Official Title: Project Uplift: Substance Use and Mental Health Treatment for Young Sexual and Gender Minorities

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DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Project Uplift
Study participant consent

CONCISE SUMMARY

This is a study to examine whether a comprehensive outreach and treatment program is beneficial in improving health-related outcomes as well as connection to and use of community resources. Participation in the study includes receiving screening for substance use, behavioral health and medical needs, intensive case management, peer support education services, and provision or referral for treatment as needed. As part of the study you will be asked to complete a 30-minute survey about about mental health, substance use, sexual behavior, medication use, use of health care services, job-readiness, and life skills before beginning the program and again 6 months later. If you are interested in learning more about the study continue reading below.

You are being asked to take part in this research study because you have indicated a need for substance use and/or mental health services as well as case management. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide that you will take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Susan Reif and Sara LeGrand will conduct the study and it is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). The sponsor of this study, SAMHSA, will pay Duke University to perform this research, portions of Dr. Reif's and Dr. LeGrand's salary are being paid by this grant.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to examine whether providing outreach services, case management, peer support services, and behavioral health treatment is associated with better outcomes for physical and emotional health, life stability, and life quality.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 80 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to participate in this study, you will be asked to sign and date this consent form. All participants have access to case management, peer support, and counseling over a 6-month period at the site closest to where you reside (either Charlotte or Durham NC). The study also includes completion of a study survey two times during the duration of your participation. The surveys will take about 30 minutes to complete. The survey will ask about mental health, substance use, sexual behavior,

medication use, use of health care services, job-readiness, and life skills. The surveys will be self-administered on a computer; for all surveys, a trained interviewer will be there to explain the process and address any related questions**.** Surveys can take place at the treatment location or at an alternative location you and the interviewer agree on. Information we get from you will be combined with information from others who have joined the study to help us examine the results of providing the comprehensive case management and treatment.

Social media through Facebook may be used to maintain contact with participants and to offer additional support. All messages will be sent through private messaging rather than on the participant Facebook page.

If you become incarcerated in the Mecklenburg County or Durham County jail while a Project Uplift participant, Project Uplift staff will be available to assist with planning for resumption of Project Uplift services and linkage to other needed services post-release.

HOW LONG WILL I BE IN THIS STUDY?
Your participation in this study will be approximately 6 months in duration. You may reenroll in the program for an additional 6 months of treatment if you meet eligibility criteria. If you reenroll, you will be asked to complete the survey before you re-enter the program and 6 months later. You can choose to stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the survey questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and may take a break from the survey at any time. The interviewer will be prepared to support you if this should happen and to provide a referral to see a counselor if needed. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefit as a result of the services, however this cannot be guaranteed. We hope the information learned from this study will benefit people similar to you in the future.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
There are other behavioral health treatment options, if additional or alternative services are needed. Individuals who choose not to participate or withdraw from the study will be offered other treatment referral options.

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WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or for your care, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University. For records disclosed outside of Duke, you will be assigned a unique code number. The key to the code will be kept securely by a contractual agent of Duke and may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study, which includes a subcontractor for the program: Mecklenburg County Community Support Services who will have access to your personal information as needed to provide services for participants residing in Mecklenburg or surrounding counties. This includes electronic and paper storage of data. We will share only the minimum necessary information in order to conduct the research.

For all study participants, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the project funder Substance Abuse and Mental Health Services Administration (SAMHSA), the Duke University Health System Institutional Review Board and others as appropriate. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to you or others.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at Duke University Health System (DUHS).

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2. you have consented to the disclosure, including for your medical treatment; or

3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

WHAT ARE THE COSTS TO YOU?
The costs of participation are the time it takes to travel to and participate in the program.

WHAT ABOUT COMPENSATION?
You will receive substance use and mental health screening and education, psychoeducation, case management, and peer support as a part of this research study. The sponsor, SAMHSA, will pay for your services. You or your insurance company will not be charged or held responsible for the costs of services. As compensation for participation, you will receive a $20 gift card after the baseline study survey and a $25 gift card after the 6-month survey is completed. If you are incarcerated at the time of interview completion, compensation will be held until your release from jail.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center or a local hospital in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. Your decision to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care. If you do decide to withdraw, we ask that you contact Dr. LeGrand in writing and let her know that you are withdrawing from the study. Her mailing address is Center for Health Policy and Inequalities Research Duke University, 310 Trent Drive, Box 90392, Durham NC 27708.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. LeGrand at **919 438-0448**. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form.

_____	_____	_____
Signature of Subject	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time