**Title of the Research Study:**

**Predicting AOD Relapse and Treatment Completion from Social Media Use**

**Protocol Number: 821616**

**Principal Investigator:**

**Brenda Curtis, Ph.D.**

**3440 Market Street, Suite 370**

**Philadelphia, PA 19104;**

**215-746-7306;**

**bcurtis@mail.med.upenn.edu**

**Emergency Contact:**

**(215) 662-6059 (after 5PM and on weekends)**

**Ask for Psychiatry Department Resident On Call**

You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends, family doctor and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

**WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?**

The University of Pennsylvania is doing a study looking at social media use to better understand risk factors, attitudes, and behaviors associated with relapse and dropout in alcohol and drug treatment. About 1,000 patients will take part in this study.

**WHY AM I BEING ASKED TO VOLUNTEER?**

We are asking you to be in this study because:

* You are a patient at this outpatient drug treatment center.
* You have an active social media account (Facebook and/or Twitter)

You cannot be in this study if:

* You are under 18 years of age.
* You are not currently enrolled in drug treatment.
* You are not an active social media users (Facebook and/or Twitter)
* You cannot understand this consent form.

**WHAT AM I BEING ASKED TO DO?**

Your part in this study will take about six months. If you agree to be in this study, we will ask you to:

* **Complete interviews and surveys** that ask about your health, mental health, education, family, drug and alcohol use, risky behaviors (e.g. partner violence), and use of other services (e.g. housing, employment). We will ask you to complete these today. It will take you about 1 hour to do this. You will also be asked to complete short weekly online surveys on a secure server that will require a unique ID code to gain access. These weekly surveys will take about 2 minutes to complete. You will receive a reminder each week to complete the survey through the platform of your choice, including: Facebook or Twitter private message, SMS text, email, or another platform you prefer. A link to the online survey will be included in your weekly reminder message. The reminder will say: "Please take your weekly health survey (link to survey). After completion, please call 215-746-7720 to discuss payment options." Overall, you will be asked to complete these weekly surveys 26 times (for about 6 months). If you do not complete the weekly online survey we will contact you by phone to answer the questions you missed. If you are incarcerated in the next 6 months, we will not ask you to complete any surveys while you are incarcerated.
  + - * **Give our research staff your contact information.** We will ask for your addresses, phone numbers, and the contact information of family and friends who know how to find you. We will use this information in the event that you do not complete the weekly online survey. This will take about 10 minutes to complete today.
* **Allow your treatment center to share information from your medical chart** with the research team. This information includes your name, treatment entry dates, clinic discharge statuses and dates, the last date of services received, and the results of any urine drug tests done while you were in treatment.
* **Allow access to your social media accounts:** We will ask you to allow research staff to access information in your Facebook and/or Twitter accounts. You will need to sign up for an application on Facebook, which will prompt you to give us permission to access your Facebook data. The prompt lists the specific data which includes any information on your Facebook profile such as your education, hometown, interests, friends, statuses on your wall, etc. We will show you how to sign up for the application and give us access. After you accept the application, you may be provided with two separate word clouds: one based on language used in your status updates and one based on language associated with your interests, likes, work history, and education listed on their profile. We will also ask for your Twitter handle. We will use this to access your tweets, number of followers, people you are following, and your profile information. We will collect social media data until 26 weeks after admission. We will send you a message through the platform of your choice alerting you when your participation in the study is complete.

**Will I be paid for being in this study?**

You will receive $30 for completing the interview today with the research staff. You will receive $4 for completing each weekly survey. We will provide you with a GreenPhire ClinCard, gift card or cash. The total amount that you can earn for being in this study is $134. We will not be collecting participants’ social security numbers. Please call 215-746-7720 to receive your payments (this number will also be provided at the end of each completed online survey.)

**WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?**

You will experience no direct benefits from participating in this study.

**WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?**

This is considered a minimal risk study. There are two potential risks that might happen to you.

* **Certain parts of this study may make you feel uncomfortable. You may feel uncomfortable or experience distress during the interview and surveys.** **Participation may increase your awareness of your drug and/or alcohol use, which may cause you to feel distressed or uncomfortable.**
* The research staff members are trained to assist in dealing with difficult feelings. If you feel uncomfortable at any time, please let us know and we will talk to you about it.
* If you feel uncomfortable when answering questions, you can ask to take a break. You can also choose to not answer any question.
* You may also drop out of the study at any time and not affect your care at this center.
* **Risk to Your Confidentiality.** We keep the information that we collect from you in this study private. Although it is unlikely, it is possible that others may learn that you are in this study or about information you tell us. We will take the following steps to reduce any chance that this would happen:
* The interviews and surveys that you complete for this study will not have anything on them that can identify you. Instead, we will use a research number for all of these. All study materials are kept in locked filing cabinets or are stored on a secure computer system. Only University of Pennsylvania research staff will be able to access these forms and use this system. What you say in the interviews and on the surveys will not be shared with your counselor or anyone else at the center.
* Any information that includes your name (like this form and your contact form) will be kept in a locked cabinet separate from your interviews and surveys. Only staff working with the University of Pennsylvania on this study will have access to these forms. These forms will be destroyed three years after the study is over.
* We will also protect your privacy when you complete your weekly surveys. The information collected from the weekly surveys will be stored on the University of Pennsylvania’s secure server.
* If we must reach you over the phone, we state that we are from a health survey. University of Pennsylvania staff will not mention this study until we know that it is you on the telephone.
* The risks involved in allowing the research team access to your Facebook profile and wall postings and/or to your Twitter tweets are no greater than the risk involved in daily activities such as posting information on Facebook or tweeting on Twitter. However, we consider this information to be sensitive and private—especially if it could be combined with health information. Your social media information will be kept secure and confidential and separate from any identifiable health information. In order to reduce the likelihood that your participation in this research study could be linked to your social media use, we have taken the following measures:
* We will never post to your Facebook or Twitter accounts and we will not send any “Friend” request. This helps eliminate the possibility that others will know you are participating in this research study.
* We will use a unique ID number to access your Facebook account—not your Facebook user id. This unique ID number cannot be traced back to you.
* We use two computer systems to obtain your social media data: one that downloads data from your social media accounts and one that stores the downloaded data. This data is downloaded and stored with a unique ID, not your Facebook user id or Twitter user id. In addition, neither of these computer systems will have your name attached to the data.
* The computer systems are secured by an SSL encryption. Additionally, these servers are protected by two firewalls.

We do recommend that you read the Facebook privacy protection guidelines that allow you to personalize your privacy settings. Personalizing your privacy settings enables you to control who can see or interact with your posts on the site. For more information go to: <https://www.facebook.com/policy.php>

**WILL I HAVE TO PAY FOR ANYTHING IF I PARTICIPATE IN THIS STUDY?**

* If you choose to have us send you weekly reminders via SMS text message, message and data rates may apply from your mobile phone company and you will be responsible for these charges.

**WHAT INFORMATION ABOUT ME MAY BE COLLECTED, USED OR SHARED WITH OTHERS?**

* Locator information (your name, address, and telephone number; additional contact names and telephone numbers)
* Demographic information (e.g., sex, race, age)
* Answers on forms and questionnaires regarding your health, mental health, education, family, drug and alcohol use, risky behaviors, and additional treatment services
* Clinic Medical Records (your name, your primary and secondary substances of abuse, treatment entry date, clinic discharge status and date, last date of service, and the results of any urine drug tests done while you were in treatment)

**WHY IS MY INFORMATION BEING USED?**

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

* do the research
* oversee the research
* see if the research was done right

**WHO CAN SEE OR USE MY INFORMATION?**

**The following individuals may use or share your information for this research study:**

* The Principal Investigator and the Investigator’s study team (other Penn staff associated with the study)
* The Penn Institutional Review Board (the committee whose job it is to protect the safety and privacy of research subjects)
* The City of Philadelphia Department of Public Health Institutional Review Board

**Who, outside of the School of Medicine, might receive my information?**

* The National Institutes of Health (the institution which sponsors this research and provided funds to the Treatment Research Institute to conduct this research)
* The Office for Human Research Protections (OHRP) (the federal agency that oversees the safety of research studies)
* Any other investigators conducting similar research. This information would be provided without identifying information so that other investigators would not have your name or any information that would allow you to be identified.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

**How long may the School of Medicine use or disclose my personal health information?**

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

* You have given written authorization
* The University of Pennsylvania’s Institutional Review Board grants permission
* As permitted by law

**HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

The information that you share with us will be kept private.

* The interviews and surveys you complete will not include any information that can identify you.
* Only research staff for this study will have access to your research forms. We will not include your name or anything else that can identify you in any publication, presentation, or grant application.
* This research study has a Certificate of Confidentiality from the U.S. Government. This helps so that researchers with this study do not have to give out information that says who you are (even under a court order). However, the Certificate of Confidentiality will not protect ALL your information from being subpoenaed. For example, your cell phone records could be subpoenaed from your phone company or your social media data from Facebook or Twitter for reasons unrelated to this study. You can tell others that you are in this study if you want. If you give someone written consent to receive your research information, then we cannot use the Certificate to refuse to give this information.

**Exceptions to Confidentiality.** There are certain times when we will break our privacy agreement. The Certificate of Confidentiality does not prevent us from voluntarily disclosing these things without your consent:

* If you tell us that you have been abusing a minor or an elder, then we will report this to the appropriate authorities.
* We will also break your privacy if study staff determines (or you tell us) that you present a serious threat of harm to yourself or someone else. We will also break our privacy agreement if you have a medical emergency. Finally, if we think that your safety is at risk, we will break your privacy and talk to your counselor.

**WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?**

You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

**WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?**

We will collect data until you are 26 weeks post admission but you may leave the study at any time, without penalty. If you decide to leave the study, you will still receive regular treatment from your treatment program. If you want to leave the study, please contact Brenda Curtis either by phone, 215-746-7306, or by letter (at the address listed at the top of the first page of this form).

Also, you may withdraw your permission allowing the research team to use and share your personal health information/study data at any time by contacting the Principal Investigator, Brenda Curtis, Ph.D., at 215-746-7306. If you withdraw your permission for the research team to use and share your study data, the Principal Investigator will destroy all records in the research files connecting your identity with the data. If you withdraw your permission to use your personal health information/study data that means you will also be withdrawn from this research study.

**REASONS FOR REMOVAL FROM STUDY:**

University of Pennsylvania research staff may remove you from the study for the following reasons:

* If you are in jail or prison, University of Pennsylvania research staff will not contact you.
* If you begin having medical or mental health issues that prevent you from being in the study, research staff will remove you from the study.
* If the study is stopped for any reason.

**WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?**

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Your Name *(please print)* Date

Your Signature Date

Name of Person Obtaining Authorization Date

Signature of Person Obtaining Authorization Date