COMPOUND AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE
DEPARTMENT OF PSYCHIATRY

AND

SUBSTANCE ABUSE TREATMENT UNIT (SATU)
CONNECTICUT MENTAL HEALTH CENTER

Title: Targeting self-regulatory deficits through cognitive remediation intervention
Principal Investigator: Arielle Baskin-Sommers, PhD
Study Sponsor: National Institute on Drug Abuse

Invitation to Participate and Description of Project

You are invited to participate in a research study evaluating a computer learning program for people with alcohol or substance use problems. You have been invited because you are seeking treatment for an alcohol or substance use problem at this clinic.

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study that a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

This study will last for 4 weeks. If you are willing to participate in the study and sign the consent form, you will be interviewed by a member of the research team, asked to fill out questionnaires (this should take about 3 hours), and provide a urine and breath specimen for drug and alcohol testing. These questions will include information on your current drug use and drug use history, as well as drug-related problems you may be having.

You will then be assigned to one of two treatments. We will decide what treatment you will receive by random selection. This means that your treatment will be decided by luck of the draw and not selected deliberately because of any special characteristics or problems you have. Each participant will be assigned by random selection to <u>one</u> of the two following treatments:

1). Standard treatment *plus* active control
This is the same as the treatment you would normally receive at this clinic. This will be tailored to your needs, but generally includes individual or group sessions and regular urine monitoring. In addition, you will complete a series of computerized word games. You will also be asked to complete a brief questionnaire and to provide urine and breath specimens for drug and alcohol each time you come to the clinic. Staff will be available at all times while you are using the program at the clinic if you have any concerns or questions about the training sessions. This will take about 35 minutes each time.

OR

2). Standard treatment *plus* cognitive remediation
In addition to the same treatment you would normally receive at this clinic, as described above, you will play computerized games that focus on learning and decision making. Staff will be available at all times while you are using the program at the clinic if you have any concerns or questions about the computer program. You will be asked to complete a brief questionnaire about your drug use since we last saw you and to provide urine and breath specimens for drug and alcohol testing each time you come to the clinic. This part will take about 35 minutes.

Assessments

At the end of the 4 weeks you will be asked to fill out more questionnaires, provide a urine and breath specimen for drug and alcohol testing, and be interviewed again: this will take about 1 hour. Again, these questions will focus on your current drug use and any drug-related problems you may be having. At the end of this part of the study, you may continue treatment at this clinic, or if you wish, be referred elsewhere or leave treatment.

We will ask you to provide the names and telephone numbers of several persons in your life who are likely to know your whereabouts, to help us locate you for interviews. These persons will be contacted only if we cannot locate you directly first; we will ask them only about where we may contact you (we will not ask about drug use or other problems); and we will not tell these persons any information about this study or your participation in it.

Risks and Inconveniences

We believe that there are very few risks to participating in this treatment. We would like you to tell us about any times you use alcohol or illegal drugs while you are in the study. It is not illegal to report past substance use. Also, we know that stopping alcohol or substance use can be quite difficult. In order to be helpful to you, we simply need to know about your alcohol or substance use. The urine drug tests and the breathalyzer tests for alcohol enables us to be certain of our results. The only way you might be dismissed from the study is if you repeatedly do not come to treatment or violate the rules of this clinical program. We would only ask that you do your best to stop using alcohol or drugs, be honest about yourself and your problems and to be available at your appointment times for both the research assistant and your counselor.

Further, we believe both cognitive remediation and the computerized control are safe since they have been used with similar populations in previous work. Thus, psychological risks appear to be minimal and not different from those of equivalent non-study psychotherapeutic interventions.

If you become uncomfortable for any reason or at any time in using the computer program, you should inform your counselor, the Research Assistant, or Dr. Baskin-Sommers immediately.

Benefits

There is no direct benefit from participating. This program may help you control your drug use; however, there is no guarantee that you will benefit from participating in this program. If the computer program is shown to be an effective treatment for alcohol or drug use, it may help other substance users stop taking drugs.

Economic Considerations

You will be paid $35 for completing the questionnaires at pretreatment, $10 for completing each training session two times per week, (thus a total of $80 for treatment part of the study), $35 at the end of study (week 4), and a $50 bonus if you complete all training sessions and all assessments and $50 for a follow up interview 1 month after the completion of treatment. Therefore, if you complete every component as scheduled you would be paid a total of $250.

If you leave the study prior to completing it, you will be paid only for those assessments you have completed.

Subject Compensation Schedule

Activity	Compensation Available	Form of Payment
Pretreatment	$35	Cash
Completing training sessions during 4 weeks	$80 Total (@ $10 a session)	Cash
Post (end of study, week 4)	$35	Cash
Bonus for completing all training and assessments	$50	Cash
Follow up at one month	$50	Cash
Total Available	$250	

Alternative Treatments

You are free to choose not to participate, and if you do become a subject, you are free to withdraw from the study at any time. If you withdraw it will not adversely affect your relationship with this clinic or the clinicians or doctors here. If you decide to withdraw, you will be referred to the regular evaluation and intake procedures and will receive treatment as usual at this clinic.

In case of injury

If you develop any mental or physical problems as a direct result of being in this study, we will refer you for treatment. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. Your legal rights are not waived by signing this consent form.

Confidentiality and Privacy

If you decide to take part in this research study, you will be required to give us information about your substance use. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities reportable diseases, known or suspected abuse of a child or elderly person, or if you become a danger to yourself or others. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator, Arielle Baskin-Sommers, PhD. will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. All personal information will be coded and stored in a locked cabinet and any data stored on a computer will be password protected to further protect your confidentiality. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for the 1 year follow up period after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form for a minimum of 3 years after the study has ended and then will be destroyed.

The information about your health that will be collected in this study includes:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Information obtained during this research about:

- Laboratory test results
- The diagnosis and treatment of a mental health condition

Information about you and your health, which might identify you, may be given to

- Yale New Haven Hospital (only in case of an audit)

- Yale University School of Medicine
- Graham Massey Laboratory (specimen lab used by SATU)
- National Institute of Health (NIH) (the research sponsor)
- Members of the Human Investigations Committee or ethics Committee(s)
- Key Investigators
- Key Study Personnel
- Data and Safety Monitoring Board and others authorized to monitor the conduct of the study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

The research team can only give information about you to others for research with your permission. We will make every effort to insure your confidentiality. In all records of the study you will be identified only by a number. Your name will not appear in any publication or be released to anyone without your written consent. However, you should understand that there is a risk that you will be recognized by other participants or staff involved in the study, but this is no greater than the usual risk of identification that occurs in our usual treatment in this clinic. If you find this risk unacceptable you should not sign this consent form.

If you decide to take part in this research study, you will be required to give us information about your substance use and we will test you for drug use. We will apply for a Certificate of Confidentiality (CoC) issued by the NIH. Once granted, the researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. When the CoC is obtained, we will inform all active study participants.

Because this research is sponsored by the Department of Health and Human Services through NIDA, staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

Voluntary Participation

You are free to choose not to participate, and if you do become a participant, you are free to withdraw from the study at any time. If you withdraw it will not adversely affect your relationship with this clinic or the clinicians or doctors here. If you decide to withdraw, We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.

Withdrawing From the Study

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments

The researchers may withdraw you from participating in the research if necessary only for not coming in for treatment or if you show signs of clinical deterioration and need more intensive care.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your clinician or anyone here, at SATU.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Arielle Baskin-Sommers, PhD; 2 Hillhouse Avenue; New Haven, Connecticut 06511. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

Please feel free to ask about anything you do not understand and please consider this research and the consent form carefully before you decide whether or not to participate. You may take as much time as necessary to think it over.

SUMMARY

This is a study looking at the effects of adding a computerized gaming, to standard treatment at this clinic. Individuals who participate will be assigned by random assignment (luck of the draw) to either standard treatment *plus* active control at this clinic or standard treatment *plus* cognitive remediation. The study will last four weeks. You will be asked to complete some forms and answer some questions before beginning treatment (this will take about 3 hours), each time you come to the clinic (this will take about 35 minutes each time), and at the end of the 4 weeks (this will take about 1 hour).

Authorization and permission:

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

Name of Subject: _____

Signature:_____

Date:_____

_____ _____
Signature of Person Obtaining Consent Date

If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, Arielle Baskin-Sommers, PhD at 203 432-9257. If you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.