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[a] 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?
    - How will I know if it is working?

[a] 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 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?[1,2]

- Will my insurance cover any of these costs?[b] 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)?[3,4] 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?

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

[c] 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.

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?

1. The MRCT Center. (2022). *An IRB resource for participants: Costs and payments*. Available from: https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/8/2022/06/MRCT-Center-An-IRB-Resource-for-Participants.pdf

2. National Cancer Institute. *Who Pays for Clinical Trials?* Available at: https://www.cancer.gov/research/participate/clinical-trials/paying

3. Gay and Lesbian Medical Association. (2012). *Ten things transgender persons should discuss with their healthcare providers.* Available from: https://researchguides.gonzaga.edu/ld.php?content_id=67945995

4. J.P. Morgan Wealth Management. (2024). *International transgender day of visibility: Seeking gender-affirming healthcare.* Available from: https://www.jpmorgan.com/insights/wealth-planning/estate-planning/thoughtful-planning-for-transgender-persons