CONSENT FORM
Functional Connectivity Changes During Early Recovery as a Marker for Relapse

You are invited to participate in a research study designed to find out if there are structural or functional differences in the brains of people who use cocaine/amphetamines and participants who do not have this problem. You were selected as a possible participant because either you were referred to the study by your counselor, or you responded to a flyer asking for cocaine/amphetamine users to volunteer to be in a study that involves completing a psychological assessment and a brain scan. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Kelvin O. Lim, M.D from the Department of Psychiatry at the University of Minnesota.

Background Information:
The purpose of this study is to examine whether there are structural or functional differences in the brains of individuals who use cocaine or amphetamines in contrast to individuals who have never used cocaine or amphetamines. This study will allow us to examine the interaction between cocaine/amphetamines and impulsivity (meaning to act on impulse rather than thought) in a number of ways. People who are overly impulsive may be unable to curb their immediate reactions or think before they act. It is hoped that by discovering such differences further studies can be done to allow us to develop more effective treatments for cocaine and amphetamine abuse. This study, however, is not a treatment study. You were selected as a possible participant in this study because you are currently in treatment for cocaine or amphetamine use.

Procedures:
If you agree to participate in this study, research staff from the University of Minnesota will meet with you at three separate points in time during your treatment. The first will be within 3 to 7 weeks of your sobriety (Timepoint 1), and then again 30 days (Timepoint 2) later and 60 days (Timepoint 3 later. At each timepoint you will undergo a clinical and behavioral assessment and a brain scan. Clinical and behavioral assessments will be conducted at your treatment facility and the brain scans will be at the University of Minnesota Center for Magnetic Resonance Research (CMRR) building which is located at 2021 6th Street SE in Minneapolis. If you are not in residential care and it is more convenient to you, Timepoint 2 and Timepoint 3 assessment visits may occur at the University of Minnesota. A saliva and/or urine drug screen will be obtained at each session. A breathalyzer will be used to screen for alcohol use at each session. Details of procedures conducted at each timepoint are as follows:

1. Assessments: You will take part in an interview about psychiatric or emotional problems you may have had. Additionally, you will fill out a number of rating scales that ask you about the severity of certain psychological and emotional symptoms you may have experienced. There will also be questions that ask about your stimulant drug use. Some of these questions may be upsetting and you are free to skip questions that you don't feel you can answer. You will also be asked about the medications you are currently taking or have taken in the past. Finally, a neuropsychological assessment will be performed where you will be asked to complete a number of computerized neuropsychological tests. This will take approximately four hours and will be completed over two sessions. Once it is determined that you are eligible, an MRI

brain scan will be scheduled.

2. MRI Brain Scan: If you are selected to continue in the study, you will undergo a brain scan at the Center for Magnetic Resonance Research (CMRR) located at the University of Minnesota campus. The brain scan will take about 90 minutes. In preparation for these measurements you will be asked to empty your bladder and change into scrubs. Once you are in the scanner, you will be asked to lay still in the same position for the duration of the MRI pictures (about one hour). We will make you as comfortable as possible. Cushions will be placed under your head and neck to make you more comfortable and to help you stay still while we take the pictures. Other forms of support such as a knee cushion and a lumbar support will be provided both to increase comfort and to minimize movement. As it can be a little cool in the scanner room a blanket will be provided upon request. To help protect your hearing you will be required to wear ear plugs and/or head phones while we take the pictures.
3. You will return for Timepoint 2 (30 days) and Timepoint 3 (60 days later) to repeat one assessment session and an MRI Brain Scan.
4. After the Timepoint 3 visits you will be contacted by phone once a month (for a 9-month period) to query relapse status. We will ask you to share with us the phone number of a good friend or relative who always will know your whereabouts to help us in re-contacting you in case you move or change your phone number.

Timepoint	**Procedures**	**Time**	**Participant Compensation**
Timepoint 1 (Baseline)	Assessment 1a Assessment 1b MRI Brain Scan 1	2 hours 2 hours 1.5 hours	$25 $25 $25
Timepoint 2 (30 days)	Assessment 2 MRI Brain Scan 2	2 hours 1.5 hours	$40 $40
Timepoint 3 (60 days)	Assessment 3 MRI Brain Scan 3	2 hours 1.5 hours	$60 $60
Months 4, 5, 7, 8, 9, 10, 11	Follow-up Phone Calls	15 minutes	$10 gift card each month
Month 6	Follow-up Phone Call and Online Surveys	30 minutes 25 minutes	$25 gift card
Month 12	Follow-up Phone Call and Online Surveys	35 minutes 25 minutes	$40 gift card

Risks and Benefits of Being in the Study:
The MRI machine used in this study uses a strong magnet (3 Tesla field strength) and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an

x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

The risks associated with MRI scans are:

- Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and we control access to the scanner. Your personal items will be stored securely during your participation. Additionally, you will want to avoid bringing any credit card, driver's license, cassettes or watches into the scanning area as the magnetic field may damage these articles.
- Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.
- Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.
- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. These symptoms are expected, but if it is uncomfortable please notify the investigator.
- Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device, notify the investigator.
- Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.
- The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.
- There is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. You will be asked to remain very still for a long period of time (up to 90 minutes) and you may become stiff during this time. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

This study has the additional following risks.

- Some of the questions in the psychiatric interview may make you feel anxious or uncomfortable as they are of a personal nature. You may refuse to answer any of the questions that make you uncomfortable.
- There are certain privacy risks that are also associated with the nature of this study. Confidential information is disclosed throughout the interview process. Therefore, a potential risk is the release of confidential information.

If at any time it is clear that you are too uncomfortable with the interview, the neurological assessment, the brain scan, or the investigator becomes concerned about your physical and mental health, we will discontinue the study.

If at any time during these assessments you become excessively distressed or otherwise need access to mental health resources, the clinicians involved in the study with meet with you. Thus, therapists will be available to provide emergency mental health service.

Email/text communication risks: You may opt in or out to receive communication via email. There is also some loss of privacy that may happen as a result of communicating via email, and these risks increase when messages are sent without a security technology called encryption.

Examples of these risks may include but are not limited to the following:

- Others can intercept messages
- If you receive messages on an employer-owned device, your employer may have the right to save and read you messages. Your Internet service provider may also have the right to save and read your messages.
- A copy of a message may be saved on your device or a computer system, even if you delete it.
- If an email address is not entered correctly, the message can be sent to the wrong person.
- Emails can be used to spread computer viruses
- Others may be able to access messages on a device that was lost, stolen, or thrown away.
- If your email address changes, we will not know unless you notify us.

We will try as much as possible to prevent this from happening by using a university-owned device to communicate with you. We will save emails that are sent to our email addresses or study phone as part of your study record. We will protect your emails and as we do with any other records. You should think about the risks before sending emails with sensitive information (such as information about health conditions and symptoms). You do not have to use email communication to participate in this study. You may choose whether or not to provide us your email address below.

If you decide to use the standard unencrypted email, you will be asked to sign the Unsecure Email Authorization form. If you change your mind about communicating via unencrypted email, please notify a study staff.

Benefits to Participation:
There is no direct benefit to you to participate in this study. Learning more about brain function in stimulant use disorder recovery could aid in directing recovery treatment in the future.

Incidental Findings:
The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your pictures. The investigator, Dr. Kelvin Lim or his designated staff person, will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

Compensation:
You will receive $25 for each session at Timepoint 1 ($75), $40 for each session at Timepoint 2 ($80) and $60 for each session at Timepoint 3 ($120). You will receive $10 (months 4, 5, 7, 8, 9, 10 and 11), $25 (month 6) and $40 (month 12) for the monthly follow-up phone visits that you complete (up to $135 value). The total amount of potential compensation for participation in this study is $410.00.

You will receive payment at the completion of each study visit either with cash or a pre-paid debit card called Greenphire ClinCard.

The Greenphire ClinCard works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

You will be provided with transportation via a commercial transportation service to and from study visits as needed. If you are in a residential facility, we will offer meals when visits overlap with the treatment program meal time. You will not be charged for any transportation or meals that we provide.

You will not be charged for any of the procedures or tests completed as part of this study. Your

treatment center may have a policy that you may not hold any money during your treatment. In this case, the money you are paid for the study will be logged in as part of your belongings and will be paid out to you upon your discharge form your treatment center.

Research Related Injury:
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality:
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Information received for the purpose of this study will not be entered into your permanent medical record. There will be no one reviewing the records for the study other than the investigators and research personnel involved in the study. However, the records may be examined by persons with regulatory authority to assure that the study is conducted properly. To that extent, confidentiality is not absolute.

We have additionally obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges. However, appropriate authorities will be notified if we become aware or have reason to believe that you are at risk to harm yourself or others.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Your health information (PHI) created or received for the purpose of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study:
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:
The researcher conducting this study is Dr. Kelvin O. Lim. You may ask any questions you have now. If you have questions later, you may contact Dr. Lim at (612) 273-9800 or kolim@umn.edu. This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research.

Permission for Optional Email Communication:
The following optional research activity is for future re-contact, meaning that you do not have to agree to it in order to participate in the research study. Please indicate your willingness to participate in this optional activity by placing your initials in the box next to the activity.

Yes, I agree	No, I disagree	
		I give the study staff permission to communicate with me using unencrypted email.

Email Address: _____

You will be given a copy of this form to keep for your records. You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate.

Statement of Consent:
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject:_____ Date:_____

Printed Name of Subject:_____ Time of day: _____

Signature of Person
Obtaining Consent:_____ Date:_____

Printed Name of Person
Obtaining Consent: _____ Time of day: _____

CONSENT FORM
Functional Connectivity Changes During Early Recovery as a Marker for Relapse

You are invited to participate in a research study designed to find out if there are structural or functional differences in the brains of people who use cocaine/amphetamines and participants who do not have this problem. You were selected as a possible participant because you responded to a flyer or an advertisement asking for healthy volunteers to be in a study that involves completing a psychological assessment and a brain scan. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Kelvin O. Lim, M.D from the Department of Psychiatry at the University of Minnesota.

Background Information:
The purpose of this study is to examine whether there are structural or functional differences in the brains of individuals who use cocaine or amphetamines in contrast to individuals who have never used cocaine or amphetamines. This study will allow us to examine the interaction between cocaine/amphetamines and impulsivity (meaning to act on impulse rather than thought) in a number of ways. People who are overly impulsive may be unable to curb their immediate reactions or think before they act. It is hoped that by discovering such differences further studies can be done to allow us to develop more effective treatments for cocaine and amphetamine abuse. This study, however, is not a treatment study. You were selected as a possible participant in this study because you are a healthy volunteer.

Procedures:
If you agree to participate in this study, research staff from the University of Minnesota will meet with you at two timepoints 60 days apart. At each timepoint you will undergo clinical and behavioral assessments and a brain scan. Clinical and behavioral assessments will be conducted at 717 Delaware Street Research Building in Minneapolis and the brain scans will be at the University of Minnesota Center for Magnetic Resonance Research (CMRR) building which is located at 2021 6th Street SE in Minneapolis. A saliva and/or urine drug screen will be obtained at each session. A breathalyzer will be used to screen for alcohol use at each session. Details of procedures conducted at each timepoint are as follows:

1. Assessments: You will take part in an interview about psychiatric or emotional problems you may have had. Additionally, you will fill out a number of rating scales that ask you about the severity of certain psychological and emotional symptoms you may have experienced. There will also be questions that ask about drug or alcohol use. Some of these questions may be upsetting and you are free to skip questions that you don't feel you can answer. You will also be asked about the medications you are currently taking or have taken in the past. Finally, a neuropsychological assessment will be performed where you will be asked to complete a number of computerized neuropsychological tests. This will take

approximately four hours and will be completed over two sessions. Once it is determined that you are eligible, an MRI brain scan will be scheduled.

2. MRI Brain Scan: If you are selected to continue in the study, you will undergo a brain scan at the Center for Magnetic Resonance Research (CMRR) located at the University of Minnesota campus. The brain scan will take about 90 minutes In preparation for these measurements you will be asked to empty your bladder and change into scrubs. Once you are in the scanner, you will be asked to lay still in the same position for the duration of the MRI pictures (about one hour). We will make you as comfortable as possible. Cushions will be placed under your head and neck to make you more comfortable and to help you stay still while we take the pictures. Other forms of support such as a knee cushion and a lumbar support will be provided both to increase comfort and to minimize movement. As it can be a little cool in the scanner room a blanket will be provided upon request. To help protect your hearing you will be required to wear ear plugs and/or head phones while we take the pictures.

3. You will return 60 days later for Timepoint 2 to repeat one assessment and an MRI Brain Scan.

Session	Procedures	Time	Participant Compensation
Timepoint 1 (Baseline)	Assessment 1a Assessment 1b MRI Brain Scan	2 hours 2 hours 1.5 hours	$25 $25 $25
Timepoint 2 (60 days)	Assessment 2 MRI Brain Scan	2 hours 1.5 hours	$40 $40

Risks and Benefits of Being in the Study:
The MRI machine used in this study uses a strong magnet (3 Tesla field strength) and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

The risks associated with MRI scans are:

- Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and we control access to the scanner. Your personal items will be stored securely during your participation. Additionally, you will want to avoid bringing any credit card, driver's license, cassettes or watches into the scanning area as the magnetic field may damage these articles.
- Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.
- Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.
- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.
- Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.
- Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

- The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

- There is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. You will be asked to remain very still for a long period of time (up to 90 minutes) and you may become stiff during this time. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify

the researcher right away and your participation will stop and you will be taken out of the magnetic field.

This study has the additional following risks.

- Some of the questions in the psychiatric interview may make you feel anxious or uncomfortable as they are of a personal nature. You may refuse to answer any of the questions that make you uncomfortable.

- There are certain privacy risks that are also associated with the nature of this study. Confidential information is disclosed throughout the interview process. Therefore, a potential risk is the release of confidential information.

If at any time it is clear that you are too uncomfortable with the interview, the neurological assessment, the brain scan, or the investigator becomes concerned about your physical and mental health, we will discontinue the study.

If at any time during these assessments you become excessively distressed or otherwise need access to mental health resources, the clinicians involved in the study with meet with you. Thus, therapists will be available to provide emergency mental health service.

Email/text communication risks: You may opt in or out to receive communication via email. There is also some loss of privacy that may happen as a result of communicating via email, and these risks increase when messages are sent without a security technology called encryption.

Examples of these risks may include but are not limited to the following:

- Others can intercept messages
- If you receive messages on an employer-owned device, your employer may have the right to save and read you messages. Your Internet service provider may also have the right to save and read your messages.
- A copy of a message may be saved on your device or a computer system, even if you delete it.
- If an email address is not entered correctly, the message can be sent to the wrong person.
- Emails can be used to spread computer viruses
- Others may be able to access messages on a device that was lost, stolen, or thrown away.
- If your email address changes, we will not know unless you notify us.

We will try as much as possible to prevent this from happening by using a university-owned device to communicate with you. We will save emails that are sent to our email addresses or study phone as part of your study record. We will protect your emails and as we do with any other records. You should think about the risks before sending emails with sensitive information (such as information

about health conditions and symptoms). You do not have to use email communication to participate in this study. You may choose whether or not to provide us your email address below.

If you decide to use the standard unencrypted email, you will be asked to sign the Unsecure Email Authorization form. If you change your mind about communicating via unencrypted email, please notify a study staff.

Benefits to Participation:
There is no direct benefit to you to participate in this study. Learning more about brain function in stimulant use disorder recovery could aid in directing recovery treatment in the future.

Incidental Findings:
The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your pictures. The investigator, Dr. Kelvin Lim or his designated staff person, will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

Compensation:
You will receive $25 for each session at Timepoint 1 ($75) and $40 for each session at Timepoint 2 ($80). The total amount of potential compensation for participation in this study is $155.00. You will not be charged for any of the procedures or tests completed as part of this study.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your

information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Research Related Injury:
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality:
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Information received for the purpose of this study will not be entered into your permanent medical record. There will be no one reviewing the records for the study other than the investigators and research personnel involved in the study. However, the records may be examined by persons with regulatory authority to assure that the study is conducted properly. To that extent, confidentiality is not absolute.

We have additionally obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges. However, appropriate authorities will be notified if we become aware or have reason to believe that you are at risk to harm yourself or others.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Your health information (PHI) created or received for the purpose of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study:
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Contacts and Questions:
The researcher conducting this study is Dr. Kelvin O. Lim. You may ask any questions you have now. If you have questions later, you may contact Dr. Lim at (612) 273-9800 or kolim@umn.edu.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about

your research experience, call the Research Participants' Advocate Line at 612-625-1650 or (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants.. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Permission for Optional Email Communication:
The following optional research activity is for future re-contact, meaning that you do not have to agree to it in order to participate in the research study. Please indicate your willingness to participate in this optional activity by placing your initials in the box next to the activity.

Yes, I agree	No, I disagree	
		I give the study staff permission to communicate with me using unencrypted email.

Email Address: _____

You will be given a copy of this form to keep for your records. You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate.

Statement of Consent:
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject: _____ Date:_____

Time of day: _____

Printed Name of Subject:_____

Signature of Person
Obtaining Consent:_____ Date:_____

Time of day: _____

Printed Name of Person
Obtaining Consent: _____

Eye CT Consent Form
Functional Connectivity Changes During Early Recovery as a Marker for Relapse

If you have been a metal worker or had metal in your eyes, we need to check for metal in your eyes before you can do an MRI study. You cannot be in this study if you are a minor or if you are pregnant. Women of child bearing potential will undergo a pregnancy test. If you do not have metal in your eyes, you might qualify for the MRI study designed to find out if there are structural or functional differences in the brains of people who use cocaine/amphetamines and participants who do not have this problem. While you have already signed the consent form for the whole study, we are asking you to review this additional consent form because you know that you have had metal in your eye(s) and/or have worked as a metal worker. We are asking you to read this form and ask any questions you may have before agreeing to have a CT of your eyes.

This study is being conducted by Kelvin O. Lim, M.D. from the Department of Psychiatry at the University of Minnesota. It is funded by National Institutes of Drug Abuse.

Study Purpose The purpose of the CT study is to check for metal fragments in your eyes.

Study Procedures To participate in this study you will lie still in the CT scanner for about 5 minutes. You might not be eligible if you have participated in any other study within the past 12 months. You are responsible for informing the investigator of such involvement before you have this CT.

Risks of Study Participation As part of this study you may undergo one CT scan of the head. This procedure involves exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from this procedure is less than 20% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv). This exposure involves minimal risk and is necessary to obtain the research information desired.

Benefits of Study Participation There are no direct benefits to participation as this is strictly for an experiment.

Alternatives to Study Participation If you already had an x-ray or CT that cleared you for metal in eyes, you could give us those results instead of having another scan.

Study Costs/Compensation We do not expect you to incur any costs from this study. You will be given $10 to compensate for time and inconvenience.

Research Related Injury In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by the Center for Magnetic Resonance Research (CMRR) personnel, by departments at the National Institutes of Health and University of Minnesota

Institutional Review Board with appropriate regulatory oversight and as required by law. When the CT images are given to the radiologist over the internet, they will be encrypted according to current University policy for protection of confidentiality. To these extents, confidentiality is not absolute.

Protected Health Information (PHI) Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions The researcher conducting this study is Kelvin O. Lim. You may ask any questions you have now, or if you have questions later, you are encouraged to contact Dr. Lim at (612) 273-9800 or kolim@umn.edu.

This research has been reviewed and approved by an Institutional Review Board (IRB) within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to www.irb.mn.edu/report.html. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

You will be given a copy of this form to keep for your records. You are making a decision whether or not to participate. Your signature indicates that you have read the information provided above and have decided to participate.

Statement of Consent I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject _____ Date_____

Printed Name of Subject _____

Signature of Person Obtaining Consent _____ Date_____

Printed Name of Person Obtaining Consent _____