

Creating Welcoming and Affirming Clinical Studies for LGBTQIA+ Participants Toolkit



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This toolkit was developed to guide clinical research sites in creating affirming study environments and building trusting relationships with LGBTQIA+ participants. Taking this step is essential for greater inclusion and equity in clinical studies.

For further learning on this topic, access the companion e-learning module at <https://www.lgbtqiahealtheducation.org/collection/clinical-studies-toolkit>

Introduction

Health Disparities of Marginalized People

The healthcare experiences and outcomes of underserved populations and marginalized people based on their age, sex assigned at birth, gender identity, sexual orientation, race, ethnicity, access, genetic background, and disability, are different from others. These differences are known as health disparities, which are often influenced by social and environmental factors. While health disparities result from many factors, these generally include being less likely to have access to affirming and culturally responsive health care, being more likely to delay medical care or treatment due to mistrust caused by barriers, prejudice, and discrimination from health care providers and systems, and having a need for uniquely tailored health treatments. Disparities may also result from systemic barriers in clinical research, including a lack of representation in demographic data collection, restrictive eligibility criteria, or gendered, binary medical language that excludes diverse patients in clinical studies.¹

Having multiple oppressed and intersecting identities can further increase health disparities and create barriers to study participation. For example, a Black/African American transgender woman with a hearing disability may experience participation barriers related to anti-transgender stigma, racism, and lack of accessibility for the hearing impaired.

Historical Erasure of LGBTQIA+ People in Clinical Studies

Lesbian, gay, bisexual, transgender, queer, intersex, aromantic, asexual, and all sexually and gender diverse (LGBTQIA+) people are among the communities that have historically been underrepresented and invisible in clinical research studies. Because of this erasure, we often lack information about the effects of health treatments and interventions on specific LGBTQIA+ populations, which contributes to a broad range of LGBTQIA+ health disparities. Reasons for exclusion and lack of visibility of LGBTQIA+ people in research include restrictive eligibility criteria based on binary sex, and limited collection of data on the sexual orientation and gender identity (SOGI). In addition, many LGBTQIA+ people mistrust clinical research due to historical

discrimination, bias, and mistreatment within health care and study settings. A lack of trust can result in reluctance to participate in clinical studies, or discomfort with providing personal SOGI data for study purposes.

Achieving Health Equity for LGBTQIA+ People in Clinical Studies

In order to support health equity for LGBTQIA+ people, it is essential to design and implement inclusive clinical studies that engage LGBTQIA+ communities and effectively collect participant SOGI data. By creating welcoming and affirming study environments, we can better retain LGBTQIA+ participants in studies. By collecting SOGI data, we can examine whether treatments have differential health effects and safety profiles among LGBTQIA+ populations. Ultimately, these practices will enable us to identify health inequities, which can lead to positive impactful changes in policies and systems.

At the protocol development stage, greater inclusion can be achieved by partnering with LGBTQIA+ patient advocates and community leaders to design inclusive, culturally responsive, and ethically sound eligibility criteria and data collection. At the implementation stage, study leaders can select sites with demonstrated capacity for fostering trust with LGBTQIA+ participants through community engagement, and can collaborate with LGBTQIA+ community groups and educators to train sites in using culturally affirming terminology, forms, and practices.

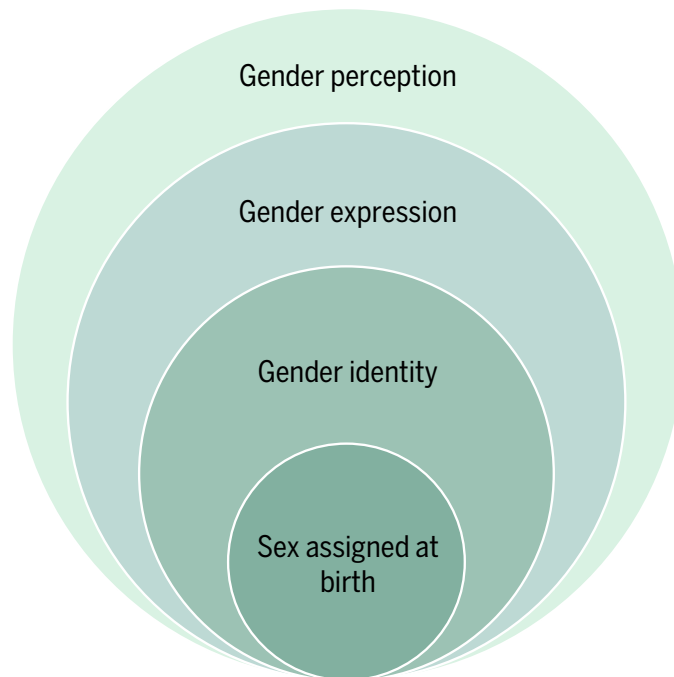
Building Culturally Responsive Study Sites

This toolkit focuses on the implementation stage of training sites to successfully engage and retain LGBTQIA+ participants. Within the toolkit, you will find information on foundational LGBTQIA+ concepts and terminology, best practices for affirming transgender and gender diverse participants, and recommendations for collecting SOGI data as part of participant demographics. By learning these competencies, all study staff can become skilled and confident in supporting the dignity of LGBTQIA+ participants, and ultimately, can contribute to improving health equity for LGBTQIA+ communities.

Concepts and Terminology

In preparing for culturally responsive engagement of study participants, clinical study staff can familiarize themselves with foundational concept and terms related to sex development, gender identity, sexual orientation, and LGBTQIA+ health care.

It is important to note that the terms sex and gender, while sometimes used interchangeably, have different meanings. The term 'sex' refers to biological and physical characteristics. The term 'gender' refers to identity-related, psychological, behavioral, and cultural characteristics. Below is a diagram illustrating layers of experience related to gender, followed by detailed definitions of important concepts and terminology.



Sex assigned at birth, gender identity (inner sense of gender), gender expression (how gender is communicated), and gender perception (how gender is perceived), are all separate but interrelated elements that inform individual experiences of gender.

Sex Development (*noun*): The physical process by which bodily sex characteristics emerge or become apparent at various stages throughout a person's life, including in utero, at birth, in childhood, at puberty, in adolescence, or across adulthood. Intersex variations in physical sex development do not fit traditional notions of female or male bodies.

Sexual Orientation (*noun*): How a person experiences their physical, emotional, and romantic attachments to other people.

Gender Identity (*noun*): A person's inner sense of being a girl/woman/female, boy/man/male, both, neither, something else, or having no gender.

Gender Expression (*noun*): The way a person communicates their gender to the world through mannerisms, clothing, speech, behavior, etc. Gender expression varies depending on culture, context, and historical period.

Foundational LGBTQIA+ Concepts and Terminology

LGBTQ+ or LGBTQIA+
adjective

An acronym and umbrella term that includes Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Aromantic, Asexual, and all sexually and gender diverse people. The '+' refers to the existence of many different identities.

Queer
adjective

An umbrella term describing people who think of their sexual orientation or gender identity as being beyond traditional societal norms. Some people view the term queer as more fluid and inclusive than traditional categories for sexual orientation and gender identity. Although queer was historically used as a slur, it has been reclaimed by many as a term of empowerment. Nonetheless, some still find the term offensive.

Affirm
verb

The act of recognizing, respecting, honoring, and/or supporting a person's gender identity, gender expression, sexual orientation or sex development through sensitive and effective communication, as well as welcoming and inclusive environments.

Ally
noun

A person who actively supports the rights of a marginalized community even though that person is not a member of that community; for example, a straight person who campaigns for the rights of gay people.

Coming out
verb

The process of identifying and accepting one's own sexual orientation or gender identity (coming out to oneself), and the process of sharing one's sexual orientation or gender identity with others (coming out to friends, family, etc.).

Pronouns
noun

Words like she, he, or they, which are used to refer to a person without use of the person's name. While many people have 'she' or 'he' pronouns in English, some people have less binary pronouns, such as 'they' or 'ze.' Some people do not have any pronouns at all, and just use their names instead.

Sex Development Concepts and Terminology

<p>Sex development <i>noun</i></p>	<p>The physical process by which bodily sex characteristics emerge or become apparent at various stages throughout a person's life, including in utero, at birth, in childhood, at puberty, in adolescence, or across adulthood. Intersex variations in physical sex development do not fit traditional notions of female or male bodies.</p>
<p>Assigned female at birth/Assigned male at birth <i>noun</i></p>	<p>Refers to the sex that is assigned to an infant, most often based on the infant's physical characteristics.</p>
<p>Intersex <i>adjective</i></p>	<p>Describes variations in physical sex development that do not fit traditional notions of female or male bodies. These variations may be apparent at birth or noticed at any subsequent stage of physical development. A related term sometimes used is differences in sex development, though at present the term intersex is most acceptable to community members.</p>

Gender Identity Concepts and Terminology

<p>Gender identity <i>noun</i></p>	<p>A person's inner sense of being a girl/woman/female, boy/man/male, both, neither, something else, or having no gender.</p>
<p>Agender <i>adjective</i></p>	<p>Describes a person who identifies as having no gender, or who does not experience gender as a primary identity component.</p>
<p>Bigender <i>adjective</i></p>	<p>Describes a person whose gender identity combines two genders.</p>
<p>Cisgender <i>adjective</i></p>	<p>A person whose gender identity is consistent with societal expectations based on their sex assigned at birth; for example, a person assigned female sex at birth whose gender identity is woman/female. The term cisgender comes from the Latin prefix <i>cis</i>, meaning 'on the same side of.'</p>
<p>Gender diverse <i>adjective</i></p>	<p>Describes people whose gender is beyond the binary paradigm of girl/woman/female or boy/man/male (e.g., non-binary, gender queer, and gender fluid people).</p>
<p>Gender dysphoria <i>noun</i></p>	<p>Distress experienced by people when their body does not align with their gender identity. Dysphoria can also occur when gender identity is not affirmed socially, politically, or in other ways.</p>
<p>Gender expression <i>noun</i></p>	<p>The way a person communicates their gender to the world through mannerisms, clothing, speech, behavior, etc. Gender expression varies depending on culture, context, and historical period.</p>

<p>Gender fluid or Genderfluid <i>adjective</i></p>	<p>Describes a person whose gender identity is dynamic and may evolve over time. A person who is genderfluid may always feel like a combination of more than one gender, or may feel more aligned with a certain gender some of the time, another gender at other times, multiple genders sometimes, and sometimes no gender at all.</p>
<p>Gender queer or Genderqueer <i>adjective</i></p>	<p>An umbrella term that describes a person whose gender identity is beyond the traditional binary gender paradigm of girl/woman/female or boy/man/male. Some people use the term gender expansive. A related term is gender non-conforming; however, some people consider this term to be outdated.</p>
<p>Legal gender affirmation <i>noun</i></p>	<p>Describes changes to gender markers and name on official government-issued documentation, such as a driver's license or passport.</p>
<p>Non-binary <i>adjective</i></p>	<p>Describes a person whose gender identity is beyond the traditional binary gender structure of girl/woman/female and boy/man/male. Sometimes abbreviated as NB or enby.</p>
<p>Pangender <i>adjective</i></p>	<p>Describes a person whose gender identity is comprised of multiple genders beyond the traditional cultural parameters that define gender.</p>
<p>Psychological gender affirmation <i>noun</i></p>	<p>Refers to the individual process of gender identity exploration, discovery, and self-acceptance.</p>
<p>Questioning <i>adjective</i></p>	<p>Describes a person who is unsure about, or is exploring their sexual orientation and/or gender identity.</p>
<p>Social gender affirmation <i>noun</i></p>	<p>Non-medical actions taken to support a person living in greater alignment with their own gender identity and gender expression. Examples include changes to name, pronouns, clothing, hairstyle, chest binding, genital padding, and genital tucking. These actions are sometimes referred to as 'social transition,' but the term 'social affirmation' is more accurate.</p>
<p>Transgender <i>adjective</i></p>	<p>Describes a person whose gender identity and sex assigned at birth do not correspond based on traditional societal expectations; for example, a person assigned female sex at birth who identifies as a man (transgender man); or a person assigned male sex at birth who identifies as a woman (transgender woman). Transgender can also include people with gender identities beyond the binary gender paradigm of girl/woman/female and boy/man/male, for example people who are gender fluid or non-binary. Sometimes abbreviated as trans.</p>
<p>Two-Spirit <i>adjective</i></p>	<p>A term used among Indigenous American, American Indian, and First Nations people that encompasses diversity in spiritual, sexual, gender, and cultural identity, and may also relate to a person's community roles and contributions.</p>

Sexual Orientation Concepts and Terminology

Sexual orientation <i>noun</i>	How a person experiences their physical, emotional, and romantic attachments to other people.
Aromantic <i>adjective</i>	Describes a person who experiences little or no romantic attraction to others, and/or does not have interest in forming romantic relationships. Aromantic people may still have intimate relationships.
Asexual <i>adjective</i>	Describes a person who experiences little or no sexual attraction to others. Asexual people may still engage in sexual activity.
Bisexual <i>adjective</i>	A sexual orientation that describes a person who is emotionally and physically attracted to women/females and men/males. Some people define bisexuality as attraction to all genders.
Gay <i>adjective</i>	A sexual orientation describing people who are primarily emotionally and physically attracted to people of the same sex and/or gender as themselves. Commonly used to describe men who are primarily attracted to men, but can also describe women attracted to women.
Heterosexual/ Straight	A sexual orientation that describes women who are primarily emotionally and physically attracted to men, and men who are primarily emotionally and physically attracted to women.
Lesbian <i>adjective, noun</i>	A sexual orientation that describes a woman who is primarily emotionally and physically attracted to other women.
Pansexual <i>adjective</i>	A sexual orientation that describes a person who is emotionally and physically attracted to people of all bodies and gender identities, or whose attractions are not related to other people's gender.
Questioning <i>adjective</i>	Describes a person who is unsure about, or is exploring their sexual orientation and/or gender identity.

Medical Care Concepts and Terminology

Anatomical inventory <i>noun</i>	A form of documentation for tracking retained organs and any surgical interventions. Clinicians can use anatomical inventories to help guide individually tailored preventive screenings and care. Study staff can use the inventory to systematically and comprehensively ask participants about retained organs and body modifications. Sometimes referred to as an 'organ inventory.'
Binding <i>verb</i>	The process of wrapping the chest tightly to create the appearance of a flatter chest. The most common way for people to bind is by wearing an undergarment called a binder. People may use other materials to bind such as cloth strips or bandages.

Chest reconstruction <i>noun</i>	Surgical procedure to create a masculine chest. Also known as top surgery.
Colpocleisis <i>noun</i>	Surgical closure of the vagina/front hole.
Gender-affirming care <i>noun</i>	The provision of evidence-based health services that support a person living in greater alignment with their own gender identity and gender expression. Some examples include pubertal suppression, gender-affirming mental health care, gender-affirming primary and preventive care, gender-affirming hormone therapy (e.g., estradiol- or testosterone-based regimens), and gender-affirming surgical procedures.
Gender-affirming hormone therapy (GAHT) <i>noun</i>	Hormone therapy (typically estradiol- or testosterone-based regimens) to align secondary sex characteristics with gender identity. This is sometimes referred to as 'medical gender affirmation' or 'medical gender transition.'
Gender-affirming surgery (GAS) <i>noun</i>	Surgeries to modify a person's body to be more aligned with that person's gender identity. Types of GAS include chest and genital surgeries, facial surgeries, body sculpting, and hair removal. This is sometimes referred to as 'surgical gender affirmation' or 'surgical gender transition.'
Hysterectomy <i>noun</i>	Surgical removal of the uterus.
Mastectomy <i>noun</i>	The surgical removal of a breast or breasts.
Metoidioplasty <i>noun</i>	Surgical procedure to create a new phallus/penis using existing genital tissue, after the clitoris has been enlarged using testosterone therapy.
Orchiectomy <i>noun</i>	Surgical removal of one or two testicles.
Penectomy <i>noun</i>	Surgical procedure to remove a penis.
Phalloplasty <i>noun</i>	Surgical procedure to create a new phallus/penis
Prostatectomy <i>noun</i>	Surgical removal of the prostate.
Salpingo-oophorectomy <i>noun</i>	Surgical removal of a fallopian tube and ovary, or of both fallopian tubes and ovaries.
Vaginoplasty <i>noun</i>	Surgical procedure to create a new vagina, i.e., a neovagina.

Affirming Transgender and Gender Diverse Participants

Understanding Gender Affirmation

- Gender affirmation (sometimes referred to as transition) is the process of undergoing changes to live in greater alignment with one's own gender identity, rather than with society's expectations based on the sex assigned at birth.
- This process can vary widely across transgender and gender diverse people, and it may include:
 - *Psychological affirmation*: gender identity exploration, discovery, and self-acceptance
 - *Social affirmation*: changes to name, pronouns, clothing, hairstyle, chest binding, genital padding, genital tucking, or other aspects of gender expression
 - *Legal affirmation*: changes to gender markers and name on official government-issued documentation, such as a driver's license or passport
 - *Medical affirmation*: pubertal-suppressant medication to temporarily pause development of secondary sex characteristics in early puberty, and/or hormone therapy initiated in adolescence or adulthood, typically with either an estradiol- or testosterone-based medication regimen
 - *Surgical affirmation*: facial surgery, chest surgery, gonadal surgery, genital surgery, or other procedures.
- Not all transgender or gender diverse people desire, pursue, or access these various types of gender affirmation. Many people who desire access to medical, legal, or social affirmation are legally, financially, logistically, or socially prevented from doing so. Transgender and gender

diverse people may undergo some of these types of gender affirmation, or none at all. As a result of this broad diversity, we cannot assume a person's gender identity based on name, pronouns, or other aspects of gender expression.

Gender Affirmation Often Includes Name Change

- Transgender and gender diverse people will often affirm their gender identity and expression through social changes such as a name change.
- Changing name and gender markers on official government-issued documentation, such as a driver's license or birth certificate, is prohibited for gender affirmation in certain jurisdictions. Where these official documentation changes are possible, it is often still costly, time-consuming, and burdensome to do so.
- Participants may wish to go by affirming names in the context of a clinical study without having legally changed name or gender markers, including their name or gender markers on their health insurance. Even in these instances, it is important to refer to the participant by their affirming name.
- It is therefore critical for clinical study intake forms to include a field for the name a participant goes by (affirming name) in addition to the name on their government-issued documents and health insurance.
- It is equally important for staff to learn how to correctly use affirming name vs. legal name in the context of handling participant information and building rapport and retention.

Talking About Affirming Names

It is appropriate to model behavior and then ask someone what name they go by. Asking about affirming names is a good practice with participants of all gender identities. For example, a participant whose legal name is "Robert" may go by the affirming name "Bobby."

- *"Hi, my name is [your name], my pronouns are [your pronouns]. Can you tell me what name you go by and what your pronouns are? I want to make sure I'm referring to you respectfully."*
- *You may consider wearing a visible pronoun pin on your coat/clothing as a symbol of allyship, refer to the "Flyer on Importance of Correct Pronouns" for more information.*

What Are Pronouns?

- Pronouns are words like she, he, or they. For example:
 - “Her chart is ready.”
 - **“Her”** is the pronoun in this sentence.
 - “He is picking up a chart.”
 - **“He”** is the pronoun in this sentence.
- While many people have “she” or “he” pronouns in English, some people have less binary pronouns, such as singular “they” or “ze.”
- Some people don’t have any pronouns at all, and just use their names instead.
- Some people have more than one type of pronoun, such as “she/they.”

Using Pronouns in a Sentence

- **She/Her/Hers**
 - She is picking up a chart.
 - Her chart is ready now.
 - That chart is hers.
- **They/Them/Theirs (singular usage)**
 - They are picking up a chart.
 - Their chart is ready now.
 - That chart belongs to them.
- **He/Him/His**
 - He is picking up a chart.
 - His chart is ready now.
 - That chart belongs to him.
- **Ze/Hir/Hirs**
 - Ze is picking up a chart.
 - Hir chart is ready now.
 - That chart is hirs.
- **No Pronouns**
 - [Name] is picking up a chart.
 - [Name’s] chart is ready now.
 - That chart is [Name’s].

Avoiding Assumptions

- You cannot assume someone’s gender identity based on name or pronouns (e.g., the name

“Julia” and “she/her/hers” pronouns do not indicate a person identifies as a woman).

- You also cannot assume someone’s pronouns based on how they look, how they sound, or their disclosed gender identity.
- To avoid assuming pronouns:

Instead of: “She/He is here for the visit.”

Say: “The new participant is here for the visit.”

Sharing Your Own Pronouns and Asking About Affirming Name and Pronouns

- Introducing your name and pronouns creates a welcoming invitation for study participants and colleagues to share their own pronouns comfortably.
 - You can wear a pronoun pin that indicates your pronouns in writing.
 - You can also say the name you go by and your pronouns when you introduce yourself to other people in the workplace:

“Hi - my name is Dr. Jones and my pronouns are she/her.”

- It is ok to ask someone about their pronouns. Practice clarifying your own pronouns and asking about participants’ pronouns:

“Hi, my name is [your name], my pronouns are [your pronouns]. Can you tell me what name you go by and what your pronouns are? I want to make sure I’m referring to you respectfully.”

- If a person’s name does not match identity documents or the medical record:

“Could your information be under a different name?”

“What is the name on your insurance/in your chart?”

Apologizing and Recovering from Mistakes

- Transgender and gender diverse people have a history of experiencing stigma and discrimination in many settings.
- Don't be surprised if using the wrong pronoun or legal name (misgendering) results in a participant becoming upset, even if they do not display this emotion outwardly.
- Apologizing when someone becomes upset, even if what was said was well-intentioned, correcting the name you used, and thanking the participant for letting you know, can help defuse a difficult situation and re-establish a constructive dialogue.

Accountability and Intervening

- Creating an environment of accountability and respect requires everyone to work together.
- Don't be afraid to politely correct your colleagues if they do not use the affirming name of a participant:

"I wanted to let you know that they go by the name Jesse now. I heard you say Jesse's legal name, and I wanted to make sure you know for the future."

Affirming Vs. Legal Name and Pronoun Usage in Written Communication

- It is important to ask each participant whether to use the affirming name or legal name and affirming pronouns in different forms of written communication, such as any paper mail sent to the participant's home, emails, lab orders, medication prescriptions, and referrals to external services.
- This way, we can avoid inadvertently disclosing or 'outing' the participant's gender identity in other settings, where the participant may not go by the affirming name and/or pronouns and may not have disclosed a particular gender identity or expression to other people. This protects the participant's confidentiality.

Case Scenario 1

Study Site Coordinator

"Last time you were here Kai, your pronouns were he/him. I don't want to make any assumptions, and I like to check in with participants. Are these still your pronouns?"

Kai

"Thanks for asking. They are ze/hir/hirs."

Study Site Coordinator

"Is it okay for me to make a note in your chart about your pronouns and let the other staff know?"

Kai

"Sure."

Case Scenario 2

Participant

"Hello, I am here for my appointment. My name is Camille Murray."

Front Desk Staff

"I'm sorry. I'm not showing that name in the system. Might your record be under a different name?"

Camille

"Yeah, it could be under Charles Murray"

Front Desk Staff

"I am showing that name. Can you confirm your date of birth to verify I have the correct record?"

Front Desk Staff

"I apologize for not having your name updated in our system. It can sometimes take time for all the information to be updated. I will do everything I can to try to make sure this doesn't happen again."

Camille

"Ok. Thank you so much."

Case Scenario 3

Gladys, the medical assistant, is asked to prepare a participant for screening in a clinical study. Gladys glances at the chart and notes that the name on the chart is “Ethan Turner.” When Gladys enters the examination room where the participant is waiting, she sees the participant leaning against the exam table.

The participant says:

“Hi, I’m Emily.”

- How can Gladys politely determine if she is in the correct room and if the participant is here for a study screening visit ?

Gladys will want to affirm the participant’s identity by saying:

“Hello Emily, I’m Gladys.”

Gladys can then say something like:

“I’m sorry, but the chart I was given has a different name. Is it possible that your chart is listed under a different name?”

- At this point, Emily might explain that Ethan is the name in the medical chart, but that the correct name is Emily. Gladys may be able to make a note in the chart explaining this. At this point, she can also ask Emily about pronouns, and mark those down as well.

- What is the best way to convey a participant’s affirming name to all staff who work with them?

It is recommended to establish a process that enables participants to share their correct/affirming name, gender identity, and pronouns, which may consist of entry into study registration forms and other relevant documents, and a workflow for study staff to then communicate this information to any relevant team members who may subsequently interact with the participant.

Creating such a system is also helpful for participants who are not transgender or gender diverse, since some participants may go by nicknames or middle names. In addition, this approach is very useful for participant rapport-building and retention. In this example, a procedure to share this information with other site staff will help Emily avoid duplicating this conversation in the future, a process that Emily may find frustrating and burdensome.

Relevance of Medical and Surgical Gender Affirmation among Study Participants

- A participant's past and current medical and/or surgical gender affirmation is relevant to study participation. For example, gender-affirming hormone therapy has potential drug-drug interactions with study medications. Gender-affirming hormones can also alter the participant's physiologic hormonal milieu in a manner that influences study laboratory results which may affect the interpretation of laboratory findings.
- Gender-affirming medical care may inform the interpretation of clinical study results. For example, gender-affirming hormone therapy and/or gender-affirming surgery such as bilateral orchiectomy (i.e., removal of the testicles) could influence the prostate-specific antigen level, which is a relevant endpoint in prostate cancer studies such as the LIBERTAS study (*A Phase 3, Open-label, Randomized, Prospective Study of an Intermittent Androgen-Deprivation Therapy Approach with Apalutamide Monotherapy in Participants with Metastatic Castration-Sensitive Prostate Cancer*).
- Study staff eliciting a participant's clinical history, including medical history, procedures, and concomitant medications, can say:
 - *In order to ensure your safety and to correctly interpret your results in this study, it is important for us to be aware of any past or present gender-affirming care you may have received.*
 - *Have you received any gender-affirming hormone therapy in the past, or are you currently on gender-affirming hormones? Are you considering initiating gender-affirming hormones?*
 - *Have you undergone any gender-affirming surgeries in the past, or are you considering any gender-affirming surgeries in the future?*

Anatomical Inventories

Many transgender and gender diverse people receive gender-affirming medical and surgical care such as gender-affirming hormones, facial surgeries, chest surgeries, gonadal surgeries, and genital surgeries.

Of note, transgender and gender diverse people may not desire or access any gender-affirming medical or surgical care.

Knowing the retained anatomy for transgender and gender diverse participants requires inquiring directly with the participant and/or accessing existing health records. An anatomical inventory is a form of documentation to track retained organs and any surgical interventions, in order to guide health screenings and care in an individually tailored manner.

Study staff can document and track body modifications and retained organs in an anatomical inventory, which is a helpful health record tool that features a checklist of organs and body modifications to assist study staff in systematically and comprehensively asking participants about their retained organs. An example of an anatomical inventory is shown on the next page.

The inclusive terminology from this anatomical inventory can also be adapted by researchers for survey questions on sexual health, surgical histories, etc. Anatomical inventories are valuable for participants of all gender identities, as any participant may have anatomical variations or prior body modifications.

Action Steps at Study Sites

Below are three concrete actions site staff can take to contribute to a welcoming, inclusive, and affirming study environment:

- Staff can wear a pin indicating personal pronouns, to signal that the study environment does not make assumptions about any person's pronouns, and to normalize the process of sharing correct pronouns as a standard way to introduce ourselves. This will help transgender and gender diverse participants feel more comfortable.
- Site staff can post the Pronouns Flyer (Appendix A) on the wall at their clinical site. This flyer serves to remind all staff to use correct pronouns and to signal to participants that study staff will honor correct pronouns and affirming names. **Please note that all participant-facing materials must be approved by your study site's Institutional Review Board (IRB) or Evaluation Center (EC) prior to being displayed.**

- Sites should make sure there are restrooms designated for use by all genders. Often single-stall restrooms can serve this purpose as long as signage makes it clear that all genders are

welcome. All site staff should be aware of the location of these restrooms so they can assist participants in finding them.

Example of an anatomical inventory. Each data field should link to a corresponding code from the International Statistical Classification of Diseases and Related Health Problems. The format of this anatomical inventory is designed for expansion to accommodate additional variables and emerging health priorities over time.

Breasts Present Absent

- Chest reconstruction
- Bilateral mastectomy
- Unilateral mastectomy, R
- Unilateral mastectomy, L
- Breast augmentation/implants

Uterus Present Absent

- Hysterectomy—cervix removed
- Hysterectomy—cervix remains

Ovaries Present Absent

- Bilateral salpingo-oophorectomy
- Unilateral salpingo-oophorectomy, R
- Unilateral salpingo-oophorectomy, L

Cervix Present Absent

Vagina Present Absent

- Colpocleisis—closure of the vagina
- Vaginoplasty

Penis Present Absent

- Phalloplasty/penile implant
- Metoidioplasty
- Erectile device
- Penectomy

Testes Present Absent

- Testicular implant(s)
- Bilateral orchiectomy
- Unilateral orchiectomy, R
- Unilateral orchiectomy, L

Urethra Present Absent

- Urethral lengthening

Prostate Present Absent

- Prostatectomy

Adapted from:

Grasso C, Goldhammer H, Thompson J, Keuroghlian AS. Optimizing gender affirming medical care through anatomical inventories, clinical decision support, and population health management in electronic health record systems. *J Am Med Inform Assoc* 2021; 28(11):2531-2535. ²

Collecting Sexual Orientation and Gender Identity (SOGI) Data

Are Participants Likely to be Offended by Sexual Orientation and Gender Identity (SOGI) Questions?

- A primary reason for asking SOGI questions with participants is that LGBTQIA+ participants experience greater personal safety, inclusion, and affirmation in a clinical study context when asked SOGI questions.
- A study of 301 randomly selected patients from four racially and geographically diverse U.S. health centers found high acceptability by patients of routine SOGI data collection: most expressed believing the questions are important and reported they would answer these again in the future, even among most participants who did not identify as LGBTQIA+.³
- In a nationally representative survey, 78% of Emergency Department providers believed that patients would refuse to provide sexual orientation data; however, only 10% of patients said they would refuse, if asked.⁴
- In a study from three Midwestern U.S. clinics, there were no differences in patient attitudes toward registration forms that included SOGI questions vs. forms that did not; only 3% of patients reported being distressed, upset or offended by SOGI questions.⁵

Preparing for SOGI Data Collection

- **Clinicians:** Need to learn about LGBTQIA+ health and how to tailor care based on gender identity
- **Administrative Staff:** Need to learn about LGBTQIA+ health, communicating with LGBTQIA+ participants, documenting SOGI, and high-quality service delivery with LGBTQIA+ participants; confirm local legal, privacy and regulatory guidelines on collecting personal information such as SOGI
- **Participants:** Need to learn about why it is important to communicate this information, and feel comfortable that it will be used appropriately, whether or not a participant identifies as LGBTQIA+

Starting the Process

- *Create Your Team*
 - Include key staff who can be champions and provide feedback
 - Ensure support from senior management, or enlist an executive champion
- *Training*
 - Provide SOGI data collection and cultural responsiveness training to clinical staff, flex staff (e.g., lab technicians who draw samples) and non-clinical/administrative staff (e.g., front desk, data entry coordinators)
 - Ask your study sponsor about additional training opportunities that are available in addition to this toolkit
- *Privacy and Confidentiality*
 - Follow HIPAA/Legal protections
 - Assure participants that question responses are optional, and that this information will be used appropriately in study reports as de-identified aggregate data.
 - Clarify that the purpose of collecting this data is to benefit both medical research and LGBTQIA+ communities. Specifically, explain that SOGI data advances representation in research, more accurately reflects the diverse populations of people who may use the intervention being studied, and thus helps to determine if the results are generalizable to LGBTQIA+ communities. Moreover, the data can help with identifying and ultimately addressing LGBTQIA+ health disparities. Review and confirm with the study sponsor if SOGI demographic data collection is permitted by the local regulations where the study is conducted
- *Electronic Health Record Customization*
 - Study sites may work with their organization's information technology department to tailor the electronic health record as needed for SOGI data collection.

- The following article is a helpful resource for electronic health record customization to collect and utilize SOGI data:

Grasso C, McDowell MJ, Goldhammer HB, Keuroghlian AS. Planning and implementing sexual orientation and gender identity data collection in electronic health records. *J Am Med Inform Assoc* 2019; 26(1): 66-70.⁶

Responding to Staff Concerns

- Some staff may need extra coaching and reassurance.
- Supervisors should explain that the organization is trying to create a welcoming and inclusive environment for all participants, and staff do not need to change their own values to collect gender identity or sexual orientation data.
- Regular check-ins with staff members will help identify and address their concerns.

SOGI Data Collection Process

Guiding Principles for Participant SOGI Data Collection

Participants experience their sexual orientation, gender identity, and sex development in a variety of ways. These identities also interact and intersect with additional identities a participant may hold, such as race, ethnicity, religion, language, age, socioeconomic status, and ability.

A key principle for study staff is to avoid making assumptions about how participants will experience or describe their identities, and to consistently mirror participants' own language during oral and written communication with and about them. When participants share their correct names, correct pronouns, and other identity-related terminology with study staff, it is important to consistently use this terminology moving forward.

While most people have at least one sexual orientation, gender identity, and sex development identity, this is not always the case: for example, asexual participants may report that they do not have a sexual orientation. Of note, some participants will hold multiple identities at once within a given domain: for example, a given participant may simultaneously hold both transgender and non-binary gender identities.

Rationale and Ethics of Participant SOGI Data Collection

When collecting participant SOGI data, the equity-based rationale for doing so should inform all study staff's decision-making processes and approach. It is important to keep in mind that participant SOGI data collection helps achieve the study's goals and objectives with regard to improving care for LGBTQIA+ communities, increasing recruitment and retention of LGBTQIA+ individuals in clinical research, and ultimately addressing LGBTQIA+ health disparities. In the context of historical exclusion of, erasure of, and discrimination against LGBTQIA+ communities in research settings, it is important to anticipate potential medical and scientific mistrust and to ensure that SOGI data collection occurs in an ethical manner, in the context of informed consent with each participant.⁷

For SOGI data collection with study participants, we adopt the following approaches:

- Only collecting the minimum SOGI information necessary to achieve the study's goals, rather than asking participants any extraneous, intrusive, or voyeuristic questions
- Assuring participants that their SOGI information will only be used in a confidential, deidentified way in reporting of aggregate study data
- Asking SOGI questions with all adult participants, and not just those whom we guess might be LGBTQIA+, or whom we assume would welcome SOGI questions
- Considering letting participants know that SOGI questions are asked of all participants in the study
- Accounting for local and national laws regarding privacy and data collection with participants under age 18, as relevant
- Responding respectfully and informatively to all questions from study participants who request additional clarifying information about the SOGI questions or listed response options
- Giving all participants the option, once they have received appropriate explanation of SOGI data questions, to choose not to disclose their sexual orientation, gender identity, or sex development
- If a participant asks why SOGI data collection matters, study staff can reply:

“We are asking all participants these questions in order to assess safety and efficacy of the therapy in different populations and to also ensure our studies reflect diverse populations. Your disclosure of this information is not a requirement for study participation nor will it influence your study participation in any way. Please note that you have the right not to disclose such information.”

Offering the best study experience for participants requires suitable training for study staff who administer and analyze responses from participant SOGI questions. Optimizing participants’ study experience also requires building welcoming and inclusive environments within study sites for all participants, including LGBTQIA+ participants.

Standardized SOGI Data Questions

Using standardized SOGI questions can help to maintain consistency and data sharing across studies. The Clinical Data Interchange Standards

Consortium (CDISC), a non-profit organization that issues and updates consensus standards for medical and health care data, has developed recommended SOGI questions and responsive options (Released October 2024, <https://www.cdisc.org/kb/ecrf/sexual-orientation-gender-identity-sogi>). Keep in mind that SOGI terms can vary across cultures and communities and evolve over time. To ensure that SOGI terms are both current and suitable for local study populations, it is important to check the CDISC website for updated question wording, and to ask for feedback from community partners.

SOGI questions can be asked verbally, through a paper form, on a tablet or other device, or via electronic health record systems. When choosing a method for participants, consider health literacy levels, language(s) spoken, comfort with technology, and privacy concerns. Regardless of approach, be sure to allow for self-identification of SOGI.

Case Scenario 1

- Mandy, a study participant, arrives at the study site, which has implemented collection of SOGI data. Mandy has not previously disclosed his sexual orientation identity as gay.
- When the study nurse takes Mandy to an exam room and goes over his forms, he says:

Study Nurse

“So when did you know you were gay?”

- Are there more appropriate questions to ask Mandy about his sexual orientation?
 - *Study staff should only ask questions that are necessary for study participation. Discussions about sexual orientation may be an important part of care for some participants, however asking participants these questions in order to satisfy one’s curiosity is not appropriate. Instead, staff who work with LGBTQIA+ participants are encouraged to read SOGI data training materials and take continuing education courses to learn more about the experiences of LGBTQIA+ people. Asking SOGI-related questions upon informed consent by the participant is relevant in the context of all demographic data collection that occurs during screening.*
- How is collecting SOGI data in the electronic health record helpful for participants and study staff?
 - *Collecting SOGI data helps study staff understand relevant considerations for the participants they work with, in an effort to enhance study diversity and representation. SOGI data can be used like any other demographic data – e.g., to track population-specific progress on health and clinical study outcomes (including efficacy and safety), to evaluate quality, and to compare participant satisfaction scores across populations.*

Case Scenario 2

- Jack, a study participant, arrives at the study site, which has implemented collection of SOGI data as part of the demographics page. Jack has not previously been asked about his sex assigned at birth or his current gender identity.
- Jack answers the study nurse's question:

Study Nurse

"What is your sex assigned at birth?"

Jack

"Male"

- The study nurse later asks Jack:

Study Nurse

"What is your current gender identity?"

- Jack responds by asking back:

Jack

"Why are you asking me about my gender twice?"

- How can the study nurse best respond to Jack's question?

- The study nurse can respond with the following explanation:

Study Nurse

“Thank you for asking, and I am happy to explain further. When I asked you about your sex assigned at birth, this referred to the sex you were assigned when you were born, such as female, male, or intersex, based on physical sex characteristics.”

“The second question I asked was about your current gender identity, which refers to your current inner sense of you gender, such as the response options listed here that I can explain further to you.”

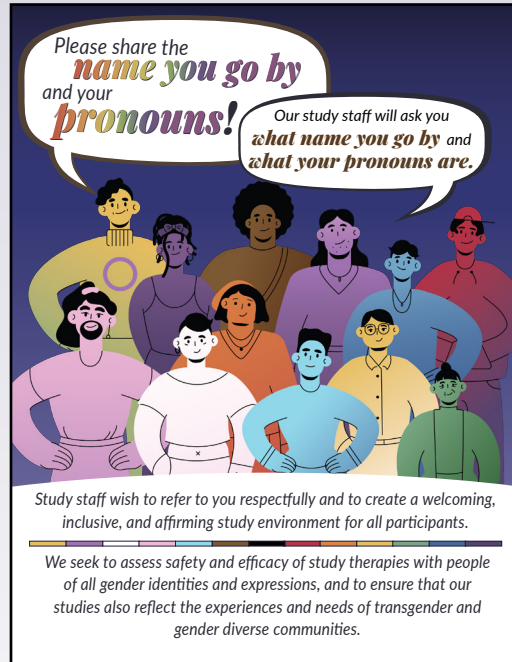
“A person’s sex assigned at birth and current gender identity do not necessarily align based on society’s expectations. Did my explanation answer your question?”

References and Resources

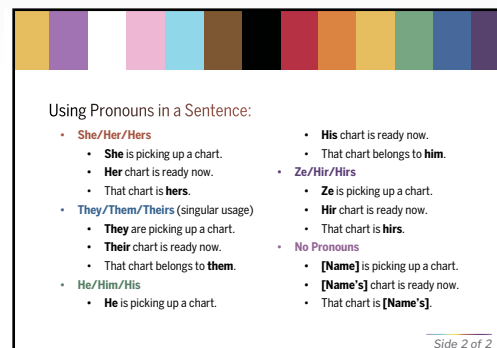
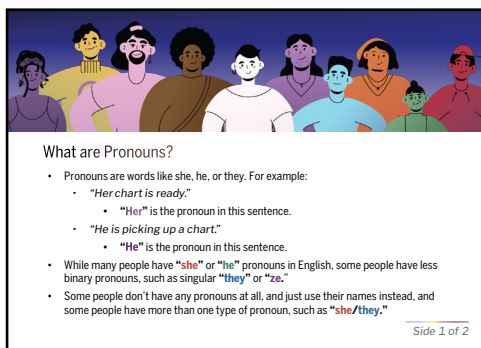
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Appendices Table of Contents

Appendix A: Pronouns Flyer (for posting on walls at study sites)



Appendix B: Pronouns Desk Card (for placing on study staff’s desks)



Institutional Review Board approval is required for all participant-facing materials.

Please share the
name you go by
and your
pronouns!

Our study staff will ask you
what name you go by and
what your pronouns are.



Study staff wish to refer to you respectfully and to create a welcoming, inclusive, and affirming study environment for all participants.

We seek to assess safety and efficacy of study therapies with people of all gender identities and expressions, and to ensure that our studies also reflect the experiences and needs of transgender and gender diverse communities.



What are Pronouns?

- Pronouns are words like she, he, or they. For example:
 - “Her chart is ready.”
 - “**Her**” is the pronoun in this sentence.
 - “He is picking up a chart.”
 - “**He**” is the pronoun in this sentence.
- While many people have “**she**” or “**he**” pronouns in English, some people have less binary pronouns, such as singular “**they**” or “**ze**.”
- Some people don’t have any pronouns at all, and just use their names instead, and some people have more than one type of pronoun, such as “**she/they**.”

Side 1 of 2



Using Pronouns in a Sentence:

- **She/Her/Hers**
 - **She** is picking up a chart.
 - **Her** chart is ready now.
 - That chart is **hers**.
- **They/Them/Theirs** (singular usage)
 - **They** are picking up a chart.
 - **Their** chart is ready now.
 - That chart belongs to **them**.
- **He/Him/His**
 - **He** is picking up a chart.
 - **His** chart is ready now.
 - That chart belongs to **him**.
- **Ze/Hir/Hirs**
 - **Ze** is picking up a chart.
 - **Hir** chart is ready now.
 - That chart is **hirs**.
- **No Pronouns**
 - **[Name]** is picking up a chart.
 - **[Name’s]** chart is ready now.
 - That chart is **[Name’s]**.

Side 2 of 2

