UNIVERSITY OF CALGARY
IMPLIED CONSENT TO PARTICIPATE IN RESEARCH

TITLE:

Exploring sexual function and practices among transgender and non-binary people

INVESTIGATORS:

Principal Investigator:
Lauren Walker, PhD, RPsych
Adjunct Associate Professor
Department of Oncology, Division of Psychosocial Oncology, University of Calgary
Department of Psychology, University of Calgary
Phone: 403-355-3214
Email: lauren.walker@ahs.ca

Co-Investigators:
Tristan Bilash (He/Him), BSW, RSW
Transgender Health Advocate
Research Collaborator
University of Calgary, Division of Psychosocial Oncology
Cumming School of Medicine

Nicole Thompson, MD
Resident, Obstetrics and Gynecology, University of British Columbia

Pablo Santos-Iglesias, PhD
Assistant Professor, Department of Psychology, Cape Breton University

Ted Jablonski, MD, CCFP, FCFP
Clinical Assistant Professor, University of Calgary, Department of Family Medicine

Study Coordinator:
Carly Sears, Research Assistant, University of Calgary

Study Assistants:
Mira Gitelman, Research Assistant, University of Calgary
Lane Begalke, Research Assistant, University of Calgary

INTRODUCTION

This study was originally conceptualized by Tristan Bilash, a transgender man, transgender health advocate and clinical oncology social worker, and Lauren Walker, a cis-gender female sex researcher and sex therapist. The study team include experts in measurement in sexuality research (Pablo Santos), physicians who work with transgender patients (Ted Jablonski, Nicole Thompson), and a team of transgender and non-binary (TNB) advisors (unnamed for confidentiality). There are few tenured, senior transgender scholars in this field to direct and shape these types of studies, therefore the team includes a variety of cisgender sexuality and health experts, and includes invaluable input from TNB community members who have been consulted and collaborated at every step of the project's development.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information.

You are invited to be in this study because you: (1) Are transgender or non-binary (2) Are over the age of 18 (3) Able to read and write, or speak and comprehend English fluently (4) Reside in North America, Continental Europe and Australia or New Zealand.

Your participation in this research study is voluntary.

WHY IS THIS STUDY BEING DONE?

Transgender and non-binary (TNB) people continue to be overlooked in sexuality-based research due to limitations in the questionnaires used to assess sexual outcomes. The way human sexuality research is conducted to date, typically forces people to use questionnaires meant to assess cis-male or cis-female individuals. These questionnaires narrowly focusing on physical capacity to engage in particular kinds of sexual activity (e.g. erectile firmness sufficient for penetration, vaginal intercourse etc.). However, we know that people do a wide variety of things with their bodies sexually, both alone and with other people. These activities vary based on who they are engaging in sexual activity with, and how they feel about their body parts. This limitation to research methodology and to the practice of sexual medicine, contributes to TNB erasure, wherein TNB experiences are excluded from or not accurately represented in human sexuality research literature. This practice is problematic and needs to change.

While there have been some advancements in developing questionnaires specifically for transgender people following Transition Related Surgery (TRS) these are too specific to be used for people who have not undergone TRS and cannot be used across the gender spectrum. To date, there are also no studies on non-binary individuals' sexual well-being or sexual practices. An extremely limiting factor, is that there are no questionnaires available for use across all types of people, regardless of

sex, gender, physical ability, body parts, and sexual orientation. Such questionnaires need to be developed and validated for use within TNB populations.

We want to change this, to ensure that TNB experiences are accurately included in research on human sexuality. The eventual goal, from this program of research, is that the results of this study will be used to inform the development of gender inclusive measures of sexual function and to improve sexual health services for TNB people. Our hope is that this will result in better understanding of the unique needs of TNB people, in order to guide clinicians to provide more sensitive and tailored sexual health care to TNB patients. This will also allow for inclusion of TNB people in sexuality research studies, which have largely focused on cisgender people over the past 70 years.

Please be advised that by participating in this study, you will be asked questions about your body, how you use your body to engage in sexual activities and about your mental and physical experiences during sexual activity. This project will take place in several phases. The first phase involves the currently described qualitative interview – for this phase, we are keen to hear both your responses to the interview questions, and also your feedback about the whether the questions themselves feel relevant to you, as a transgender or non-binary person. You are also able to opt not to answer any of these questions. Results of the study will be shared with you, provided you are interested in receiving them. Results may take 12-18 months to prepare, but we are actively interested in your feedback on those results. You may choose to offer feedback about the study methodology, questions and results at any time during the study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 30 people will take part in this initial pilot study across North America, Europe, Australia and New Zealand.

If this methodology is successful, we plan to continue to expand the project in the future, to be more representative and include a larger study sample.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Before consenting, you will be asked to review a short video (8 minutes) about the study, from the study developers. Once you have signed the consent form you will be prompted to complete a short 10-item survey collecting demographics information (e.g. age, geographic location, educational background etc). You will also be asked to participate in a structured interview. The interview will take place on the phone or via Zoom. During the interview you will be asked a series of questions concerning your gender identity, sexual expression (partnered, solo and group activities, use of toys or prosthetics), and sexual function (e.g. experiences of sexual desire, arousal, orgasm, pleasure, and pain). Questions are provided below in the interview guide for you to review in advance of the interview, in order to help you make an informed decision about participating in the study. Before your interview you will be asked to consider

which questions you are and are not comfortable answering. If you elect not to answer certain questions, you will also be asked your reasoning for why you have chosen not to answer those question(s), which you may also decline to answer. It will take approximately 60 minutes to complete this interview.

Your participation is completely voluntary; you may refuse to participate altogether or to participate in only parts of the study. You may also decline to answer any and all questions and may withdraw from the study at any time without penalty.

After reviewing the interview guide, if you choose that you are not comfortable being a participant in the study and would like to share with the study investigators why, or would like to share how you think the study could be improved to make it more appropriate, or to make you (or others) feel more comfortable, we welcome receiving this feedback from you. You can provide it either in the form of an email to the investigative team, or by scheduling your interview and letting the team ahead of time know that instead of answering the questions in the interview guide, you'd like to provide feedback on the study itself.

If you do consent to the study and you do complete the interview, following your participation you will be asked if you would like to stay involved in the project. If you indicate that you are interested, the study results will be shared with you at a later date, and you will be provided with an opportunity to give your feedback on the results. You may provide your contact information for this purpose, should this be of interest to you.

As indicated above, this study is the first of several studies that ultimately aim to develop inclusive measures of sexual function. We welcome collaboration in the development of future study methodologies, as well as your participation in future studies. You may provide your contact information for this purpose, should this be of interest to you.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

There are no economic, physical, or long-term psychological risks associated with your participation. Given the sensitive nature of some questions asked within the study, some questions may cause discomfort in responding, for example your responses describing intimate sexual experiences, or experiences of gender dysphoria. If at any point of the study you experience psychological distress, or symptoms of gender dysphoria, you may decline answering or withdraw your participation. The study team is concerned about your well-being and should participating in the study cause you distress, the team would like to be informed about it. If you are comfortable providing feedback this can be done over email or by telephone. The study investigators are available to discuss this further with you. Unfortunately, there are no funds to support counselling, but the team will endeavor to support you in finding access to local support resources where able. In addition to this, a resource list will also be provided to you, should you prefer to not communicate directly with the study team.

For some people in some geographic locations, there may be potential social risks to participation. While the study is confidential, online security is never an absolute guarantee. For this reason, if you are at all concerned for your safety related to the discovery of your gender identity or sexual orientation, it may be in your best interest not to participate in this study.

HOW LONG WILL I BE IN THIS STUDY?

The interview will take an estimated 60 minutes to complete. You will only be required to complete the interview once.

If you are interested in receiving the study results and providing feedback on them, or in being involved in future phases of this research program, you may continue to be engaged in the study periodically, to the extent that you would like to be involved. Results should be available for review between 12-18 months from the start of the study (late 2022 to mid 2023).

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

No direct benefits to study participants are anticipated. Benefits of participation include contributing to greater scholarly understanding of sexual functioning among TNB individuals. It is our hope to use the information provided in this study to ensure that the experiences of TNB people are included in the literature describing sexual function and sexual response. Inclusion in the scientific literature and dissemination of this information within the scientific and health care community will ultimately improve health care providers competence with TNB patients, and improve the quality of sexual resources that are offered to TNB patients. Results from the implementation of this project include participant feedback on the study procedure, the questions being asked, and the process of engaging study participants. These results will also better inform the knowledge base surrounding conducting ethical research with TNB populations.

There are no costs associated with participation in the study. A token of appreciation for your time is being offered in the amount of $50 CAD, or $37 USD (based on current exchange rate) for those who reside in the United States. Compensation will be sent by e-transfer using your personal email address, or Paypal using Paypal account information. We understand your time is valuable and this is compensation for your time and effort. Compensation will be provided after completion of the interview and short follow-up survey. You will still be provided with compensation if you opt to withdraw and remove your data from the study after completing the interview and follow-up survey.

CAN I STOP BEING IN THE STUDY?

Your participation in this study is voluntary and you may withdraw from it at any time. You may withdraw by closing your browser and exiting the study (e.g. demographic

questionnaire) or by indicating to the interviewer that you would no longer like to participate.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

When completing the interview via phone you will be asked for your first name or a nickname/pseudonym of your choice.

You will be asked to complete a short demographic form before completing your interview. This demographic form includes questions about age, sex, and gender identity, and geographic location (state/province and country). Other than this, no personal identifying information will be collected in this study. Other information to be collected includes: ethnicity, educational background, and relationship status, experiences of disability, trauma and degree of social support.

At the end of the survey, you will be directed to a webform (i.e. short follow-up survey) in which an email address will be requested. Providing your email address is not required but will be collected as a potential contact method based on your responses to 2 questions: 1. You will be asked if you would like the study results to be shared with you, and 2. You will be asked if you are willing to be contacted to participate in a future research study on this same study topic. You can decline or consent to either question. If you consent to at least 1 of the 2 options, you will be asked to enter an email address as a contact method. This information is collected separately from your survey and cannot be traced back to your survey responses.

The data you provide in the study will be identified with an ID number, this is not associated with your name or any other personal identifying information. This ID number will only be used for collection and analysis for the purpose of this study. If your responses are used in a scientific article or report, you will be given a pseudonym.

Telephone interview data will be captured via audio recording and transcribed by a member of the study team. All study team members have signed confidentiality agreements. Following data analysis, recordings will be deleted and only transcripts will be retained.

Online data for the demographic form will be collected through Qualtrics Survey Software, an online survey platform with servers in Toronto, Ontario, Canada. All data is encrypted and stored on its servers. Researcher access to the survey data is password protected and the transmission is encrypted. Any information linked to your personal computer (i.e. IP address) will not be linked to your survey responses.

All data will be stored on the academic laptop of the principal investigator and secured with password protection.

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

Data will be retained for a period of 7 years following the publication of scientific articles on the study results. This data will be stored on the academic laptop of the principal investigator and secured with password protection. Data will also be retained by co-investigators involved in research analysis for a period of 5 years, after which all data will be deleted.

Any future use of this research data is required to undergo review by a Research Ethics Board.

WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact the study coordinator, Carly Sears at (403) 465-2640, or carly.sears@ahs.ca with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB):
If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

AGREEMENT TO PARTICIPATE

Your decision to complete and click past this consent form to access the study will be interpreted as an indication of your agreement to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time.

First Name:

Last Name: