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INFORMATION STATEMENT
Project PHARM Personalized Feedback Study

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Researchers' Statement

We are asking you to be in a research study. The purpose of this information statement is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." You may wish to print a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this research is to evaluate the impact of a web-based brief personalized feedback tool on reducing prescription stimulant misuse and other substance use among college students on each of 9 campuses: the University of Washington, University of Maryland, University at Albany, State University of New York, Whitman College, Colorado College, University of Denver, Dartmouth College, University of South Carolina, and Florida State University. If the study is right for you and you complete the Project PHARM Personalized Feedback Study Survey, you may be randomly selected (e.g., like flipping a coin) to receive web-based personalized information about your prescription stimulant use and use of other substances, motivations for using, perceived and actual norms for prescription stimulant, marijuana, and alcohol use, and academic behaviors, in five separate components spaced two days apart. The information you provide for this study may help our research team evaluate the usefulness of these 5 components.

STUDY PROCEDURES

Participation in this research is completely voluntary and confidential. You can stop participation at any time for any reason. If you choose to participate, here is what will happen:

The survey will be conducted over the internet. You will be asked to read and acknowledge this information statement. If you agree to participate, we will ask you to fill out a 15 minute online Eligibility Survey to evaluate whether the study is right for you. All participants that complete the Eligibility Survey will receive a $10 Amazon.com gift card. If you are not eligible for this study, we may contact you if there are any future research opportunities available. If you are eligible and choose to participate, you will be notified and asked to continue your participation by taking the Project PHARM Personalized Feedback Study Survey. This survey will take up to 45 minutes to complete. The first 1,050 participants that are eligible and complete the survey will receive an additional $20 Amazon.com e-gift certificate. All Amazon.com e-gift certificates will be emailed within one week of submitting the survey. You will only be eligible to receive the e-gift certificates after submitting your survey responses at the end of the survey.

After submitting your survey, you may be randomized (e.g., like flipping a coin) to receive the web-based personalized feedback tool on prescription stimulant use. If you are randomized to receive the personalized feedback tool, you will immediately be shown the first component of five individual components of the web-based feedback tool. Each component should take no more than 10 minutes to view. You will receive an additional 4 components of the feedback tool spaced two days apart. Following each component, you will be asked to complete a brief 5 minute post-feedback questionnaire about the information you just received. You will receive an additional $3 Amazon.com e-gift certificate

for completing each of these post-feedback questionnaires and participants that complete all 5 of the post feedback questionnaires will receive an additional $5 Amazon.com e-gift certificate for a total of up to $20 for completing this phase of the study. If you are randomized to the control condition, you will receive some information on resources available to you following the survey. Regardless of which condition you are in, we will contact you to complete two additional surveys approximately 6 months and 12 months from now. The content will be similar to the first survey and you will receive a $20 and $25 Amazon.com e-gift certificate for completing each of these surveys.

To begin your participation in the study, all you will need to do is click on the button below marked "I agree". You will then be taken to the Eligibility Survey. To ensure your confidentiality, please make sure that you are accessing the survey from a private location and do not share your personalized identification number (PIN) with anyone. After completing the survey, the first 1,050 will receive a confirmation for the e-gift certificate emailed to the account you specified in the survey within one week.

We will contact you with email reminders to complete the study up to 8 times if you do not decline or complete your participation (you can opt out of the study at any time). In addition, you may receive phone calls from our study staff reminding you to complete the survey. We may leave you a voicemail message if we are able to confirm your identity from your personal voicemail message. If you log on and complete part of your survey, but do not finish your survey, the data you provided will be retained unless you request that it be deleted from the study.

The survey will ask you to report on your use of the following medication: ADHD prescription stimulant medication (e.g., Ritalin, Dexedrine, Adderall, Concerta, methylphenidate), pain medication (i.e., opioids such as Vicodin, OxyContin, Tylenol 3 with codeine, Percocet, Darvocet, morphine, hydrocodone, oxycodone), sleeping medication (e.g., Ambien, Halcion, Restoril, temazepam, triazolam), and sedative/anxiety medication (e.g., Ativan, Xanax, Valium, Klonopin, diazepam, lorazepam). In addition, you will be asked questions about your mood and your use or non-use of alcohol, marijuana and other illicit drug use. If you report consuming a dangerous amount of alcohol or report potentially dangerous patterns of other substance use, we may follow-up with you via email and/or phone call to provide you with some information about resources available to you as well as information on alcohol poisoning. Some of the most personal and sensitive questions included in the survey ask about your use of prescription medications and include items such as:

- Over the last 2 weeks, how often have you felt down, depressed or hopeless?
- Has a friend or relative or anyone else ever expressed concern about your non-medical use of prescription stimulants?
- Have you ever tried and failed to control, cut down, or stop using prescription opioids non-medically?
- How often during the past 6 months have you been asked by another student to sell or give them your ADHD prescription stimulant medication?
- How often during the past 6 months have you sold or given another student your ADHD prescription stimulant medication?

RISKS, STRESS, OR DISCOMFORT

While there are no known physical risks of participating in research of this kind, participants may be exposed to both emotional and social risks. More specifically, some of the questions included in the survey may be rather sensitive in that they relate to thoughts, feelings, and personal experiences that may be deemed private. Other questions will relate to personal behaviors such as alcohol use and drug use. These questions may make you feel uncomfortable, bring back unpleasant memories, or be perceived as an intrusion on your privacy. Additionally, although we are unable to completely rule out the possibility of a technical mishap involving the loss of confidentiality, as we note below, every precaution will be taken to ensure your privacy, and that your name will not be directly connected with your survey responses. Loss of confidentiality could be a risk if identifiable responses were accessed by someone other than the research team members. See CONFIDENTIALITY OF RESEARCH INFORMATION section below.

BENEFITS OF THE STUDY

There may be no direct benefit to you for your participation. However, you may benefit from receiving the web-based personalized feedback tool and may gain increased self-knowledge, as well as a greater understanding of your prescription stimulant use and other substance use behavior. The knowledge gained from this study may also benefit future college students. Accordingly, as a participant, you may indirectly benefit, knowing that by participating in this research, you played a role in shaping programs and interventions designed to prevent and reduce the misuse of prescription stimulants.

SOURCE OF FUNDING

This study is funded by the National Institute on Drug Abuse (NIDA).

CONFIDENTIALITY OF RESEARCH INFORMATION

We have taken steps to protect you from the risks mentioned above. Participation in this research is voluntary, and you are free to skip over any questions you do not want to answer or to stop participating at any time. All of your data will be kept confidential. **Data storage and security:** The data will be coded in such a way that no names will be directly linked with any strand of data (names and identification numbers will be kept separate and will be electronically secured). For online collection of data, participants will log into a secured server (site certificate provided by Digital Fortress, Inc.) with an individual PIN created solely for this study. Data transfer will be protected via a Secure Socket Layer with 128-bit encryption and offers a high level of security (this level is used for most banking transactions). The server itself is physically located in a secure commercially protected co-location facility with 24-hour locked and monitored key-card access within a locked room, with a locked server rack, with a locking faceplate protecting the server itself from non-authorized physical access. Electronic protection is provided by a commercial-grade firewall with continuous monitoring for attempts at electronic invasion. All data stored in the online repository will remain encrypted using the official Advanced Encryption Standard (AES) algorithm with a 128-bit key length. Additionally, name and contact information for participants will be entered and stored separately from research data in a password protected database accessible only by research project staff. All information will be encrypted to further ensure confidentiality. **Access to Identifiers:** The password to the account will only be known to the PIs and Project Coordinator. Access to the master list that links study IDs with participant name/address information will be restricted to study personnel on a need-to-know basis, via password and encryption. All study personnel will sign a confidentiality agreement which is maintained throughout the life of the study and renewed on an annual basis. **After the Study:** The master list with identifying names and other information will be deleted from the server 1 year after the completion of the study, on or before 6/30/2021.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have obtained a federal Certificate of Confidentiality from the National Institutes of Health (NIH). This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;

- individuals at the University of Washington, University of Maryland, the University at Albany, SUNY, or the funding agency, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- the appropriate authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

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

OTHER INFORMATION

Your involvement in this research is completely voluntary. You may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make you feel uncomfortable, with no penalty, nor any impact on your academic standing, record, or relationship with the university or other organization or service that may be involved with this research. You need not complete any survey in one sitting. You may log back onto the secure study website using your personalized survey link and pick up where you left off. If a survey is deemed incomplete, our automated system will remind you to complete it so that you will receive your payment.

RESEARCH-RELATED INJURY

If you become concerned about your use of prescription stimulant or opioid medications, alcohol, or other drugs, experience discomfort as a result of participation, or experience a medical problem or illness related to this research, you can contact the investigators below right away.

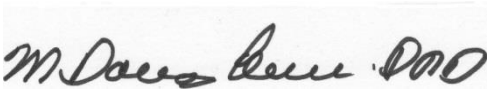
- Dr. Kilmer (206-685-4512; jkilmer@uw.edu).
- Dr. Cimini (518-442-5800; dcimini@albany.edu).

They will talk with you about any problems you are experiencing as a result of your participation and can provide you with a referral for treatment in your area. In addition, you are free to participate in other programs such as support groups, treatment, therapy, etc. while involved in the study.

If you would like to participate, please indicate your consent below. If you have questions about the study or wish to withdraw your participation at any time, you should contact the main study office at 206-685-1499, or email us at phrm2015@uw.edu.

Jason Kilmer, Ph.D., UW Co-Principal Investigator

Amelia Arria, Ph.D., UMD Co-Principal Investigator



M. Dolores Cimini, Ph.D., UAlbany Co-Principal Investigator

Participant's statement:

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later on about the research, or if I feel I have been harmed as a result of my participation, I can contact one of the investigators listed above. If I have questions about my rights as a research subject, I can call the UW Human Subjects Division at (206) 543-0098, the UMD Institutional Review Board at (301) 405-4212, or the UAlbany Office of Regulatory & Research Compliance at (518) 437-3850.

○ I accept. I want to participate in this study.

○ I do not accept. (If you wish to return and participate later, simply close this window).

You may print a copy of this information for your personal records. To print, please click the button below. If you do not print this information now, but decide later that you would like a copy of this document, you can get one by contacting the principal investigator.

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