

Efficacy of a Multi-level School Intervention for LGBTQ Youth
NCT05541406
August 23, 2023

Informed Consent Form

INFORMED CONSENT DOCUMENT

Project Title: Intervention: Proud & Empowered (R01)

Principal Investigator: Jeremy Goldbach

Research Team Contact: Jeremy Goldbach, jgoldbach@wustl.edu

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Jeremy Goldbach, PhD, having to do with testing the effects of a school program for sexual and gender minority youth. You should carefully consider the information in this assent/consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you. Instead of being in this study, you could choose to not participate.

If you agree and sign this assent/consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the assent/consent document below. The research team must give you a copy of this signed assent/consent document.

How will this study affect me?

- The purpose of this study is to test the efficacy of the Proud & Empowered (P&E) program.
- As a voluntary participant, you will be asked to spend time completing 3 surveys, at the start, middle, and end of the school year, and to attend 10 weekly 45 minute long sessions of the P&E program over one semester.
- You were selected because you attend are a sexual and/or gender minority youth who attends a school where we are providing the Proud & Empowered program.
- You will be in this study for 1 school year.
 - 10 P&E sessions, once per week, of approximately 45 minutes each
 - 3 surveys, one at the start of P&E, one at the end of P&E, and one at the end of the school

year

- You will need to come to the 10 P&E sessions
- The main risks to you are experiences of discomfort while responding to survey questions on mental health, behaviors, and drug use and the risk of breach of confidentiality. More detail about risks is provided below.
- You may or may not benefit from being in this study, but your participation will help us understand the impact of the P&E program on school climate for LGBTQ+ students and LGBTQ+ student wellbeing.
- You will be paid in gift cards for participating in each survey for this study; \$20 for the first survey, \$25 for the second survey, and \$30 for the third survey. You will not have costs for participating in this study.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this study because you identify as LGBTQ+ and attend a school selected to be part of this study.

The purpose of this study is to determine if the Proud & Empowered Intervention for LGBTQ+ youth impacts mental health among LGBTQ+ youth.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to take part in this study, you will either participate in the Proud & Empowered intervention and complete three surveys, or only complete three surveys. This is a 50/50 chance and depends on if your school is selected as an intervention school or control school.

We will ask you to complete three surveys as part of this study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use. All surveys will take about 30 minutes to complete. You will create a unique code that will be used to link to your survey responses so that no one at the school will know how you answer.

If you are in a school selected to receive the intervention, you will participate in an intervention group for about 45 minutes once a week for 10 weeks during the semester. In this group we'll talk about specific issues that you and other LGBTQ+ youth might be facing and ways to deal with those issues,

including stress and coping skills, disclosure, family, school-related stress, peers and friendship, race/ethnicity and social justice, and history of the LGBTQ+ community.

The intervention sessions will take place at school during school hours, either during homeroom/advisory or during class. If participation is during class, you will need to miss class to participate in the sessions. We will schedule these sessions at different times and days each week so that you will not miss the same class every week.

Your private information collected as part of this study will NOT be used for future research studies or shared with other researchers for their studies, even if we remove identifiers.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 450 people will take part in this study conducted by investigators at Washington University in St. Louis over the next 4 years.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 1 year. This includes the three surveys that happen at the start of the school year, 10 weeks after the first survey, and at the end of the school year, each which take about 30 minutes to complete. The study also involves participating in the 45-minute intervention groups on a weekly basis for 10 weeks. The intervention groups are scheduled during school hours.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Survey: The survey will ask you to respond to questions about sensitive information and some personal experiences at home, within school, within community and within your relationships. You will also be asked to respond to questions about your mental health, different behaviors, and drug use. Some of these questions may make you feel uncomfortable or become upset. If this happens, we have listed some resources within the survey that you can contact and who can provide you with support. You may also skip or stop answering any questions that make you uncomfortable.

Breach of Confidentiality: One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this assent/consent form titled *“How will you keep my information confidential?”* for more information. You are providing highly sensitive, personal information in this study. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, finding housing, or getting insurance (health, disability, or life insurance). In highly unlikely situations, you could be charged with a crime.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the research may improve the overall climate at your school, and increasing knowledge about what interventions help LGBTQ+ young people.

WHAT OTHER OPTIONS ARE THERE?

The alternative to participating in this study is to not participate in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for taking three surveys as part of this research study: at the beginning of the school year, at 10 weeks after the first survey, and at the end of the school year. You will receive a \$20 gift card for the first survey, \$25 for the second, and \$30 for the last one, for a total of \$75 in gift cards if you complete all three surveys. You will be paid separately for each survey completed and do not need to complete all of the surveys in order to receive each individual payment.

WHO IS FUNDING THIS STUDY?

The National Institute of Minority Health and Health Disparities is funding this research study. This means that the Washington University in St. Louis is receiving payments from the National Institute of Minority Health and Health Disparities to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institute of Minority Health and Health Disparities for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institute of Health
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of

research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will collect, store, and transmit electronic data using devices that are password protected. Data collected via Redcap and Qualtrics will be protected by dual factor authentication. Data will be encrypted and access to data will be limited to authorized study team members.

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this assent/consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study facilitator or your school counselor you are no longer interested in participating in the study. Your decisions will not be held against you.

If you withdraw from the study, you will no longer be able to participate in the study. No new information will be collected about you or from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your health, welfare, or willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because, in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or if you feel that you have been harmed in any way by your participation in this study, please contact: Jeremy T. Goldbach at jgoldbach@wustl.edu

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Checking the box below indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Do not check any box below if today's date is after **EXPIRATION DATE: 08/20/24.**

[Check this box in RedCap] Yes, I wish to participate in this study

[Check this box in RedCap] No, I do not wish to participate in this study