MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER OF
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD

Representation
in Research
LGBTQIA+

Tool 5: Site Feasibility Decision Tree from the LGBTQIA+ Participant Perspective

Introduction

This tool is meant to empower potential LGBTQIA+ participants[a] 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).

- 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).

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[a] 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.

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](#)).[b]

- In an area where nearby businesses or community spaces advertise Pride events, LGBTQIA+ artists, and LGBTQIA+ authors, and post Pride flags.

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

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

[c] 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

Reputation in the LGBTQIA+ Community

- o Recognized by queer groups inclusive of diverse sexual orientations/identities as a trusted collaborator in community engagement.

- o Sponsors Pride events, LGBTQIA+ artists, and LGBTQIA+ authors, and posts Pride flags in, on, or around the building or campus.

- o Known to attend local PRIDE events and give back to the community.

- o Known to produce study recruitment and other patient-facing materials in collaboration with, and acknowledgment of, LGBTQIA+ community partners.

- o Known to produce study recruitment and other patient-facing materials that use LGBTQIA+ imagery and language and are accurate and representative.

- o Reviewed positively on the crowdsourcing forums (e.g., social media) preferred by LGBTQIA+ groups and allies.

Organizational/Site Relationships

- o [If a private facility] Has leadership/ownership (e.g., religious or business corporation, family foundation) that is supportive of LGBTQIA+ rights.

- o Funds or partners with political groups and/or politicians who are supportive of LGBTQIA+ rights.

- o 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).[d]

Cost (financial accessibility)

- o Accessible to local and distant LGBTQIA+ populations by public and private transportation, and preferably with options that are safe and affordable.

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.

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

- 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 of 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,[1, 2] and supporting bed assignment based on gender identity for transgender patients (whenever possible and in collaboration with the participant).[3, 4, 5, 6]

- 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.[7]

- 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[8]
- A history of programs and/or departments dedicated to improving the well-being of and reducing disparities in LGBTQIA+ populations.
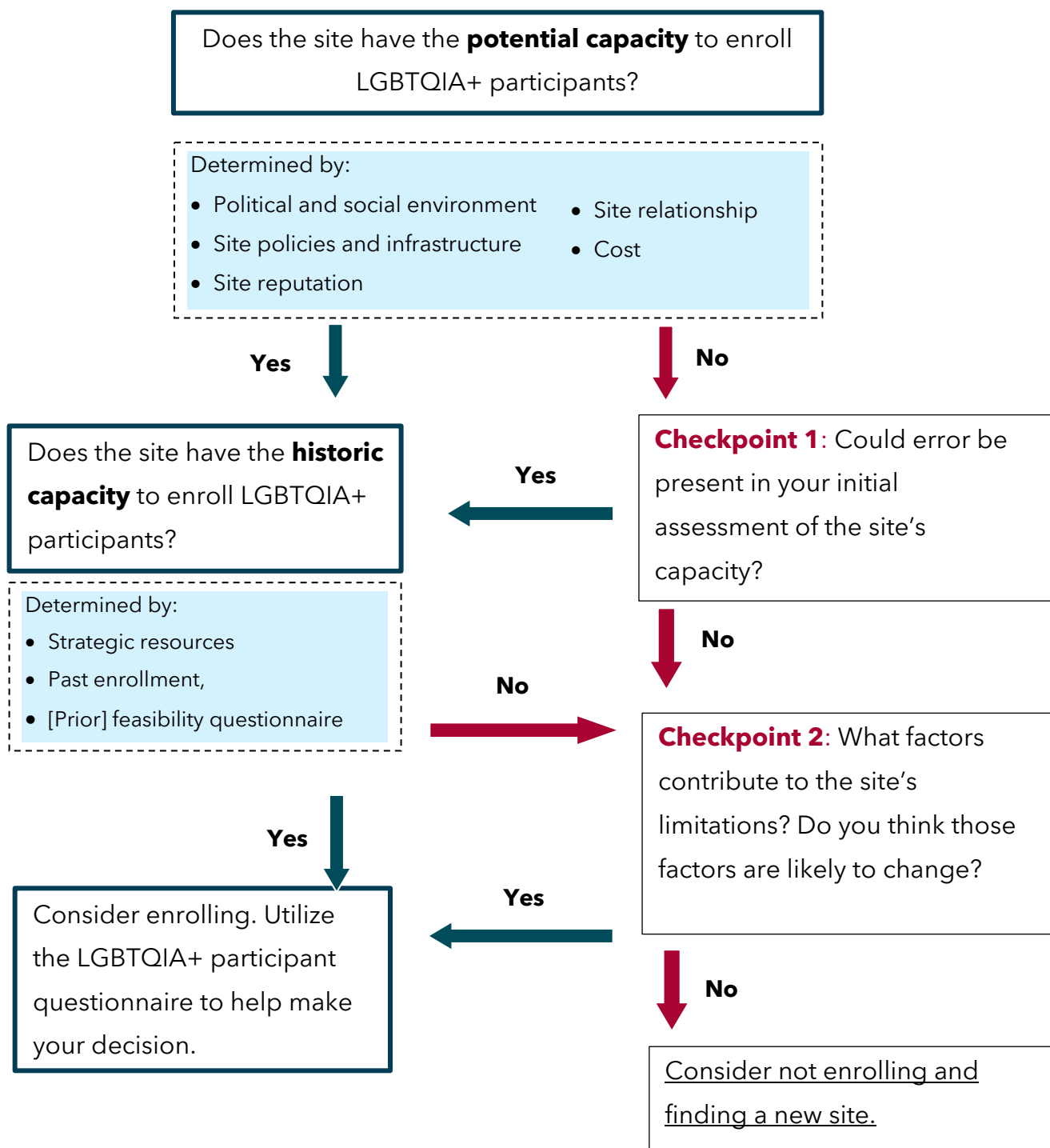
- o A history of launching fellowships, research, and publications dedicated to health equity and improving the well-being of LGBTQIA+ populations.

- o 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
- o A history of caring for health conditions that disparately affect LGBTQIA+ communities (e.g., HIV).

- o 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)

- o 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 has a clear history of actively working toward doing so.

- o 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. [e]

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[e] 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

Does the site have the **potential capacity** to enroll LGBTQIA+ participants?

Determined by:
- Political and social environment
- Site policies and infrastructure
- Site reputation
- Site relationship
- Cost

Yes

No

Does the site have the **historic capacity** to enroll LGBTQIA+ participants?

Determined by:
- Strategic resources
- Past enrollment,
- [Prior] feasibility questionnaire

Yes

Checkpoint 1: Could error be present in your initial assessment of the site's capacity?

No

No

Checkpoint 2: What factors contribute to the site's limitations? Do you think those factors are likely to change?

Yes

Yes

Consider enrolling. Utilize the LGBTQIA+ participant questionnaire to help make your decision.

No

Consider not enrolling and finding a new site.

References

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3. Lambda Legal, Human Rights Campaign Foundation, Hogan Lovells, & the New York City Bar. (2016). *Creating equal access to quality healthcare for transgender patients: Transgender-affirming hospital policies*. Available from: https://assets2.hrc.org/files/assets/resources/TransAffirming-HospitalPolicies-2016.pdf

4. Hackensack Meridian Health. *Treatment/Management of Transgender Patients.* Available from: https://www.hackensackmeridianhealth.org/-/media/project/hmh/hmh/public/about-us/files/transgenderpatientpolicy.pdf

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7. Keuroghlian AS, Goldhammer H. Creating Welcoming and Affirming Clinical Studies for LGBTQIA+ Participants Toolkit. The Fenway Institute and Johnson & Johnson; 2024. Available from: https://www.lgbtqiahealtheducation.org/collection/clinical-studies-toolkit/

8. Gonzaga University Foley Library. (2024). *LGBTQIA+ Health: Patient Resources*. Available from: https://researchguides.gonzaga.edu/lgbtq-health/patients