

PRS Cover Page for Consent Forms

Title: Parent Feedback Intervention Targeting Student Transitions and Alcohol Related Trajectories (+) Efficacy Study (FITSTART+)

Date: April 26, 2021

ClinicalTrials.gov Identifier: NCT04549454

CONSENT APPENDIX

INFORMED CONSENT FORMS AND HUMAN SUBJECTS BILL OF RIGHTS

1. FITSTART+ Terms of Service
2. Efficacy Study- Student Informed Consent/Assent Form
3. Efficacy Study- Parent of Minors Informed Consent/Assent Form
4. Human Subjects Bill of Rights

[FITSTART+ Terms of Service & Privacy Policy]

By creating a FITSTART+ account, these terms will automatically apply to you – you should make sure therefore that you read them carefully before creating an account. We are offering you this app to use for your own personal use without cost, but you should be aware that you're not allowed to copy, or modify the app, any part of the app, or our trademarks in any way. You are not allowed to attempt to extract the source code of the app, and you also should not try to translate the app into other languages, or make derivative versions. The app itself, and all the trade marks, copyright, database rights and other intellectual property rights related to it, still belong to the FITSTART+ team.

ACCEPTABLE USE

FITSTART+ offers a way for parents of LMU first-year students to receive parenting advice, and learn about resources at LMU. To use FITSTART+ you must be 18 years of age or older and be a parent of a first-year LMU student who meets all of the following criteria: (a) received invitation to participate in FITSTART+ directly from a source authorized by HeadsUp Labs to send invitations to participate in FITSTART+; (b) completed the parent verification form on the FITSTART+ launch website; (c) received a link to the FITSTART+ web app after completing the parent verification form; and (d) created an account on FITSTART+.

VOLUNTARY NATURE OF PARTICIPATION

Participation in FITSTART+ and any surveys associated with FITSTART+ is entirely voluntary. You may choose not to participate, or, if you agree to participate, you may stop at any time. Your decision not to participate will not involve any penalty or loss of benefits to which you or your student are otherwise entitled.

POTENTIAL RISKS/BENEFITS

Risks associated with program participation include feeling uncomfortable or embarrassed due to the personal nature of some of the questions. You may decline to answer any questions you do not feel comfortable answering. A decision by you not to participate in the program or to discontinue your participation will in no way jeopardize your eligibility for any services or benefits to which you or your student are otherwise entitled. Your participation in FITSTART+ may benefit your child's transition to college and success during their first year. Your participation (or lack thereof) in using FITSTART+ also help us evaluate the feasibility of making the program available to parents of first-year students at different universities across the country.

DATA USAGE

If you're using FITSTART+ outside of an area with wi-fi, you should remember that your terms of agreement with your mobile network provider will still apply. As a result, you may be charged by your mobile provider for the cost of data for the duration of the connection while accessing the website, or other third-party charges. In using the FITSTART+, you're accepting responsibility for any such charges, including roaming data charges if you use the website outside of your home territory (i.e. region or country) without turning off data roaming. If you are not the bill payer for the device on

which you're using the website, please be aware that we assume that you have received permission from the bill payer for using the website.

PRIVACY POLICY

Last updated 11 December 2020

FITSTART+ ("we" or "us" or "our") respects the privacy of our users ("user" or "you"). This privacy policy explains how we collect, use, disclose, and safeguard your information when you visit our mobile application (the "application"). Please read this privacy policy carefully. If you do not agree with the terms of this privacy policy, please do not access the FITSTART+ application. We reserve the right to make changes to this privacy policy at any time and for any reason. We will alert you about any changes by updating the "last updated" date of this privacy policy. You are encouraged to periodically review this privacy policy to stay informed of updates. You will be deemed to have been made aware of, will be subject to, and will be deemed to have accepted the changes in any revised privacy policy by your continued use of the application after the date such revised privacy policy is posted.

COLLECTION OF YOUR INFORMATION

We may collect information about you in a variety of ways. Much of the information collected via the application depends on your actions and the permissions you grant or deny within the application.

PERSONAL DATA

Includes demographic and other personally identifiable information that you voluntarily give to us when electing to create an account to use FITSTART+. This data includes your student's gender, your gender, location, number of children in/graduated college, occupation, email address, and any other information you provide in your profile's bio. The application also employs standard social media authentication options for user login and collects profile photo and name, and grants FITSTART+ these permissions. Data-related information about your FITSTART+ account and Facebook authentication are detailed in the next section.

ACCOUNT DATA, SOCIAL MEDIA PERMISSIONS, & PRIVACY SETTINGS

You have the option to authenticate with an existing Facebook account or creating a new username and password as well as uploading a profile photo manually. If you choose to authenticate with Facebook, you will be prompted to enter your credentials for the platform and then permit or deny FITSTART+ access to your email address and profile picture associated with your Facebook account. This allows you to skip the steps associated with registering a new username a password and uploading a profile photo. Regardless of whether you choose to create your account manually or login with social media credentials, you will have an opportunity to complete a public profile which includes your profile photo (if you choose to provide one), location, child's gender, number of children in/graduated college, occupation, and a brief bio in which you can tell other parents a bit about yourself (similar to an Instagram or Twitter bio). If you choose to create a public profile will be viewable to other users in the "community" area

of the app. Importantly, with the exception of your location, child's gender, number of children in/graduated college, occupation, and a brief bio, none of your personal data will be viewable by other users accessing the application.

DERIVATIVE DATA

Includes information our servers automatically collect when you access the application, such as your native actions that are integral to the application, including responses to questions of the week, points wagered, judgments of other students' behaviors, submitted questions, question votes, and points scored. Importantly none of your actions in the app, including your answers to questions, will be viewable by other users accessing the application. In application settings you can, however, chose whether, to share your total score with other users by having it included with your profile photo in a leaderboard within the application.

USE OF YOUR INFORMATION

Having accurate information about you permits us to provide you with a smooth, efficient, and customized experience. Specifically, we may use information collected about you via the application to:

1. Compile anonymous statistical data and analysis for internal use. Create and manage your account.
2. Allow you to view the other parents using FITSTART+.
3. Generate a personal profile to make your future visits to the application more personalized.
4. Increase the efficiency and operation of the application.
5. Monitor and analyze usage and trends to improve your experience with the application.
6. Notify you of updates to the application.
7. Request feedback and contact you about your use of the application.
8. Resolve disputes and troubleshoot problems.
9. Respond to product and customer service requests.
10. Send you a newsletter.

DISCLOSURE OF YOUR INFORMATION

FITSTART+ will not share your personal, Facebook, derivative, or mobile device data with third parties.

TRACKING TECHNOLOGIES

WEBSITE ANALYTICS

We may also partner with selected third-party analytics vendors such as adobe analytics, google analytics, and/or heap analytics to allow tracking technologies on the application through the use of first party cookies and third-party cookies, to, among other things, analyze and track users' use of the application, determine the popularity of certain content, and better understand application usage. By accessing the application, you consent to the collection and use of your information by these third-party vendors.

You are encouraged to review their privacy policy and contact them directly for responses to your questions. We do not transfer personal information to these third-

party vendors.

SECURITY OF YOUR INFORMATION

We employ the most advanced technologies and internal protocols (layered security, https protocol, SSL certificates, TSL encryption in transit, etc.) To transmit, secure, and store and protect all application data. These protocols safeguard privacy between communicating applications and their users on the internet. Also used to secure bank and credit card transactions online, these protocols ensure that no third-party may eavesdrop or tamper with submitted data.

POLICY FOR CHILDREN

We do not knowingly solicit information from or market to children under the age of 18. If you become aware of any data we have collected from children under age 18, please contact us using the contact information provided below.

CONTROLS FOR DO-NOT-TRACK FEATURES

Most web browsers and some mobile operating systems [and our mobile applications] include a do-not-track ("DNT") feature or setting you can activate to signal your privacy preference not to have data about your online browsing activities monitored and collected. No uniform technology standard for recognizing and implementing DNT signals has been finalized. As such, we do not currently respond to DNT browser signals or any other mechanism that automatically communicates your choice not to be tracked online. If a standard for online tracking is adopted that we must follow in the future, we will inform you about that practice in a revised version of this privacy policy.

OPTIONS REGARDING YOUR INFORMATION

ACCOUNT INFORMATION

You may at any time review or change the information in your account or terminate your account by:

- logging into your account settings and updating your account
- contacting us using the contact information provided below

Upon your request to terminate your account, we will deactivate or delete your account and information from our active databases. However, some information may be retained in our files to prevent fraud, troubleshoot problems, enforce our terms of use and/or comply with legal requirements.

EMAILS AND NOTIFICATIONS

If you no longer wish to receive emails and push notifications from us, you may opt-out by:

- noting your preferences at the time you register your account with the application
- logging into your account settings and updating your preferences
- contacting us using the contact information provided below

CALIFORNIA PRIVACY RIGHTS

California civil code section 1798.83, also known as the "shine the light" law, permits our users who are California residents to request and obtain from us, once a year and free

of charge, information about categories of personal information (if any) we disclosed to third parties for direct marketing purposes and the names and addresses of all third parties with which we shared personal information in the immediately preceding calendar year. If you are a California resident and would like to make such a request, please submit your request in writing to us using the contact information provided below.

CONTACT US

If you have questions or comments about FITSTART+'s data privacy, terms or conditions please contact the FITSTART+ team at: headsup@lmu.edu

[Efficacy Trial Student Informed Consent/Accent Form]

First-Year Study

Loyola Marymount University

You are invited to participate in a research project being conducted by the Heads Up Research Lab at Loyola Marymount University. This study is sponsored by a grant from the National Institutes of Health. This informed consent form describes the study and tells you what you can expect if you become a participant.

Please read it carefully before checking the boxes at the end.

PURPOSE OF RESEARCH: The purpose of this project is to investigate students' health and well-being during the transition to college and first-year on campus. The aim of this study is to develop better resources for incoming first-year students and their families. Participation in this research is entirely voluntary.

WHAT IS EXPECTED OF STUDY PARTICIPANTS: Participation in this study involves completing 3 online surveys, the first you can complete now, the second in October, and the third in April. Each survey will take approximately 15 minutes to complete and will ask you questions about your social experiences, as well as health-related attitudes and behaviors. You will receive a link to complete each survey via email. You can receive up to \$85 for completing all three questionnaires. Over the course of the study, you may receive a series of email, and/or text message reminders to complete the surveys.

DATA LINKAGE AND PRIVACY: The HeadsUP lab is also currently testing an online parent program for first-year college students, a program your parent(s) will have an opportunity to take part in. If your parent participates in the program we may link up your survey data with their program data and analyze parent-student dyads in aggregate. No worries though, we will not tell your parents that you are participating in this study and we will not share any of your survey responses with them.

CONFIDENTIALITY: It is important to understand that this student survey study is confidential. This means that neither your status as a participant in the study or your responses to survey questions will not be shared with other students, your parents, or university administrators. In fact, your responses to survey questions will be stored separately from your name and contact information. For this purpose, there will be an arbitrarily assigned sequence number on all your questionnaires and survey data. The purpose of this sequence number is to keep track of materials collected in the study to be used in data analyses. Information regarding your first name, contact information, participant ID number, and whether or not each aspect of the study has been completed will be kept separate from the actual data at all times. The responses you give will be kept in a separate data file that does not include your name. These data sources will only be linked in the case that harm to you or others becomes a concern or you report lethal doses of alcohol consumption. If this occurs, you may be referred to Student Psychological Services, the Student Health Center, or appropriate community

resources. Moreover, examination of the study data by the research team will focus on highlighting group trends and not individual responses. To help keep your information confidential, the current project has obtained a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). This Certificate does not imply that the DHHS or the National Institutes of Health approves or disapproves of the project. The Confidentiality Certificate will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. Despite the presence of the Certificate of Confidentiality, you are responsible for actively maintaining your confidentiality as a participant in this project. A Confidentiality Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this study.

VOLUNTARY NATURE OF PARTICIPATION: Participation in this research is entirely voluntary. You may refuse to participate in the study, or, if you agree to participate in the study, you may withdraw from the study at any time. For example, you may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal). Your refusal to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled.

INCENTIVES: Following your completion of each survey, you will receive a payment of \$25 in the form of an e-gift card emailed to you. Thus, if you complete all 3 surveys you will receive a bonus \$10 for a potential total of \$85 for participating in this study.

POTENTIAL RISKS/BENEFITS: Survey questions may ask about your alcohol use, drug use, and/or sexual behavior. As such, risks involved in study participation include feeling uncomfortable or embarrassed due to the personal nature of some of the questions. You may decline to answer any questions you do not feel comfortable answering. A decision by you not to participate in the study or to discontinue your participation will in no way jeopardize your eligibility for any services or benefits to which you otherwise may be entitled. Your participation will provide useful information that will help increase our understanding of first year students' college experiences and help us develop better resources for incoming first-year students and their families. Participation in this research is entirely voluntary. This study will help provide insight into the role of parents during students' transition to college. If you feel uncomfortable due to your participation in this study, you may speak to a professional counselor at the Student Psychological Services located on the 2nd floor of the Burns Recreation Center, (310) 338-2868. Other campus resources include LMU's Community of Care, (310) 338-3756, and the Center for Student Collegiate Recovery, located in Malone 113.

CONTACT: Dr. Joe LaBrie can be reached at UNH 4749 on the campus of Loyola Marymount University, office phone number (310) 338-5238, jlabrie@lmu.edu, if you have any questions or concerns about your participation in this study. If you have questions regarding your rights as a research subject, you may contact Dr. David Moffet, Chair of the Human Subjects Review Committee by phone at (310) 338-4400, or email David.Moffet@lmu.edu.

I am 18 years old or older, I have read and understood this informed consent statement, and I would like to participate in this study.

I am under 18 years of age, I have read and understood this informed consent statement, and I authorize the research team to obtain permission for me to participate from my parent/guardian so that I may take part in this study.

[Efficacy Trial Parent of Minors Informed Consent/Accent Form]

First-Year Study

Loyola Marymount University

Your child (an incoming first-year Loyola Marymount University student) is invited to participate in a project being conducted by the Heads Up research lab at Loyola Marymount University (LMU). This study is sponsored by a grant from the National Institutes of Health. This consent form describes the study and tells you what you can expect if your student were to become a participant. Please read it carefully before providing consent.

PURPOSE OF RESEARCH: The purpose of this study is to investigate students' health and well-being during the transition to college and over their first year. The data collected will inform the development of additional programs and resources for first-year students.

WHAT IS EXPECTED OF PARTICIPANTS IN THE STUDY: Participation involves your child completing 4 online surveys (2 in the Fall and 2 in the Spring). Each survey will take approximately 20 minutes to complete and will ask your child questions about social and mental health experiences as well as their health-related attitudes and behaviors. Your child will receive a link to complete each survey via email and text message. They can receive up to \$90 for completing all 4 surveys.

DATA LINKAGE AND PRIVACY: The research team will also be testing an online program for parents of first-year students later in the year, and you may be invited to take part. If you take part in the program, we may link up your program data with your child's survey data and analyze parent-student dyads in aggregate.

CONFIDENTIALITY: All of your child's responses will be strictly confidential. None of their responses will be linked to their name or contact information. The responses will be kept in a separate data file that does not include names. Information regarding first name, contact information, participant ID number, and whether or not the study has been completed will be kept separate from the actual data at all times. This will ensure that the data provided from the study will always be associated with a participant ID number and will never be connected directly with any identifying information. Moreover, examination of the study data will focus on highlighting group trends and not individual responses. To help keep all identifying information confidential, the current project has obtained a Confidentiality Certificate from the U.S. Department of Health and Human Services (DHHS). This certificate will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify your child. Please be aware, however, that if harm to your child or others becomes a concern, the researchers may choose to provide information to appropriate individuals or agencies. For example, should such a situation arise, the research team may contact Student Psychological Services. Also, because this research is sponsored by the National

Institutes of Health, staff from that organization may review participation records for audit or program evaluation purposes. Despite the presence of the Certificate of Confidentiality, your child is responsible for actively maintaining his or her confidentiality as a participant in this research study.

VOLUNTARY NATURE OF PARTICIPATION: Participation in this research is entirely voluntary. You may choose for your child to not be in the study, or, if you agree for them to be included, you may withdraw them from the study at any time. For example, you may withdraw your authorization for us to use your child's data that have already been collected (other than data needed to keep track of this withdrawal). Your decision for your child not to participate (or to withdraw from the study) will not involve any penalty or loss of benefits to which they are entitled.

INCENTIVES: Your child will receive a \$20 e-gift card voucher for completing each survey and a \$10 bonus if they complete all 4. Thus, as a participant in this study your child has the potential to collect up to \$90.

POTENTIAL RISKS/BENEFITS: Risks involved in study participation include your child feeling uncomfortable or embarrassed due to the personal nature of some of the questions. Your child may decline to answer any questions he or she does not feel comfortable answering. Your child's participation will provide useful information that will help increase our understanding of students' transition to college and help develop more effective parent resources. In addition, we will provide your child with feedback at the end of the year about how he or she has changed and grown during his or her freshman year.

QUESTIONS: If you have any questions or concerns about your child's participation in this study, please contact the Project Coordinator, Dr. Bradley Trager, at bradley.trager@lmu.edu. For all other questions, please contact the Principal Investigator, Dr. Joseph LaBrie, who can be reached on the campus of Loyola Marymount University in UH 4753, by telephone at (310) 338-5238, or by email at jlabrie@lmu.edu. Your child is not waiving any legal claims, rights or remedies by participating in this study. If you have questions regarding your child's rights as a research subject, you may contact Dr. David Moffet, Chair of the Human Subjects Review Committee by phone at (310) 338-4400, or email David.Moffet@lmu.edu.

Typing YOUR NAME in the box below will serve as your electronic signature indicating that you consent to your child's participation in the study described above

In the box below, please type the CHILD'S NAME for whom you are the legal guardian and for whom you have agreed to provide consent to participate in the study described above

LOYOLA MARYMOUNT UNIVERSITY
Experimental Subjects Bill of Rights

Pursuant to California Health and Safety Code §24172, I understand that I have the following rights as a participant in a research study:

1. I will be informed of the nature and purpose of the experiment.
2. I will be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. I will be given a description of any attendant discomforts and risks to be reasonably expected from the study.
4. I will be given an explanation of any benefits to be expected from the study, if applicable.
5. I will be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous and their relative risks and benefits.
6. I will be informed of the avenues of medical treatment, if any, available after the study is completed if complications should arise.
7. I will be given an opportunity to ask any questions concerning the study or the procedures involved.
8. I will be instructed that consent to participate in the research study may be withdrawn at any time and that I may discontinue participation in the study without prejudice to me.
9. I will be given a copy of the signed and dated written consent form.
10. I will be given the opportunity to decide to consent or not to consent to the study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on my decision.