sex, sexual orientation, and gender identity may influence disease risk, manifestation of illness, and treatment response, we don't well understand when and how. That understanding requires people first be included and then be counted, and until recently, clinical trials did not collect and report sexual orientation and gender identity (SOGI) data. It is also because, until recently, clinical research organizations had not yet publicly committed to, and devoted the resources toward, supporting the visibility and prioritization of LGBTQIA+ populations in research.

Through the dedicated efforts of LGBTQIA+ advocates and allies, there have been recent promising changes relevant to clinical research. Pursuant to 2022 Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, the White House released in 2023 "Recommendations on the Best Practices for the Collection of Sexual Orientation and Gender Identity Data on Federal Statical Surveys;"[1] the National Academies of Science, Engineering and Medicine (NASEM) released in 2023 guidance on "Measuring Sex, Gender Identity, and Sexual Orientation;"[2] the National Institutes for Health (NIH) Sexual & Gender Minority Research Office (SGMRO) released in 2024 "Updated Definitions of Sexual and Gender-Minority Populations in NIH-Supported Research;"[3] and in 2024 the Clinical Data Interchange Standards Consortium finalized SOGI questions and variable definitions into their electronic case report form portal, which serve as templates for how researchers collect demographic data.[4]

Prominent medical journals now call for the collection and reporting of disaggregated data on sex and gender in the Sex and Gender Equity in Research (SAGER) guidelines,[5] and sex,

[a] Some people and organizations use acronyms such as LGBTQ, LGBTQI, or LGBTQI+, while others use the terms sexual and gender minority (SGM), transgender and gender diverse (TGD), sexual and gender diverse populations (SGD), or simply "queer" populations. In discussion with the MRCT Center Working Group on LGBTQIA+ Inclusion in Clinical Research, members stated that they welcomed all terms, but [slightly] preferred to use LGBTQIA+.

gender, sexual orientation, and gender identity in the Journal of the American Medical Association (JAMA) draft "Guidance on Reporting Gender, Sex, Gender Identity, Sexual Orientation, and Age in Medical and Scientific Publication."[6] Further, clinical research organizations including numerous pharmaceutical sponsors are working to make trial eligibility criteria more LGBTQIA+ inclusive, build SOGI data collection into their operational policies, and collaboratively share lessons learned through forums like the MRCT Center Working Group on LGBTQIA+ Inclusion in Clinical Research Working Group and the Sexual and Gender Minority (SGM) Alliance.[7]

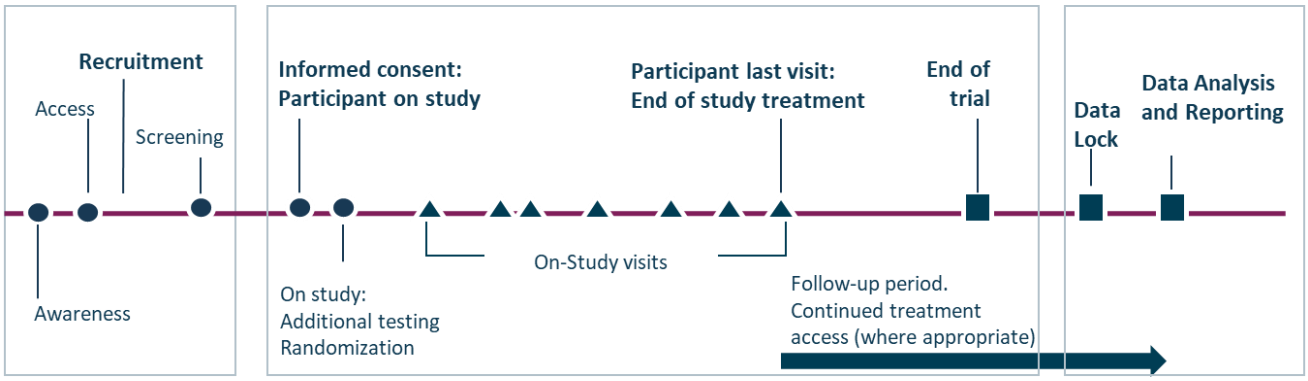
In tandem with these efforts, the MRCT Center released [in 2020] the "Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document and Toolkit"[8] that provided recommendations, tools, and case studies on how to reduce barriers commonly experienced by underrepresented populations in clinical trials. We acknowledged at the time that additional work was needed to understand and address barriers uniquely experienced by populations such as people with disabilities, people with limited English proficiency (LEP), and people who are LGBTQIA+. In July 2022, the MRCT Center convened a Bioethics Collaborative meeting on sex and gender in clinical research[9] with stakeholders across the clinical research ecosystem to discuss ethical considerations in SOGI data collection and identify potential pathways to facilitate the inclusion of LGBTQIA+ populations in clinical research. We reconvened with an expanded group of interested parties and leaders in queer healthcare to begin identifying key topics for potential guidance. Subsequently, we conducted a series of scoping interviews to better ascertain what additional resources (by topic) were needed. In August 2023, an LGBTQIA+ Inclusion in Clinical Research Working Group and, subsequently a Breakout Group on Transgender Inclusion, met monthly to advise on the development of tools.

User Guide: LGBTQIA+ Inclusion by Design in Clinical Research Toolkit

The MRCT Center LGBTQIA+ Inclusion by Design in Clinical Research Toolkit consists of seven tools to support planning for, conduct of, and participation in LGBTQIA+ inclusive clinical trials. While these tools were primarily intended for interventional clinical trials, they can be used by anyone (e.g., IRB Review Committee members, Community Advisory Group

members, pharmaceutical company representatives, investigators and their research staff, and participants and their allies) and for any study type (e.g., observational, interventional, or expanded access). The tools follow the clinical trial journey (shown in Figure 1 below) that starts with awareness about the trial, the screening and informed consent processes, on-study visits and other trial activities, and the end of the trial (where applicable and appropriate post-trial access to the tested product is considered).

Figure 1. Clinical Trial Journey: From the Recruitment Phase to the Participation Phase and the End-of Trial Phase.



The tools are divided by primary intended audience (sponsors, sites, and research teams; participants, caregivers, and allies), although it should be noted that there is something for everyone in each of the tools. While a specific tool may not exactly suit your purpose, you may still find utility in that tool and are invited to adapt it as you see fit.

For **sponsors, CROs, sites, and research teams**:

- The LGBTQIA+ Inclusive Imagery Case Study (Tool 1) and the LGBTQIA+ Inclusive Language Checklist (Tool 2) may be used in creating communication materials for recruitment of trial participants, writing inclusive eligibility criteria language for screening interested participants, and developing informed consent materials that address the concerns of all participants. These tools may also be used to provide

participant-facing materials for on-study visits (e.g., instructions, portals/apps) and for post-trial communication, such as the return of results.

- The Sexual Orientation and Data Privacy (SOGI) Data Collection Checklist (Tool 3) and SOGI Data Privacy Checklist (Tool 4) may be used to support the development of inclusive data collection and data privacy policies and templates from the screening stage, through to data analysis, and in the post-trial return of results.

For **participants, caregivers, and allies**:

- The Site Feasibility Decision Tree from the LGBTQIA+ Perspective (Tool 5) may be used by [potential] participants at the awareness, access, and recruitment stages of the trial journey to assess if a site is welcoming and trustworthy. This tool considers such factors as the local political and social environment, the reputation of the site in the community, costs for the participant to access the site and the site's services, and the site policies and infrastructure (e.g., gender-neutral bathrooms, private spaces).
- The Participant Questionnaire from the LGBTQIA+ Perspective (Tool 6) is meant to empower [potential] participants by providing questions that they may wish to ask the research team, family and/or friends [who may accompany them], and themself during the recruitment, informed consent, and on study-visit stages of the trial. Some of these questions may be brought up by the research team during the informed consent process, but some may not be, and this list is to help participants prepare.
- The Exit Survey Inclusive of the LGBTQIA+ Perspective (Tool 7) provides a template, in survey format, for participants to provide feedback on their experience in the clinical research activity. This feedback helps research teams and organizations better understand the participants' experience of the research activity and learn where they can improve on inclusion efforts. The Exit Survey is meant not only to give participants a sense of the kind of questions that they may be asked at the end of a research activity, but also to show participants that they can advocate for opportunities to give feedback and for the addition of questions important to them in feedback forms.

As mentioned above, all audiences should utilize the tools in their own way, even though certain tools may be geared more toward one audience or another. We structured the tools to align with frameworks commonly used[b] in the clinical research community trial journey that sponsors, CROs, sites, researchers, and participants are familiar with. We recognize that participants may be less familiar with these tools and, therefore, the structure of Tools 5-7 may not be intuitive at first. However, we hope that keeping tools in a similar structure between the audiences who conduct research and audiences who participate in that research will empower both parties to "speak a common language" and navigate together through the clinical research process.

We invite you to explore the full toolkit or to focus on the specific tools that you find most important to your individual or organizational journey in clinical research. Please note that this toolkit is a living document and will be improved upon with use and comment. We welcome feedback, suggestions, additional tools and resources, and concerns (please email: mrctcenter@bwh.harvard.edu). We look forward to continuing to work together with LGBTQIA+ individuals, their allies, and colleagues involved in clinical research to further the inclusion of sexual and gender minority (SGM) people in clinical research.

[b] For example, the Site Feasibility Decision Tree from the LGBTQIA+ Perspective is based on the widely used Site Feasibility Decision Tree from the MRCT Center Achieving Diversity, Inclusion, and Equity Guidance Document and Toolkit, and the Exit Survey Inclusive of the LGBTQIA+ Perspective largely aligns with the Study Participant Feedback Questionnaire developed by TransCelerate.

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Please note that each colleague has served in their individual capacity, and the views and findings expressed in project materials are those of the authors and do not imply endorsement or reflect the views or policies of the U.S. Food and Drug Administration or the affiliated organization or entity of any member who contributed to this work.

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Disclaimer

Each tool in the LGBTQIA+ Inclusion by Design in Clinical Research Toolkit is designed to give an overview of one key topic that is important for supporting the health and well-being of sexual and gender minority (SGM) populations. These topics were identified through discussion with the LGBTQIA+ Inclusion in Clinical Research Working Group and Transgender Inclusion Breakout Group. Please note that this toolkit is a work in progress, and the list of topics and tools may be expanded. Further, while we have limited the amount of detail on each topic to keep the tools brief, where applicable we provide links to more expansive resources in the toolkit footnotes and references. We hope that you do explore those resources, and the websites of the departments/organizations that produced them, as new and exciting work is continually being released to support LGBTQIA+ health and well-being.

We advise that any references, links, and examples included in this document are not intended to represent the position of or imply endorsement by the MRCT Center, Brigham and Women's Hospital, Mass General Brigham, or Harvard University. Reciprocally, entities and companies mentioned in the references, links, and examples do not necessarily endorse the work products of the MRCT Center.

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Acronyms

AMA - American Medical Association

CRO – Contract Research Organization

DEI – Diversity, Equity, and Inclusion

HBV/HCV – Hepatitis B virus/hepatitis C virus

HIV - Human immunodeficiency virus

LGBTQIA+ – Lesbian, gay, bisexual, transgender, queer, intersex, and asexual. The "+" stands for all of the other identities not encompassed in the short acronym.

NASEM – National Academies of Science, Engineering and Medicine

NIH – National Institutes for Health

PrEP – Pre-exposure prophylaxis

SGM – Sexual and gender minority

SGMRO – Sexual & Gender Minority Research Office

SOGI – Sexual orientation and gender identity

Glossary[c]

Agender/no gender - Refers to a person who does not identify with or experience any gender. Agender is different from nonbinary because many nonbinary people do experience gender.

Bisexual - Bisexual people have the potential to be emotionally, romantically, or sexually attracted to people of the same and different gender—not necessarily at the same time, in the same way, or to the same degree. Commonly referred to as bi.

Cisgender - A cisgender person is someone whose gender identity aligns with the sex assigned to them at birth; sometimes abbreviated as cis.

Gay - Having the potential to be emotionally, romantically, and/or sexually attracted to people of the same gender.

Gender - Gender is a multidimensional social and cultural construct that includes gender roles, expressions, behaviors, activities, power dynamics, and/or attributes that a given society associates with being a woman, man, girl, or boy, as well as relationships with each other. As a social construct, gender varies from society to society and can change over time.

[c] We drew definitions for the glossary terms sequentially from the sources listed below. If the first source defined the term, we use that source. If it did not, we drew the definition from the next source where it was available:

i. National Institutes of Health. NIH style guide: Sex, gender, and sexuality. Available from: https://www.nih.gov/nih-style-guide/sex-gender-sexuality

ii. National Institute of Allergy and Infectious Diseases. (2024). *NIAID HIV language guide*. Available from: https://www.niaid.nih.gov/sites/default/files/niaid-hiv-language-guide.pdf

iii. National Institutes of Health Office of Equity, Diversity, and Inclusion. *LGBTQI+ terminology*. Available from: https://www.edi.nih.gov/our-communities/sexual-and-gender-minority/resources/lgbtiq-terminology

iv. GLAAD. *GLAAD media reference guide – terms*. Available from: https://glaad.org/reference/terms/

Gender identity - An individual's sense of being a man, woman, boy, girl, genderqueer, nonbinary, etc. This identity is not necessarily visible to others.

Gender neutral - Not gendered. Can refer to language (including pronouns and salutations/titles—see Gender-neutral salutations or titles), spaces (like bathrooms), or other aspects of society (like colors or occupations).

Intersex - Term used for a variety of conditions that do not seem to fit the typical definitions of female or male, also known as variations in sex characteristics. Additionally, it can be used to refer to people who are born with genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female or develop these differences in puberty.

Lesbian - Refers to someone who identifies as a woman who has a romantic and/or sexual orientation toward other people who identify as women. Some nonbinary people also identify with this term.

LGBTQIA+ - LGBTQIA+ stands for lesbian, gay, bisexual, transgender, queer, intersex, and asexual. The plus sign includes other members of the community, such as genderfluid, nonbinary, or two-spirit, among others.

Non-binary - A nonbinary person identifies outside of a gender binary by seeing themselves as neither a man nor or woman. Nonbinary people are part of the trans community.

Outing - The deliberate or accidental sharing of another person's sexual orientation or gender identity without their explicit consent. Outing is disrespectful and presents a danger for many LGBTQ+ individuals.

Sex - Sex is a biological descriptor based on reproductive, hormonal, anatomical, and genetic characteristics. **Typical sex categories include male, female, and intersex**. Sex is used when describing anatomical, gonadal, chromosomal, hormonal, cellular, and basic biological phenomena. E.g., sex development, sex hormones, sex characteristics.

Sexual orientation - Sexual orientation describes sexual attraction, behavior, and identity. Use sexual orientation rather than sexual preference. Preference suggests that non-heterosexuality is a choice, a concept often used to discriminate against the LGBTQI+ community. Preference also suggests a selection from two or more choices, excluding bisexual people and pansexual people, among others.

Straight – an adjective to describe a person whose enduring physical, romantic, and/ or emotional attraction is to people of a sex different than their own. Also: heterosexual.

Transgender - A transgender person is someone who identifies with a gender other than the one that was assigned to them at birth. Use the term transgender or trans and not transgendered. Transgendered is a dated term that suggests a point in time when a person "became" transgender, which diverges from the lived experiences of most transgender people. Trans is an adjective that helps describe someone's gender identity, and it should be treated like other adjectives (e.g., trans man, trans woman). Merging the adjective and the noun risks suggesting that a trans man or woman is more (or less) than just a man or just a woman, which goes against how many trans people identify themselves.

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Representation in Research
LGBTQIA+

LGBTQIA+ Inclusive Imagery Case Study

Introduction

As the MRCT Center prepared to launch over 100 additional words for the Clinical Research Glossary the Health Literacy team started to develop images to visually represent each word featured in the glossary. The MRCT Center created template features to draw upon when creating new images of participants and/or researchers, to support diverse representation across the images. These features include standard colors for clothing and objects in the images; a range in skin tones, hair colors, genders, body types, and ages; and depicted use of assistive technologies (wheelchairs, canes, prosthetic devices). The Representation in Research team then asked about adding LGBTQIA+ inclusive features and collaborated with the LGBTQIA+ Inclusion by Design Working Group to provide guidance to the designers.

The key points and example images listed below are based on a distillation of the lessons learned by the MRCT Center during this process, and on the insights and comments shared by the LGBTQIA+ Inclusion by Design in Clinical Research Working Group. We invite you to draw from these options in developing inclusive participant-facing materials for your studies and sites. All people feel more welcome to participate in a clinical trial when they see themselves visually represented in the information communicated about the study, study site/s, and study staff.

Key Points

- Representation of all families and all genders is welcome, inclusive of representation of people who are non-binary,[d] no gender, or who prefer not to disclose their gender.
- The images could incorporate Pride Flag (preferably Progressive Pride Flag) symbols. However, please note that such use can sometimes be viewed as reductive,[10,11] and not everyone sees themselves in the Progressive Pride flag.[12] The specific audience/s,

[d] A nonbinary person identifies outside of a gender binary by seeing themselves as neither a man nor or woman. Nonbinary people are part of the trans community. See: https://www.nih.gov/nih-style-guide/sex-gender-sexuality

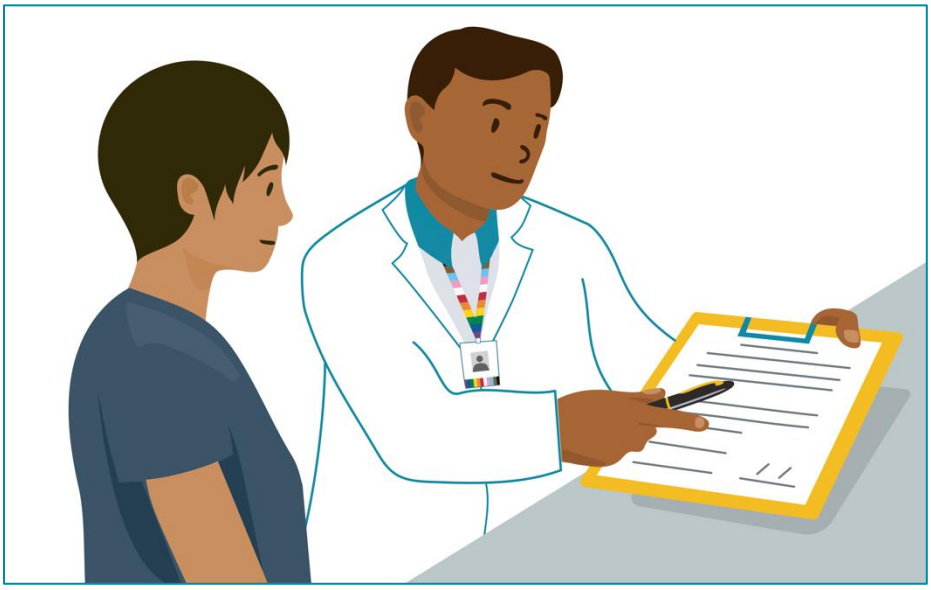
context in which images will be used, and options for capturing everyday moments of LGBTQIA+ people's participation in clinical research should be considered.[13]

- Rainbow symbols may be incorporated in many ways, for example, on lanyards, name tags, pins, watchbands or bracelets, ties, necklaces, pens, mugs, or plant holders.
- If utilized, Pride Flag symbols should be incorporated into images of both the participant/s and the researcher/s. These symbols should be visible but can be subtle, in recognition that identifying as LGBTQIA+ is but one part of a person's identity.
- Incorporation of symbols, hairstyles, and clothing used among LGBTQIA+ communities as cultural shorthand to signal identities and kinship may be considered.[e] However, note that these symbols can be interpreted differently by different audiences and are subject to change over time.

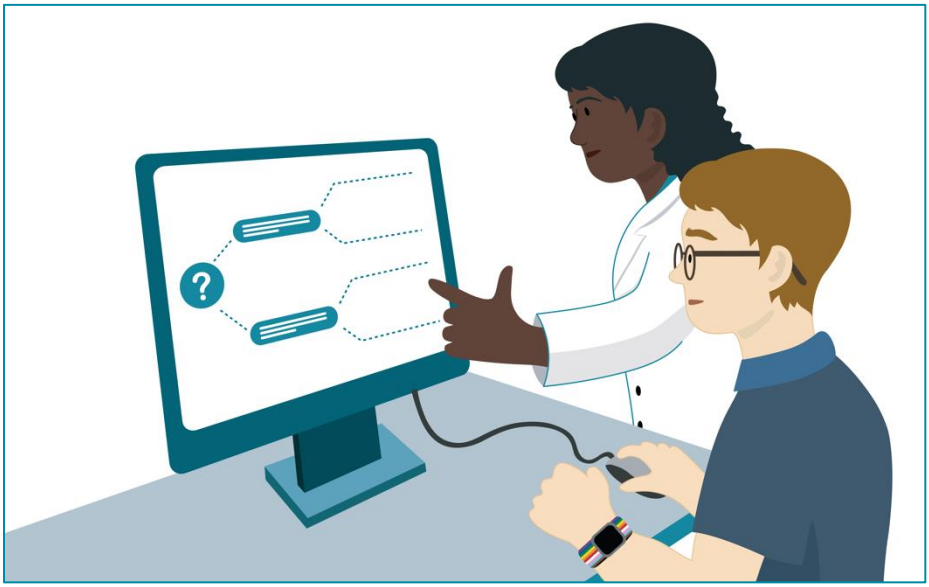
[e] Please note that we haven't been able to find a comprehensive list of symbols from a non-commercial source. The Matthew Shephard Foundation LGBTQ+ Terms and Symbols Glossary (https://www.matthewshepard.org/resources/lgbtq-terms-and-symbols-glossary/) describes numerous symbols and the UC Davis Resource Center has an extensive glossary of terms that LGBTQIA+ people can use to define themselves and their intersecting identities (https://lgbtqia.ucdavis.edu/educated/glossary). Two commercial sources that have more extensive visual listings of symbols (sometimes with explanation) are: We Are Pride Wholesale at https://www.wearepride.com/blogs/news/top-common-lgbtq-symbols and Heckin Unicorn at: https://heckinunicorn.com/collections/enamel-pins/cat The MRCT Center does not endorse these commercial entities, which are listed here, only as reference points for discussion, and with the caveat that any use of symbols should always be discussed first with LGBTQIA+ communities.

Example Adapted Glossary Images

Informed Consent



Study Conduct



LGBTQIA+ Inclusive Language Checklist

Introduction

In the checklist below, the MRCT Center provides recommendations 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 eligible 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, pregnant person, chairperson, humanity) (see Box 1 below).[14,15,16,17] If the study is focused on people of a particular gender(s), that terminology can be used.[18] In describing biological sex, use sex-related terminology (e.g., male, female, intersex).

- ☐ Avoid outdated and inappropriate language.[19, 20]

- ☐ Translate the text and concepts in participant-facing materials into the language/s used by participants locally, when possible.[f]

[f] 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

- ☐ 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).
- ☐ 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 explicitly 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.[21] Confirm with the participant that the pronouns in their medical chart are correct. Please note, for privacy and safety reasons, and particularly for children and adolescents, some participants may prefer to use different pronouns depending upon who they are speaking with. Note also and 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.
- ☐ 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

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

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.[22,23] 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 of CD4+ T-cells, 2) Detectable HIV viral load, 3) History of an opportunistic infection in the last 12 months.

SOGI Data Collection Checklist

Introduction

All study participants should be able to count themselves in the research data. However, standard demographic variables of sexual orientation and gender identity (SOGI) have rarely been reported for clinical trials. We therefore don't know whether LGBTQIA+ people are able to participate in clinical trials, or whether the safety and efficacy of tested products differs for any LGBTQIA+ participants. To begin to address this gap in respect for participants, study generalizability, and beneficence, the National Institutes for Health and Institute for Medicine now recommend collecting SOGI data. To support research teams, sites, and sponsors in following this recommendation we developed the SOGI Data Collection Checklist.

This SOGI Data Collection Checklist provides prompts to think through the process of SOGI data collection, which have been drawn from published guidance and the insights of LGBTQIA+ Inclusion by Design in Clinical Research Working Group members who have been leading in this field and piloting survey methodology. Please note that this SOGI Data Collection Checklist is meant to be utilized in tandem with the SOGI Data Privacy Checklist.

Checklist

- ☐ I will work with experts in survey (and particularly SOGI survey) methodology and analytics[g] and follow recommended guidance for statistical surveys.[24,25,26]
- ☐ I have defined the purpose of the data collection (e.g., to answer a scientific question, to confirm study eligibility, to support inclusion of diverse participants, to understand patient or caregiver barriers and types of support needed, to understand

[g] We caution that data collection can easily go awry, and the results can end up being detrimental to the people from whom data was collected. Survey research methods, and the associated preparation for analysis, are skills that can take many years of experience and study to develop. Therefore, we list working with experts in these fields first on this checklist, in addition to a thorough grounding in current guidance.

epidemiology, to assess research or advisory team composition, for administrative purposes)[h] and will communicate this purpose to survey participants in consent forms.

☐ I will only collect the data necessary for the defined purpose (as outlined in the checkpoint above) and to answer and the study question/s.[27,28]

☐ I recommend that SOGI data is collected along with other demographic data, like age, race, and ethnicity, and that it is self-reported (filled out by the participant or potentially by a family member in household surveys and not by the researcher). That said, I will not require demographic data collection, inclusive of SOGI data, and will ensure that individuals, sites, and organizations can always opt out.

☐ I have documented and clearly explained in all participant-facing materials the potential risks of SOGI data collection and how the participant's data will be protected,[29] why SOGI data collection is essential to the project or study question, how collecting SOGI data may benefit the participants, and the intended use of the SOGI data.

☐ I have defined the population of interest through reference to (or determination of) the epidemiology, the burden of disease, and other factors (e.g., social determinants

[h] "Administrative data" is defined by the US Office of Management and Budget (OMB) as: "Refers to administrative, regulatory, law enforcement, adjudicatory, financial, or other data held by agencies and offices of the government or their contractors or grantees (including States or other units of government) and collected for other than statistical purposes. Administrative data are typically collected to carry out the basic administration of a program, such as processing benefit applications or tracking services received. These data relate to individuals, businesses, and other institutions." OMB Guidance for Providing and Using Administrative Data for Statistical Purposes. Available from: https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2014/m-14-06.pdf
*Please note that administrative data is different from survey data and requires different analytical techniques. For a summary of differences between these and examples of using different types of data collection for different purposes, see the OMB White Paper (and especially Table 1) on "Using Administrative and Survey Data to Build Evidence." Available from: https://obamawhitehouse.archives.gov/sites/default/files/omb/mgmt-gpra/using_administrative_and_survey_data_to_build_evidence_0.pdf

of health) relevant to the data collection purpose and study question/s subject to data availability.[i]

☐ I have vetted the decision to collect SOGI data, the collection method, the level of subgroup detail/disaggregation, and the data collection forms and survey format (e.g., in-person oral, paper, online app) with working groups and/or advisory boards that are inclusive of people who are lesbian or gay, and people who are transgender, non-binary, or intersex. Please note that it can be helpful to add a date stamp and version number to all materials, to keep a list of reviewers associated with each version, and to track the substantiveness of community input into those materials.

☐ I have reviewed and mapped proposed data elements to select the options that best align with the data collection purpose and study question/s, current guidance on SOGI data collection,[30,31,32,33,34,35,36,37,38] and the lived experiences of the population of interest. Proposed data elements may include:

- Terminology
- Data collection questions (e.g., sexual orientation, gender identity, sex, whether a person is intersex)
- Response choices (e.g., [for sexual orientation] lesbian or gay, straight, bisexual, other)
- Response formats (e.g., open-response, checking-off multiple options)
- Question and response choice ordering (and implications for skip patterns on subsequent survey questions)

☐ I have advised sites to create space in the data collection forms for participants to report their pronouns if they choose to do so. I have recommended that staff who

[i] The NIH has collated examples of surveys that have sexual orientation and/or gender identity measures, examples of (and summary findings on) sexual orientation identity measures in the Unites States and Other Countries, examples of (and summary findings on) two-step gender identity measures in national and international surveys, and a summary of findings nonbinary sex measure and evaluation criteria. Available from: https://dpcpsi.nih.gov/sgmro/measurement-and-data/surveys-and-measures

interact with participants periodically check-in with them about their pronouns, legal name, and chosen/nickname. For example, the researcher or clinical staff member could say, "Some people update their names from time to time. Would you like to report any changes?" If the participant reports a change, the staff interacting with the participant should inform them of where this information will be viewable (e.g., by the research team, by lab personnel, and/or on patient identification wristbands used at health facilities).

☐ I have prepared with my team operational plans, budgets, and timelines for:

- Piloting and validating the data collection forms, portals, and/or apps and all participant-facing materials related to data collection, as appropriate.
- Evaluation, analysis, and dissemination of results.
- Translation of the data collection forms, portals, and/or apps and all participant-facing materials related to data collection as needed.
- Licensing fees for any software (potentially including Electronic Health Records systems), graphics/design, or copyrighted materials.
- Staff training (e.g., cultural humility, how to ask SOGI questions to adults and to children, how to respond to questions from participants.)
- Private and safe settings for participants to fill out or orally respond to data collection questions at all stages of the trial. This will vary depending upon the survey methods and the context. In each case, please be mindful of ethical and equity considerations (e.g., meetings times, locations, signage, visibility of entrances and rooms, gender identity of facilitator/s). For countries and local regions where there are punitive laws and social environments that discriminate against people who are LGBTQIA+, sites, IRBs, and/or researchers might choose not to ask the optional SOGI questions developed for common protocols or consents. Finally, please see the data privacy checklist for SOGI data privacy considerations specific to pediatric populations.

☐ I have used culturally respectful language,[39] precise (and defined) terminology, and gender-neutral color palettes and imagery, where appropriate and feasible.

SOGI Data Privacy Checklist

Introduction

Data privacy is critical not only for the safe and ethical conduct of clinical trials, but also for supporting and maintaining the trust of clinical trial participants. For clinical trial participants who may be discriminated against or otherwise harmed if their personal identifying information were to be disclosed, data privacy is even more important. In the Sexual Orientation and Gender Identity (SOGI) Data Collection Checklist we advocate for the collection of SOGI data, where appropriate and feasible.

In the SOGI Data Privacy Checklist, which is meant to accompany the SOGI Data Collection Checklist, we provide thinking prompts to support researchers, sites, sponsors, and others in maintaining privacy when collecting, storing, and sharing SOGI data. We hope that you will use the prompts in considering how to make the research environment/site a welcoming place where individuals can trust that they and their data will be respected and protected, and how to implement safeguards to protect participant identity and privacy.

Checklist

- ☐ I attest that the study team and site have acted to make this a welcoming environment and a place where individuals can trust that they and their data will be respected and protected. These actions may include:[40]
    - Developing study/site policy that respects LGBTQIA+ participants' rights to confidential care, in line with clinical, professional, and research practice and ethical guidelines, state and national laws, and the advice of legal counsel.
    - Explaining clearly when, why, and how SOGI data will be collected and used.
    - Taking training on and regularly practicing creating Safe Zones, working with SGD participants, and using respectful language and imagery.

- Describing, through as many communication modalities as possible (e.g., emails, posters, elevator video screens) what the site or organization is doing to create a welcoming environment.
- Sharing one's own pronouns. Asking about and using participants' pronouns.

☐ I have implemented necessary safeguards to protect patient identity and privacy.

Local and Site Environment

☐ I have considered the local context, including relevant local, state,[41,42] national,[43] and regional laws and the cultural environment, and how these may impact the safety and privacy of LGBTQIA+ participants. Please note that it may also be helpful to speak to local public health departments, regulatory agencies, and regulatory experts at study sites, and to keep up to date on American Medical Association (AMA) policies.[44]

☐ I have trained the clinical research team on where to find information and how to answer participant questions about safety and privacy.

Options for Participants

☐ I have assessed when it is appropriate to collect SOGI data in anonymous forms vs. separate forms with personal identifying information.[j]

☐ I have created an option for participants to opt out of answering any or all SOGI data questions and made clear in all participant-facing materials that this option may be exercised at any time during the trial. Please note, there may be cases where a participant shares their SOGI data but later decides to opt out.

[j] For example, identifying information may not be collected for some qualitative research. Such research can be important to understanding local context and social determinants of health, community engagement and community priorities for research and trial conduct, reasons for participant under/representation, and the clinical care setting in which the tested products will be introduced.

Data Storage

☐ I have a management plan for secure storage and transfer of data throughout the life cycle of the project, including defined timeframes for keeping the data, and for deletion or disposition of the data at the conclusion of those timeframes.[45] Note that researchers should have a plan in place for deleting data at a participant's request.

☐ When it is necessary to have SOGI data linked to specific participants, I will de-identify participant data [e.g., introduce code numbers].

☐ Where possible, I have created "backstops" in the medical records system to protect the participants' reported SOGI data (e.g., encryption, data segmentation, flags alerting that the data is confidential, user-defined options for different levels of visibility depending in the party viewing the records).[46]

☐ I have reviewed with legal counsel that the medical/lab and billing codes[k] to be utilized (e.g., codes for gender incongruence) are appropriate and would not inadvertently "out," compromise, or harm a participant.

Data Protection

☐ I have separated research data from clinical medical records and implemented measures to protect SOGI data. Where that is not possible, the participant knows and agrees. Please note that researchers must obtain permission to share any data collected or produced by the study with the participant's medical provider/s.

☐ I will make SOGI data available only through a controlled access environment and have considered which forms of data encryption would be most suitable.

☐ [Where possible] I have created an option for participants to opt out of sharing any or all data with other organizations and made that clear in all participant-facing materials.

[k] Some trial costs can go through institutional billing (that is not controlled by the investigator) to insurance companies, particularly in the case of trials that are comparing the tested intervention to the standard of care. Those billing systems may have codes or templates that are not optimally design to protect SOGI data.

If the trial will be sharing data with other organizations or outside the state where the trial will be conducted, the clinical research team and Informed Consent Form will need to be explicit about that. The potential limits of data privacy should also be clearly communicated.

☐ In the event of a buy-out or merger, I/my organization will advocate for the new entity's commitment to the same privacy terms.

☐ [Where possible] I have planned opportunities for participants to give feedback on data privacy, and for regular review on the privacy of SOGI data for my study and at my site. If, for example, I start hearing from the transgender community that the data privacy protections are not sufficient or effective, I will listen carefully and adjust accordingly.

Addendum for Pediatric Participants[47]

☐ I have reviewed clinical/professional practice/ethical guidelines and state/national laws, discussed with legal counsel, and implemented specific protections for pediatric participants. These may include:

- [To the greatest extent permissible by state/national law] I have set up the processes, physical space, and/or patient-preferred communication modalities to ask adolescents (age 11-17) about sexual orientation and gender identity in private, without a caregiver present.
- I have phrased SOGI questions in ways that are appropriate by age for children and adolescents, based on published guidelines and recommendations.[48,49,50]
- I have set up processes to ask adolescent pediatric participants which name and pronouns they want used and in which contexts (e.g., when caregivers are present, when non-medical staff are present).
- [To the greatest extent permissible by state/national law] I have set up processes to obtain consent from adolescent patients before entering SOGI

information in their electronic health record and to clearly explain who is able to access their health record information.

- Please note that participants may be covered under their parents' insurance until age 26. Therefore, any clinical trial costs which are billed to insurance may be visible to the parents of a participant that is under age 26. Similarly, if a parent is listed at a pharmacy to have permission to pick up prescriptions, those prescriptions and the participant's prescription history may be visible to the parent.

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

Representation in Research
LGBTQIA+

Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective

Introduction

This tool is meant to empower potential LGBTQIA+ participants[I] to assess whether a site may be trustworthy and welcoming. We hope that it will be useful in your first steps in becoming or accompanying a trial participant, when trying to figure out where a site might lie on the queer-friendly spectrum. It is modeled after the Feasibility Decision Tree in the Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document and Toolkit, which is used by pharmaceutical sponsors and research teams to assess if a site is a good fit for the trial. However, the "Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective" refines the broad view of the original tool ("underrepresented populations") to better understand the capacity of a site to conduct clinical trials with LGBTQIA+ populations.

Please note that the "Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective" is one tool in the LGBTQIA+ Inclusion by Design in Clinical Research Toolkit, and the first of three tools in the section of the Toolkit directed *more toward participants*. These participant-facing tools span the participant journey in clinical research, and we list all three below so you can see the other tools available for you on each phase in this journey:

- **Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective**. (For the recruitment phase of the trial- awareness of the trial, accessing a trial site).
- Participant Questionnaire from the LGBTQIA+ Participant Perspective. (For the participation phase of the trial- screening, informed consent, study visits).

[I] The Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective can also be used by sites and sponsors to evaluate site feasibility (for recruitment and enrollment of participants who may be LGBTQIA+) in the same manner as the original tool and was reviewed by a diverse sample of sites for this purpose.

- Exit Survey Inclusive of the LGBTQIA+ Participant Perspective. (For the end-of-trial phase- last visits, data analysis and return of results, potential follow-up and post-trial access to the study product).

Like the original Feasibility Decision Tree, this tool is structured in tiers, with checkpoints in between. The first tier is potential capacity, where we provide prompts, or "determination factors" based on what IS happening at a site (or in the area nearby) that LGBTQIA+ people can use in considering whether the site is potentially a good place to participate in a study. In the second tier we focus on "historical capacity," or the things that the site HAS/HAD done to support the well-being of LGBTQIA+ people that may inspire confidence that the site is trustworthy. This tool does not propose a scoring system, as participants may consider some determination factors more important than others. Please note that these questions are only suggestions not a set list of what "has" to be asked. We welcome you to select those questions most relevant for your situation and adapt/edit as you see fit.

Determination factors (things to consider)

Site Potential Capacity (i.e., The research site is…)

Political and Social Environment

- In a location that is a safe and accessible place for people who face multiple kinds of discrimination (e.g., racial minorities, people with disabilities).
- Co-located near a health clinic with a stated mission and demonstrated actions to support LGBTQIA+ and other underrepresented communities (note that some are listed in the LGBTQ Healthcare Directory).[m]
- In an area where nearby businesses or community spaces advertise Pride events, LGBTQIA+ artists, and LGBTQIA+ authors, and post Pride flags.

[m] For example, Whitman Walker, Fenway Health, San Francisco Community Health Center, Callen-Lorde, and Howard Brown Health.

- In a country, state, and/or locality supportive and protective of LGBTQIA+ rights[n] and without legal or regulatory restrictions.

Reputation in the LGBTQIA+ Community

- Recognized by queer groups inclusive of diverse sexual orientations/identities as a trusted collaborator in community engagement.
- Sponsors Pride events, LGBTQIA+ artists, and LGBTQIA+ authors, and posts Pride flags in, on, or around the building or campus.
- Known to attend local PRIDE events and give back to the community.
- Known to produce study recruitment and other patient-facing materials, in collaboration with, and acknowledgement of, LGBTQIA+ community partners.
- Known to produce study recruitment and other patient-facing materials that use LGBTQIA+ imagery and language and are accurate and representative.
- Reviewed positively on the crowdsourcing forums (e.g., social media) preferred by LGBTQIA+ groups and allies.

Organizational/Site Relationships

- [If a private facility] Has leadership/ownership (e.g., religious or business corporation, family foundation) that is supportive of LGBTQIA+ rights.
- Funds or partners with political groups and/or politicians who are supportive of LGBTQIA+ rights.

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[n] Examples of supportive and protective laws include sanctuary laws for transgender care and/or reproductive freedom; equity laws protecting LGBTQIA+ people from discrimination in public and private employment, housing, accommodation, credit, and service; and safe schools/anti-bullying laws. To understand the local laws and regulatory environment, it may be helpful to speak to local public health departments and to legal experts at the site, and to visit the Human Rights Campaign State Equality Index or the Human Rights Campaign website The Love that Dare Not Speak Its Name [a list of anti-LGBTQ laws by country]. Please note that looking at country, state, or local politics/laws is only one potential indicator of a welcoming environment. There are numerous sites that are supportive of LGBTQIA+ well-being that are situated in states or other localities that may not be. Site assessment will also depend upon the other points in this tool.

- Contracts with vendors/3rd parties who are members of the National LGBTQ Business Association and/or who are certified as diverse suppliers (at least 51% owned, operated, and managed by a diverse person or group of members).o

Cost (financial accessibility)

- Accessible to local and distant LGBTQIA+ populations by public and private transportation, and preferably with options that are safe and affordable.
- Accepts multiple types of insurance (e.g., public, private), preferably those most commonly used within the state/region, and which cover or assist with the cost gender-affirming care, mental health services, PrEP, and other services prioritized by LGBTQIA+ communities.

Site Policies and Infrastructure

- Guided by non-discriminatory organizational policies. For example, addressing patients with the name and pronouns that they use, recognizing same-sex partners for visitation and decision-making rights,[51,52] and supporting bed assignment based on gender identity for transgender patients (whenever possible and in collaboration with the participant).[53,54,55,56]
- Directed by safeguards to protect individual identity and privacy. For example, offering the opportunity (non-mandatory) to provide one's preferred name and SOGI data on intake forms; sharing information about why SOGI info is important to advancing affirming care at the site and in research studies; providing clear explanation of how the data will be de-identified or anonymized, used, transferred, stored, shared with staff or others (or not shared, if participants may opt out of or limit data sharing) and deleted.
- Staffed by people who are representative of the LGBTQIA+ population and/or who have been regularly trained to provide culturally competent care that is up to date on best practice and inclusive language.

° This information may be difficult to obtain unless posted or otherwise available from the website.

- Staffed by a nurse-navigator (or other participant-facing personnel) dedicated to supporting LGBTQIA+ participants, and where necessary, someone to escort participants safely into and around the site.
- Designed with gender-neutral bathrooms and private spaces for individual consultation or collective meetings (e.g., focus groups, support groups).

Site Historical Capacity (i.e., The research site has/had…)

☐ Strategic support and resources for LGBTQIA+ patients and research participants[57]
- A history of programs and/or departments dedicated to improving the well-being of and reducing disparities in LGBTQIA+ populations.
- A history of launching fellowships, research, and publications dedicated to health equity and improving the well-being of LGBTQIA+ populations.
- A history of stating that and enacting LGBTQIA+ well-being as an organizational priority on the organizational website and social media.

☐ Data available/site report on past enrollment
- A history of caring for health conditions that disparately affect LGBTQIA+ communities (e.g., HIV).
- A history of serving LGBTQIA+ people specifically (e.g., Whitman Walker Our History, Fenway Health Equality and Equity Report, San Francisco Community Health Center Impact Report, Callen-Lorde Our Accomplishments Over the Years, Howard Brown Health A Year in Review).

☐ Feasibility questionnaire or site visit (please note that that item is for consideration by sites and sponsors and is not relevant for participants/patients)
- History of including the perspectives and priorities of people who are LGBTQIA+ in the feasibility questionnaires that pharmaceutical sponsors and contract research organizations use to assess if the site is a good fit to host the study, or clear history of actively working toward doing so.

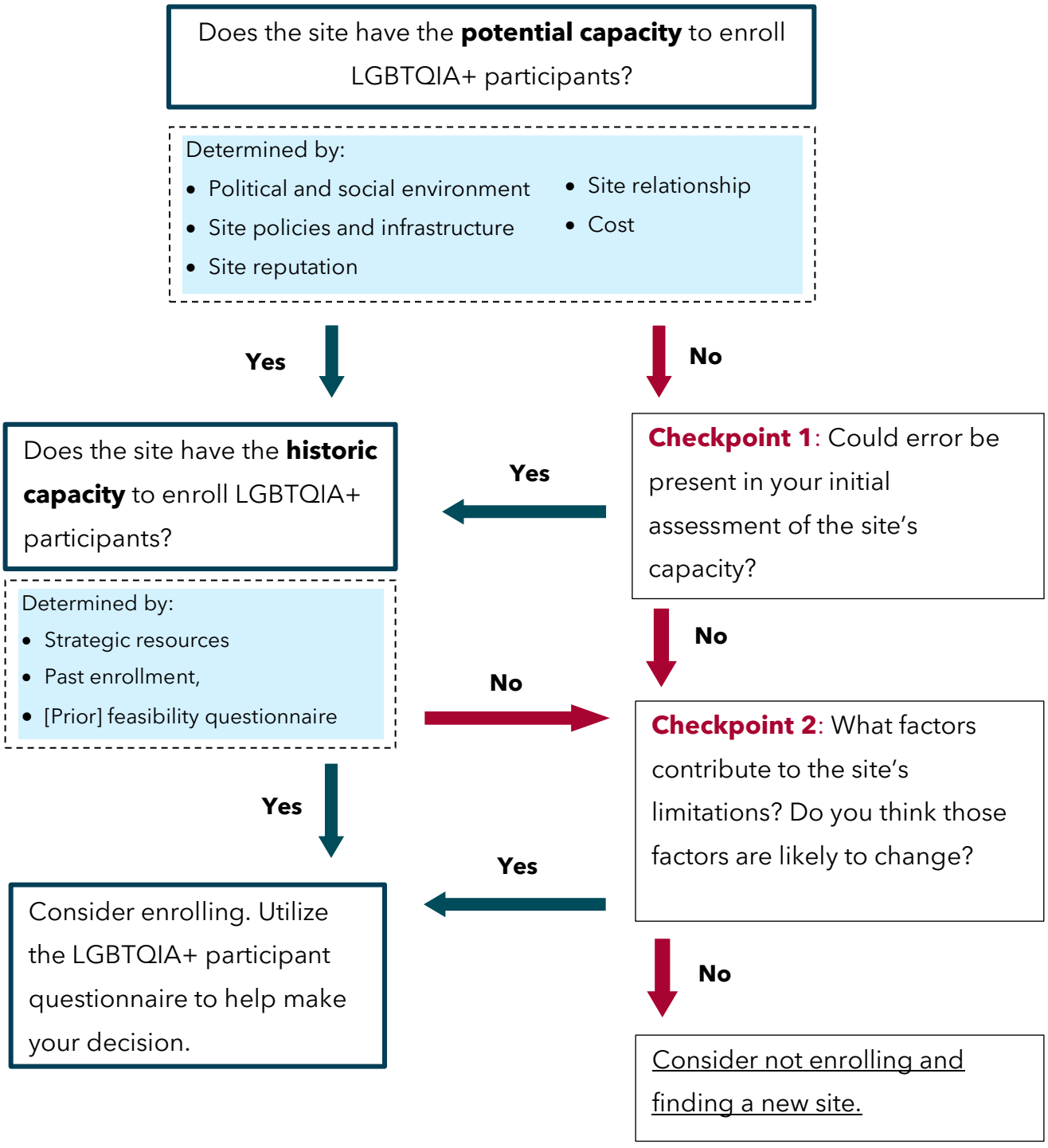
- History of including the participant journey for people who are LGBTQIA+, when in discussion with sponsors, CROs, or monitors during site visits.

Site Projected Capacity (i.e., The research site will…)

- Please note that item is for consideration by sites and sponsors and is not relevant for participants/patients, as explained in the footnote below. [p]

[p] Site projected capacity is one of the three main assessment factors, along with potential capacity and historical capacity, that is listed on the original MRCT Center [Site] Feasibility Decision Tree. However, site projected capacity depends upon sponsor internal forecasting techniques (such as geo-mapping), which are not applicable at the present time, because the sexual orientation and gender identity (SOGI) data that is needed to populate forecasting models is not yet widely collected or available. In addition, projected capacity is for consideration by site and sponsors and is not relevant for participants/patients.

Decision Tree



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

Representation in Research
LGBTQIA+

Participant Questionnaire from the LGBTQIA+ Perspective

Introduction

There are numerous questions that participants may want to ask as they move from thinking about possible trials and sites to starting the process of enrolling and participating in a trial. Some of these questions may be covered by informational materials given to participants during the informed consent process and study visits, and some may not be. This list is to help participants prepare, so that they can get the answers that they need and feel comfortable before continuing with the trial. We pulled these questions together based on a review of topics commonly addressed in MRCT Center resources, issues described in publicly available patient, [pharmaceutical] sponsor, and medical center websites, and discussion with the LGBTQIA+ Inclusion by Design in Clinical Research Working Group and the Transgender Inclusion Breakout Group (both convened by the MRCT Center).

The "Participant Questionnaire from the LGBTQIA+ Participant Perspective" is one tool in the LGBTQIA+ Inclusion by Design in Clinical Research Toolkit, and the second of three tools in the section of the Toolkit directed *more toward participants*. These participant-facing tools span the participant journey in clinical research, and we list all three below so that you can see the other tools available for you on each phase in this journey:

- Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective. (For the recruitment phase of the trial- awareness of the trial, accessing a trial site).
- **Participant Questionnaire from the LGBTQIA+ Participant Perspective.** (For the participation phase of the trial- screening, informed consent, study visits).
- Exit Survey Inclusive of the LGBTQIA+ Participant Perspective. (For the end-of-trial phase- last visits, data analysis and return of results, potential follow-up and post-trial access to the study product).

The Participant Questionnaire tool is divided into sections that include questions to ask the research team; questions you may want to ask family, friends, and others you trust; and questions to ask yourself. It includes questions that anyone might want to ask[q] and adds questions (in brick red font) that LGBTQIA+ people (and/or their accompanying friends and family) might also want to ask. Please note that these questions are only suggestions to support your personal decision-making about participating in the research, not a set list of what "has" to be asked.

Questions to Ask the Research Team

Study Process and Study Team

- ☐ Why are you looking at this research question and/or testing this product or approach?
- ☐ What is the purpose or goal of this study? Why have you chosen this as the purpose?
- ☐ Have similar studies been done before and what were the results? Were people like me included in those studies? Did the previous studies include people who are LGBTQIA+?
- ☐ Have LGBTQIA+ research staff been involved in the design of the study? Will there be/are there any LGBTQIA+ community representatives who will be included as advisors during the study data collection and interpretation of results?
- ☐ What are the possible risks and benefits of participating?
    - What tests and procedures will you do? How invasive are those tests and procedures?
    - What are the expected short-term and long-term effects, positive and negative, of the intervention being tested?

[q] The Participant Questionnaire from the LGBTQIA+ Perspective can also be used by sites and sponsors. It can also be used by participants, or by sites and sponsors, for research activities other than testing drugs, devices, therapies, or vaccines, although not all questions will be relevant.

- How will I know if it is working?
- How will you protect my personal data? Will my research data be accessible to anyone other than research staff? Will my research data be entered into my medical or other records (e.g., insurance)? What options do you have for me to opt out of sharing my data, and for me to designate who gets to see my data?
- How do you communicate about the study? For example, do you identify yourself in messages (including those left on voicemail and those sent by text or social media) with your name or with the name of the research study, research site, department, or laboratory (which may refer to LGBTQIA+ populations)? Can I opt out of receiving communication from you that could be seen or heard by others? Can I choose what name you use if communicating with me by voicemail, email, or text messages?
- How will the results of this study be used?
- Will this study help inform healthcare decisions of other people in the LGBTQIA+ community?

☐ How would the risks and benefits of the tested intervention compare with my current treatment?

☐ How would the risks and benefits of the tested intervention compare with available options for my condition other than my current treatment?

☐ What are the credentials and backgrounds of the clinical research team staff? Is there an option to change providers in the research team/site location if I do not feel comfortable with the provider/site location that I am assigned? Have the clinical research staff and other staff connected to and involved in the study been formally trained in sensitive and responsive interactions and care with LGBTQIA+ people?

☐ Will my general practitioner and other specialists (e.g., oncologist, endocrinologist) be a part of the research team if I participate in a clinical trial? If not, can I still see them during the trial? Can I decide whether or not to inform them about my progression during the clinical trial, and what information to convey? May I ask to not have my existing care team involved in or informed about my participation in this research?

- ☐ [For trials testing a product like a drug, therapy, or device] Will I be able to take my regular medications while participating? Does this include hormone therapy? PrEP? In what circumstances can I continue to take my regular medications while participating (e.g., post-gonadectomy, based on time on stable dose prior to study)?
- ☐ [For trials testing a product like a drug, therapy, or device] What happens if I am harmed during the study (e.g., physical/mental harm, leak of my data)? Who do I contact? How will I be taken care of? How can I confidentially report discrimination or harassment? Do you have mental health and/or advocacy support services?
- ☐ What are the different ways that I can reach the study team?
- ☐ Can I continue taking the study drug after the trial ends?
    - When will the study results be provided to me? Will the results be communicated back in ways that are clear and understandable?

Logistics and Impact on Participant's Daily Life

- ☐ How long is the clinical trial?
- ☐ What is the schedule of visits, labs, tests (e.g., MRI, x-ray), and other activities?
    - How much time will each of these trial activities take?
    - Are there flexible options for the timing of visits (e.g., after 5pm, weekends)?
    - Which of those activities will need to be in-person, and where are the sites for those activities located? How do you ensure privacy during these visits (e.g., do you label group discussion rooms with the topic of discussion, do you have more than one entrance, do study staff greet me when I arrive, or do I have to go through check-in at the front desk and/or other offices)? How do you support people who need visits in spaces in which they may not visibly appear to belong, such as transmen who need pelvic or breast exams/screening)?
    - Are there any parts of the trial that are virtual? If so, will you provide me with a device (e.g., tablet) and a way to access the internet? Will you have a help desk

for assistance with technology that is accessible for all people in the trial, including people with disabilities and people who do not speak English?

- ☐ Will you provide assistance with arranging transportation?
    - Scheduling a taxi, van, or rideshare to pick me up and bring me home?
    - Making sure valet parking is available at the site?
    - Booking my flights, hotels, and/or car rentals?
- ☐ [For trials testing a product like a drug, therapy, or device] Would I have to pay for any medical costs (e.g., tests, labs, visits) as part of the trial?[58,59]
    - Will my insurance cover any of these costs?[r] Will someone on the research team help me navigate discussions with my insurance to cover these costs? What if I do not have insurance? Are there any costs for gender-affirming care in this trial that some insurers consider to be cosmetic or elective (e.g., botox, hair removal, top surgery)?[60,61] How will the researchers assist me to find out if my insurance covers these treatments or what coding the procedures need to be under to get coverage?
- ☐ [For any type of clinical trial] Would I have to pay any non-medical out-of-pocket costs (e.g., for travel, food, childcare, eldercare, pet care) as part of the trial?

[r] For clinical research testing a product (unlike research that conducts a survey) there may be medical costs. These costs are often covered by health insurance or by the company/organization that is testing the product, although this is not always the case, and we list these questions so that you are prepared to ask and are not surprised. It sometimes happens that a trial is testing a product that is taken when the participant is also receiving the standard of care (or "routine" care) for their condition. For example, in a trial with breast cancer survivors, the trial may expect that the participants get two mammograms a year through their regular care. But a participant's insurer may consider only one annual mammogram to be standard of care, and therefore the participant will need to discuss the coverage of the second mammogram with the trial team. Please note that trials that are for general healthcare may not anticipate or [financially] cover some types of care, and particularly some types of gender-affirming care, that may be considered standard (or "routine") in trials focusing on queer healthcare.

- Do you provide vouchers or pre-paid cards for food, lodging (hotel, Airbnb), transport (car/mileage, flights, etc.), or other expenses?[s]
- If you do not provide vouchers or pre-paid cards, do you reimburse for my expenses? Do you also reimburse for the expenses of the person that accompanies me? Which expenses do you reimburse for?
- Which types of documents and forms of identification (ID) do you need me to submit (e.g., receipts, social security number/passport/driver's license, expense forms) to be reimbursed? Why do you need those forms of ID? Do you provide a secure means to transmit copies of my IDs or sensitive information to you? When I fill out the reimbursement forms, do you require that I use my name as it appears on identification (ID) and/or tax documents?
- How soon will you reimburse me after I submit these documents? What if I do not have an address?

☐ [For any type of clinical trial] Will I be paid for my time to participate in the trial?

- If yes, what information will I need to provide in order to be paid?
- How will the payment be made?
- At what level of payment do I need to pay taxes (e.g., $600 in payment per year)., If taxable, how are the payments reported to the IRS (e.g., a 1099 or other tax reporting form)?
- How do these payments affect public benefits (e.g., social security disability insurance, supplemental nutrition assistance, Medicaid/Medicare benefits)? Can the research team structure the payments so that they do not impact benefits (e.g., spacing the timing of payments)?

☐ Who is funding this study? Who is funding this site or organization? Are they a public (i.e., federal, state, or local government) or a private (e.g., business or religious

[s] Please note that there may also be non-medical costs in clinical trials, such as for travel to the trial site or for childcare during trial visits. These are not typically covered by insurance but are often reimbursed by the trial site or research team.

corporation; family foundation) entity? Do they support gender-affirming care and LGBTQIA+ rights?

Accommodations

- ☐ Can I have the study materials and conversations with study staff in a language I prefer (including sign language)? Can you provide a translator?
- ☐ Can I get disability accommodations to participate in this trial (e.g., pick-up in an accessible van, closed captioning, study materials that are in formats accessible for screen readers or other technologies used by people with visual disabilities, accessible medical equipment, supported decision-making)?
- ☐ I would like to bring someone with me to appointments for support. What personal and medical information about me can they access? If I become incapacitated (e.g., delirious, unconscious) and can't make my own decisions, what rights might this support person have to make decisions about my care? Do these rights differ if the person who accompanies me is not a relative or spouse, and/or if we are in a relationship that is not recognized by the state or government?

Questions You Could Ask Family, Friends, and Others You Trust

- ☐ Can you work with me on thinking about the questions I should bring forward to the trial team? What questions would you ask?
- ☐ Would you be able to attend study visits with me to support me and to help make sure I understand everything? How comfortable are you in medical environments? How do you approach situations where there may be difficult news and/or difficult decisions? How do we wish to describe our relationship to others/the study team?
- ☐ Could you take notes and help me organize the information I get during doctor visits?
- ☐ Would you be able to watch my kids, pets, or house while I go to appointments?
- ☐ Would you be able to give me a ride if I need it?
- ☐ What kinds of support would you need and/or like to learn more about?

Questions to Ask Yourself

- **(After considering the responses from study staff and family/friends to your questions above, and in your site assessment [Tool 5 in this Toolkit])**

- ☐ Is the research question being studied important to me? Does participating fit with my values and beliefs?
- ☐ What do I hope I can contribute by participating?
- ☐ What benefits would I like to get out of participating? Could the benefits impact people other than myself? Who else might be affected by my participation? How so?
- ☐ What amount of risk am I willing to take? Could the risks impact people other than myself? If so, how and who might be affected by my participation? How comfortable am I sharing my background and personal information with the study team? How confident am I that my data will be kept secure? Am I satisfied with this study team and organization/site?
- ☐ Do the possible benefits outweigh the risks?
- ☐ What are my other options? Are any of those options better than participating in this trial?
- ☐ Do I have enough time in my daily life to participate? How might participating in this trial affect my family life, my athletic or social activities, and/or my job? Can I take time off work if needed to participate?
- ☐ How would I need to arrange for childcare, care of other family members or significant others, or care of pets/animals if I participate?
- ☐ Could participation in the research activity affect my emotional well-being and mental health, for the better or for the worse?
- ☐ Do I want to participate? Why or why not?

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

Representation in Research
LGBTQIA+

Exit Survey Inclusive of the LGBTQIA+ Participant Perspective

Introduction

It is important for participants in clinical research activities to give feedback about their experience. This feedback helps research teams and organizations better understand the participant's experience of the research activity and learn where they can improve on efforts to empower research participants and the participants' supporting families, friends, and communities. One way to gather feedback is through a survey, which may be given to participants periodically (e.g., once a month), and/or (as an exit survey) at the end of research activities.[62,63] Other ways may include interviews, focus groups, or patient portals where participants can leave comments. In this tool we aim to show examples of the topics that participants[t] may be asked about in a survey or interview, or if not asked, that the participant may wish to share with the research team in a patient portal, email, or other format.

Please note that the "Exit Survey, Inclusive of the LGBTQIA+ Participant Perspective" is one tool in the LGBTQIA+ Inclusion by Design in Clinical Research Toolkit, and the third of three tools in the section of the Toolkit directed *more toward participants*. These participant-facing tools span the participant journey in clinical research, and we list all three below so you can see the other tools available for you on each phase in this journey:

- Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective. (For the recruitment phase of the trial- awareness of the trial, accessing a trial site).
- Participant Questionnaire from the LGBTQIA+ Participant Perspective. (For the participation phase of the trial- screening, informed consent, study visits).

[t] The Exit Survey inclusive of the LGBTQIA+ Perspective can also be used by sites and sponsors to evaluate participant experiences in clinical research activities (e.g., as trial participants, IRB members, reviewers of participant-facing materials) inclusive of the perspectives of LGBTQIA+ people and other minority groups.

- **Exit Survey Inclusive of the LGBTQIA+ Participant Perspective.** (For the end-of-trial phase: last visits, data analysis and return of results, potential follow-up and post-trial access to the study product).

This tool is structured in two parts: 1) Research Experience and 2) Background questions. It includes questions for everyone and adds questions (in red font) that may be important for LGBTQIA+ people and other underrepresented populations. Please note that these questions are only suggestions, not a set list of what "has" to be asked. We welcome you to select those questions most relevant for your situation and adapt/edit as you see fit.

Instructions:[u]

For the following questions, please answer to the best of your ability. If you don't know how to answer the question or the question is not relevant to your experience with the research activity, you may skip the question. Please note that this survey is anonymous. However, if you were part of a small group for the research activity and you answer all the background questions in Part 2, the researchers may know who you are (e.g., there was only one gay male age 65+). You can opt out of any of the background questions that you are not comfortable with. Thank you for taking the time to complete this survey, the results of which will be used to improve the research activity experience for future participants.

If you have any additional questions about the survey, please contact:

Name, Title: _____
Email: _____
Phone: _____

[u] Please note that these are the typical instructions that research team will give with a survey. We provide them here for reference for participants, so they can know generally what they will encounter. Through these example instructions participants can also know that if certain pieces in these example instructions (e.g., questions are optional; contact information for the research team) are not provided to them, they can ask that such options and information be provided. These instructions are NOT for participants to fill out this example survey right now.

Exit Survey (Part 1)

Clinical Research Activity Experience Questions

1. The information given to me before I joined the clinical research activity was everything that I needed to know (e.g., purpose of the trial, visits, privacy, costs).

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

2. I always had someone I could speak to about the research activity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

3. Communication materials were respectful:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

4. Staff members were respectful:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

5. Staff members communicated with me (e.g., in-person, by phone, in text or other messages) in a sufficiently private way:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

6. I felt staff members could relate to me and understand where I was coming from:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

7. I felt comfortable discussing my sexual orientation and gender identity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

8. I felt comfortable discussing other parts of my identity and my personal history:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

9. I felt comfortable discussing any questions or concerns that I had:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

10. Overall, I am satisfied with the answers I received to my questions or concerns during the clinical research activity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

11. I felt that the personal questions I was asked about were asked for a good reason:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

12. I felt that I was safe participating in this clinical research activity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

13. I felt that my personal data was kept safe during this clinical research activity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

14. The way in which trial data was collected was acceptable to me (e.g., in person, online questionnaire, diary, wearable sensors):

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

15. I feel that the clinical research activity I participated in will have a positive impact on my community:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

16. I would recommend that others in my community participate in this type of research activity in the future:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

17. I would recommend that others in my community participate in a research activity at this site in the future:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

18. I would recommend that others in my community participate in a research activity with this research activity team:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

19. I would participate in another clinical research activity:

☐ Strongly agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly disagree

20. Additional comments:

Exit Survey (Part 2)

Background Questions

21. Your role during the clinical research activity (check all that apply)

- ☐ Participant in clinical research
- ☐ Caregiver or other support person accompanying a participant in clinical research
- ☐ Part of IRB review committee
- ☐ Advisory group for clinical trial planning, recruitment, conduct, or results reporting
- ☐ Research advocate from the community (e.g., cultural ambassador, liaison, or other form of navigator between research organizations and communities)
- ☐ Other _____

22. Demographic information

a. What is your age?

☐ 0-11 ☐ 11-17 ☐ 18-24 ☐ 25-34 ☐ 35-44
☐ 45-64 ☐ 65-84 ☐ 85+

b. How would you describe your race? (check all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Middle Eastern or North African
- ☐ Native Hawaiian or Pacific Islander
- ☐ White

c. Which of the following best represents how you think of yourself?

- ☐ Gay or lesbian
- ☐ Straight (not gay or lesbian)
- ☐ `Bisexual
- ☐ I don't know
- ☐ I use a different term _____

d. What is your current gender?

- ☐ Female
- ☐ Male
- ☐ Transgender
- ☐ Nonbinary
- ☐ I use a different term _____

e. What sex were you assigned at birth, for example, on your original birth certificate?

- ☐ Female
- ☐ Male

f. Do you consider yourself to be a person with a disability? ☐ Yes ☐ No

i. Are you deaf, or do you have serious difficulty hearing? ☐ Yes ☐ No

ii. Are you blind, or do you have serious difficulty seeing, even when wearing glasses? ☐ Yes ☐ No

iii. Because of a physical, mental, or emotional condition, do you have serious difficulty concentrating, remembering, or making decisions? ☐ Yes ☐ No

iv. Do you have serious difficulty walking or climbing stairs? ☐ Yes ☐ No

v. Do you have difficulty dressing or bathing? ☐ Yes ☐ No

vi. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone like visiting a doctor's office or shopping? ☐ Yes ☐ No

23. How did you find out about the opportunity to participant in this research activity? (check all that apply)

- ☐ Health care provider e.g., doctor, nurse, therapist, social worker)
- ☐ Friend/ [chosen] family
- ☐ Patient portal/app
- ☐ Email
- ☐ Mail
- ☐ Text
- ☐ Phone call
- ☐ Religious community
- ☐ Other community group or community activity (e.g., health fair, walk-a-thon, LGBTQ festival, parade, drag show, bear week, queer wine weekend, etc.)
- ☐ Facebook, Twitter, Instagram, YouTube, or LinkedIn
- ☐ Other social media (e.g., Tumblr, Grindr, Spaces, etc.)
- ☐ Online community (e.g., gaming)
- ☐ Other: _____ _____

24. During this research activity, how did you prefer to communication with the research activity team? (check all that apply)

- ☐ In person with the research team
- ☐ Patient portal/app
- ☐ Email
- ☐ Mail
- ☐ Text
- ☐ Phone call
- ☐ Facebook, Twitter, Instagram, YouTube, or LinkedIn
- ☐ Online community (e.g., gaming)
- ☐ Other: _____ _____

Please say why you liked these communication modalities.

Also, please say if there were any communication modalities you disliked, and why.

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