Children's Hospital Los Angeles

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

fMRI Pilot Study:
The Effects of Very Brief Exposure on PTSD in U.S. Combat Veterans
Control Participants

Subject's Name:	
CHLA medical record #:	Birth Date:

KEY INFORMATION

You are being asked to participate in a research study. This section describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide the details of the research.

What should I know about this research?

- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

Participation will last approximately 4 hours over 2 days.

Why is this research being done?

This research is being done to find out whether a larger study to develop a new treatment for PTSD will be feasible.

What happens to me if I agree to take part in this research?

Study procedures for this research are:

- Complete an interview about your background, thoughts, behavior, and emotions that you may or may not have experienced.
- Take pictures of your brain using an MRI machine.
- During the scanner, you will be asked to view various stimuli and report if you saw something and if so, what it was. The stimuli that you will likely be able to see will be pictures of combat.
- If you are female, you will be asked to give a urine sample to determine if you are pregnant prior to the scan.
- You will be asked to view combat and neutral images on a computer screen and provide various rating scores.

Could being in the research hurt me?

The most likely risks or discomforts that you may expect from taking part in the research are:

- Feeling uncomfortable answering personal questions about yourself
- Feeling uncomfortable lying still in the MRI machine
- Feeling uncomfortable viewing the combat images

Please see the **POSSIBLE RISKS AND DISCOMFORTS** section for a complete list of expected risks.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research.

INTRODUCTION
You are invited to join a research study led by Bradley Peterson, M.D. from the Institute for the Developing Mind at Children's Hospital Los Angeles (CHLA). This research is paid for by the American Psychoanalytic Association (APsaA) and the International Psychoanalytic Association (IPA). You are invited to join this study because you are either a combat veteran with PTSD or a healthy control participant. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
This study is being done to learn more about how fear works in the brain and whether a larger study for PTSD treatment is feasible. The information from the research will be used to help develop a new behavioral treatment for U.S combat veterans with PTSD in the future.

NUMBER OF PARTICIPANTS
40 combat veterans with PTSD and 40 healthy control subjects will be asked to take part in this study at CHLA.

LENGTH OF PARTICIPATION
Your participation in the study will last approximately 4 hours over 2 days.

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

- **Interview:** We will ask you to complete an interview about your background, thoughts, behavior, and emotions.
    - The interview will include sensitive questions, such as your alcohol and drug use, and any thoughts of harming yourself that you may have had.
    - You may refuse to answer any of these questions if you feel uncomfortable.
    - The interview will take approximately 1 hour to complete at the beginning of the study visit.
- **MRI Scanning:** One MRI scan will be completed for this study.
    - The total time of the MRI scan will be approximately 55 minutes (with short breaks every 10 minutes or less during which you will remain in the scanner. However, the length of the scans can vary depending on your comfort level.
    - During the second part of the scan, you will be asked to do some simple things like maintaining your focus on a large "X." Then an image will flash that you will either be able or not be able to see. The images that you will likely be able to see will be scenes from combat. You will be asked to report if you saw something and if so, what

you saw. Every 15 seconds, a rating screen will appear, and you will rate your level of fear.

- Before entering the scanning unit, you will be asked questions about the possible presence of electronic and metal objects with you. The strong magnet field (3 Tesla) in the scanner can cause electronic devices like pacemakers, beepers, and watches to malfunction, and some metal objects can be pulled into the magnet. If you do have an electronic device (i.e., a pacemaker), there is a risk that the device may stop working. If you have metal in or on your body (the type of iron or steel that is attracted to a magnet) then there is a risk that the metal may move or be dislodged. You will be asked to remove all metallic objects (i.e., a watch or jewelry) before entering the scanning unit. If you are unable to remove metal objects or devices, you may not be scanned. Be sure to tell us if you know or think you have a pacemaker or other metallic implant. Please note that medicinal patches may have conductive properties. If you are currently using medicinal patches, you will be asked to remove the patch prior to scanning procedures.
- A member of the research team will explain the MRI procedure in detail before the scan and will be present throughout the scan. MR scanning requires that a person remain very still during the time that the pictures are taken. For the MRI scan, you will lie on a padded table that moves into a doughnut-shaped magnet. You are unlikely to feel any discomfort, although the magnet is noisy during the scan. This noise you will hear is knocking or buzzing sounds. This is the magnet taking pictures. We will give you ear plugs to block most of the noise; however, you will be able to hear us giving you directions. The technologist operating the scanner and a member of the research team will be able to see you, and voice contact will be maintained throughout the scan.

- **MRI Results:** While MRI scans are sometimes done for clinical purposes, the brain MRI scans that you will have as part of this study are for research purposes only. However, the scans will be read by a neuroradiologist for evidence of any abnormalities requiring follow-up. You have the option of receiving the results of the research MRI scans. You can receive the normal results, abnormal results, or both results. Given the nature of the scans, the absence of a finding does not mean that one is not present.
- **Pregnancy Test:** If you are female, you will be asked to give a urine sample to determine if you are pregnant prior to the scan. You are being asked to take a pregnancy test because MRI has not been definitely proven to be safe or unsafe during pregnancy. You will be told the results of the pregnancy test. If the results are positive, you will be unable to participate in the study. The test will take about 10 minutes.
- **Stimulus Rating:** Participants will be asked to view both combat images and neutral images on a computer screen, one at a time. You will be asked to rate how pleasant-unpleasant, arousing-non-arousing, and how distressing each image is.
-

POSSIBLE RISKS AND DISCOMFORTS

- **Interview: It** is possible that you could feel embarrassed or uncomfortable about questions that you are asked as part of the study. If this occurs, you can choose to skip or stop answering any questions that make you feel uncomfortable. Study staff will make every effort to ask these questions in a sensitive and supportive manner.

- **MRI Scans:** Except for people who have pacemakers, medicinal patches and some types of metallic implants, there are no known health hazards from the MRI scan. The MRI scan is not painful but lying still on the scanning table may be slightly uncomfortable. Sometimes people say that during the MRI scan, they feel a funny "tingling" feeling (or, very rarely, a little painful feeling). Also, some people feel nervous when they are inside the scanner because they do not like being in a small space. If you have any uncomfortable feeling, or if you get nervous while you are in the MRI scanner, tell a member of the study team, and we will stop the scan immediately. Despite these experiences, no one has had sensations from the scanning that did not stop as soon as the scanning stopped. You may stop the experiment at any time. If you are caused significant distress by the scan, you will be referred to a mental health professional.
    - While you are in the scanner, you will be asked to remain focused on a large X in the middle of the screen. Then a stimulus will flash that you will either be able or not be able to see. The stimuli that you will likely be able to see will be scenes from combat. You may experience some fear/anxiety at those times. At no point will you be in danger, and the fear/anxiety will pass shortly after the task ends. Every 15 seconds, a rating screen will appear so that you can tell us how much fear you are experiencing. To minimize any fear, a series of unrecognizable stimuli will be presented after each series of visible stimuli.
- **Stimulus viewing:** The stimuli that you will likely be able to see will be scenes from combat. You may experience some fear/anxiety at those times. At no point will you be in danger, and the fear/anxiety will pass shortly after the task ends. To minimize any fear, a series of unrecognizable stimuli will be presented after each series of visible stimuli.
- **Confidentiality**: As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).
- **Additional Risks:** There may be additional risks of being in this study that we do not know about and therefore cannot describe.

POSSIBLE BENEFITS TO SUBJECTS

You will not directly benefit from participation in this study. Participation in this study is purely for research purposes and will not improve your health or treat any medical problem or condition you may have.

POSSIBLE BENEFITS TO SOCIETY

This study may help the researchers learn more about a potential new and effective treatment for combat-induced PTSD. Hopefully this information will help in the treatment of future patients with PTSD, phobias, and a wide range of other fear- and trauma-related conditions in a variety of clinical populations.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY

This is not a treatment study. The alternative is to not participate.

COSTS TO YOU FOR BEING IN THIS STUDY

Participants are not responsible for any of the costs involved in the study. Neither you nor your insurance company will be billed for your participation in this research.

You are responsible for other costs which may result from your participation in the study, such as time off work, car fare, food purchased while at the hospital, etc.

REIMBURSEMENT FOR YOUR EXPENSES
You will be reimbursed for transportation if you provide a receipt. Reimbursement will be provided to you in cash.

PAYMENT FOR PARTICIPATION
To thank you for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows:

- Up to $225total for the in person and at home tasks:
    - $75 for completed diagnostic interviews
    - $125 for the fMRI
    - $25 for post-scan tasks and interviews

Participant payment will be in the form of cash or a gift card and given directly to you after the completion of the study visit. You will also be provided with parking validation.

RESEARCH INJURY
If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The study doctor's name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.

CONFIDENTIALITY
The data collected as part of this study will be "coded." Coded means that the data will be assigned a unique code or study ID. Your research data will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data.

People on the research team will know that you are a research subject. All results will be kept confidential.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

- The CHLA Institutional Review Board (IRB) reviewed this research, and authorized representatives of CHLA.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use

the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- voluntary disclosure by researchers of information on such things as child or elder abuse, reportable communicable diseases, or possible threat to self or others.

A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

FUTURE RESEARCH USE OF DATA

Your data collected as part of this study may be used by the researcher conducting this study or by other researchers (at CHLA or elsewhere) for future research projects that are related or unrelated to the purpose of this study. The data will be labeled with a unique code or Study ID. The link connecting your identity to your study ID will be kept by the research team at CHLA. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

STUDY WITHDRAWAL

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected from you up to that point will remain part of the study and may not be removed from the study database.

QUESTIONS ABOUT THE STUDY

If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, Dr. Bradley Peterson, at 323-361-6456 or email at brainimaginglab@chla.usc.edu

Evenings, nights, weekends or holidays you may call 323-660-2450 ask for the Psychiatry Service doctor on-call.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. 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.

This research is being overseen by the CHLA Institutional Review Board ("IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

RIGHTS OF RESEARCH SUBJECTS

You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from CHLA.
- If you decide not to take part, you can still receive medical care from CHLA.
- You will be given a copy of this signed and dated consent form and the "Experimental Subject's Bill of Rights" to keep.
- You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.

OPTIONAL PROCEDURES

Would you like to be provided with the results of your research MRI scan? Please provide your initials beside your decision.

_____Yes _____No [Subject]

SUBJECT

Your signature below indicates:

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your participation in this research study; and
- You will be given a signed copy of this form.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- You were present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject;
- The subject had an opportunity to ask questions and those questions were answered; and
- The subject voluntarily signed the consent form in your presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date

Children's Hospital Los Angeles

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

fMRI Pilot Study:
The Effects of Very Brief Exposure on PTSD in U.S. Combat Veterans
Combat Veteran Participants

Subject's Name:			
CHLA medical record #:		Birth Date:	

KEY INFORMATION

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- If you don't want to take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask the research team questions.
- Ask all the questions you want before you decide.

How long will I be in this research?

Participation will last approximately 4 hours over 2 days. You will also receive a short follow-up phone call or e-mail (whichever you prefer) at months 1, 3, and 6 after your MRI.

Why is this research being done?

This research is being done to find out whether a larger study to develop a new treatment for PTSD will be feasible.

What happens to me if I agree to take part in this research?

Study procedures for this research are:

- Complete an interview about your background, thoughts, behavior, and emotions that you may or may not have experienced.
- Take pictures of your brain using an MRI machine.
- During the scanner, you will be asked to view various stimuli and report if you saw something and if so, what it was. The stimuli that you will likely be able to see will be pictures of combat.
- If you are female, you will be asked to give a urine sample to determine if you are pregnant prior to the scan.
- You will be asked to view combat and neutral images on a computer screen and provide various rating scores.

- You may also be asked to view stimuli images on a computer at home on 5 consecutive days and provide rating scores.

Could being in the research hurt me?
The most likely risks or discomforts that you may expect from taking part in the research are:

- Feeling uncomfortable answering personal questions about yourself
- Feeling uncomfortable lying still in the MRI machine
- Feeling uncomfortable viewing the combat images

Please see the **POSSIBLE RISKS AND DISCOMFORTS** section for a complete list of expected risks.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research.

INTRODUCTION
You are invited to join a research study led by Bradley Peterson, M.D. from the Institute for the Developing Mind at Children's Hospital Los Angeles (CHLA). This research is paid for by the American Psychoanalytic Association (APsaA) and the International Psychoanalytic Association (IPA). You are invited to join this study because you are either a combat veteran with PTSD or a healthy control participant. Participation in this study is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to be in the study.

PURPOSE OF THE STUDY
This study is being done to learn more about how fear works in the brain and whether a larger study for PTSD treatment is feasible. The information from the research will be used to help develop a new behavioral treatment for U.S combat veterans with PTSD in the future.

NUMBER OF PARTICIPANTS
40 combat veterans with PTSD and 40 healthy control subjects will be asked to take part in this study at CHLA.

LENGTH OF PARTICIPATION
Your participation in the study will last approximately 4 hours over 2 days. You will also receive a short follow-up phone call or e-mail (whichever you prefer) at months 1, 3, and 6 after your MRI.

PROCEDURES
If you volunteer to be in this study, we will ask you to do the following things:

- **Interview:** We will ask you to complete an interview about your background, thoughts, behavior, and emotions.
    - The interview will include sensitive questions, such as your alcohol and drug use, and any thoughts of harming yourself that you may have had.
    - You may refuse to answer any of these questions if you feel uncomfortable.
    - The interview will take approximately 1 hour to complete at the beginning of the study visit.
- **MRI Scanning:** One MRI scan will be completed for this study.

- The total time of the MRI scan will be approximately 55 minutes (with short breaks every 10 minutes or less during which you will remain in the scanner. However, the length of the scans can vary depending on your comfort level.
- During the second part of the scan, you will be asked to do some simple things like maintaining your focus on a large "X." Then an image will flash that you will either be able or not be able to see. The images that you will likely be able to see will be scenes from combat. You will be asked to report if you saw something and if so, what you saw. Every 15 seconds, a rating screen will appear, and you will rate your level of fear.
- Before entering the scanning unit, you will be asked questions about the possible presence of electronic and metal objects with you. The strong magnet field (3 Tesla) in the scanner can cause electronic devices like pacemakers, beepers, and watches to malfunction, and some metal objects can be pulled into the magnet. If you do have an electronic device (i.e., a pacemaker), there is a risk that the device may stop working. If you have metal in or on your body (the type of iron or steel that is attracted to a magnet) then there is a risk that the metal may move or be dislodged. You will be asked to remove all metallic objects (i.e., a watch or jewelry) before entering the scanning unit. If you are unable to remove metal objects or devices, you may not be scanned. Be sure to tell us if you know or think you have a pacemaker or other metallic implant. Please note that medicinal patches may have conductive properties. If you are currently using medicinal patches, you will be asked to remove the patch prior to scanning procedures.
- A member of the research team will explain the MRI procedure in detail before the scan and will be present throughout the scan. MR scanning requires that a person remain very still during the time that the pictures are taken. For the MRI scan, you will lie on a padded table that moves into a doughnut-shaped magnet. You are unlikely to feel any discomfort, although the magnet is noisy during the scan. This noise you will hear is knocking or buzzing sounds. This is the magnet taking pictures. We will give you ear plugs to block most of the noise; however, you will be able to hear us giving you directions. The technologist operating the scanner and a member of the research team will be able to see you, and voice contact will be maintained throughout the scan.

- **MRI Results:** While MRI scans are sometimes done for clinical purposes, the brain MRI scans that you will have as part of this study are for research purposes only. However, the scans will be read by a neuroradiologist for evidence of any abnormalities requiring follow-up. You have the option of receiving the results of the research MRI scans. You can receive the normal results, abnormal results, or both results. Given the nature of the scans, the absence of a finding does not mean that one is not present.
- **Pregnancy Test:** If you are female, you will be asked to give a urine sample to determine if you are pregnant prior to the scan. You are being asked to take a pregnancy test because MRI has not been definitely proven to be safe or unsafe during pregnancy. You will be told the results of the pregnancy test. If the results are positive, you will be unable to participate in the study. The test will take about 10 minutes.
- **Stimulus Rating:** Participants will be asked to view both combat images and neutral images on a computer screen, one at a time. You will be asked to rate how pleasant-unpleasant, arousing-non-arousing, and how distressing each image is.

- **At-home Computer Task:** Some combat veteran participants will be asked to view the same stimuli previously shown in the MRI and complete short questionnaires at home. You may do so on 5 consecutive days using either a desktop or laptop computer that you have at home by logging into one of our computing servers. If you do not have a home computer, we will loan you one for the duration of the study. Each at-home computer task is 20 minutes long.
- **Follow up**: Research staff will call or email you (whichever you prefer) at month 1, 3, and 6 after your MRI. We will ask if you have received any mental health treatment or service since your participation in the study.
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POSSIBLE RISKS AND DISCOMFORTS

- **Interview: It** is possible that you could feel embarrassed or uncomfortable about questions that you are asked as part of the study. If this occurs, you can choose to skip or stop answering any questions that make you feel uncomfortable. Study staff will make every effort to ask these questions in a sensitive and supportive manner.
- **MRI Scans:** Except for people who have pacemakers, medicinal patches and some types of metallic implants, there are no known health hazards from the MRI scan. The MRI scan is not painful but lying still on the scanning table may be slightly uncomfortable. Sometimes people say that during the MRI scan, they feel a funny "tingling" feeling (or, very rarely, a little painful feeling). Also, some people feel nervous when they are inside the scanner because they do not like being in a small space. If you have any uncomfortable feeling, or if you get nervous while you are in the MRI scanner, tell a member of the study team, and we will stop the scan immediately. Despite these experiences, no one has had sensations from the scanning that did not stop as soon as the scanning stopped. You may stop the experiment at any time. If you are caused significant distress by the scan, you will be referred to a mental health professional.
    - While you are in the scanner, you will be asked to remain focused on a large X in the middle of the screen. Then a stimulus will flash that you will either be able or not be able to see. The stimuli that you will likely be able to see will be scenes from combat. You may experience some fear/anxiety at those times. At no point will you be in danger, and the fear/anxiety will pass shortly after the task ends. Every 15 seconds, a rating screen will appear so that you can tell us how much fear you are experiencing. To minimize any fear, a series of unrecognizable stimuli will be presented after each series of visible stimuli.
- **Stimulus viewing:** The stimuli that you will likely be able to see will be scenes from combat. You may experience some fear/anxiety at those times. At no point will you be in danger, and the fear/anxiety will pass shortly after the task ends. To minimize any fear, a series of unrecognizable stimuli will be presented after each series of visible stimuli.
- **Confidentiality**: As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality may occur. The researchers have procedures in place to lessen the possibility of this happening (see the CONFIDENTIALITY section below for details).
- **Additional Risks:** There may be additional risks of being in this study that we do not know about and therefore cannot describe.

POSSIBLE BENEFITS TO SUBJECTS
You may benefit from participation in this study by experiencing a reduction in PTSD symptoms. However, participation in this study is purely for research purposes..

POSSIBLE BENEFITS TO SOCIETY
This study may help the researchers learn more about a potential new and effective treatment for combat-induced PTSD. Hopefully this information will help in the treatment of future patients with PTSD, phobias, and a wide range of other fear- and trauma-related conditions in a variety of clinical populations.

YOUR OPTIONS IF YOU CHOOSE NOT TO BE IN THIS STUDY
This is not a treatment study. The alternative is to not participate.

COSTS TO YOU FOR BEING IN THIS STUDY
Participants are not responsible for any of the costs involved in the study. Neither you nor your insurance company will be billed for your participation in this research.

You are responsible for other costs which may result from your participation in the study, such as time off work, car fare, food purchased while at the hospital, etc.

REIMBURSEMENT FOR YOUR EXPENSES
You will be reimbursed for transportation if you provide a receipt. Reimbursement will be provided to you in cash.

PAYMENT FOR PARTICIPATION

- To thank you for your time participating in this research, the study team would like to offer you payment. The payments for participation are as follows: : $75 for completed diagnostic interviews
- $125 for the fMRI
- $25 for post-scan tasks and interviews
- $50 bonus for completing all three aspects of the study (diagnostic interviews, fMRI, and post-scan tasks)

In total, you can earn up to $275 from participating in this study,

- If you are asked to complete the at-home exposure task and questionnaires, you will receive an additional $50, In total, participants who complete this task will receive up to $325 from participating in this study.

Participant payment will be in the form of cash or a gift card and given directly to you after the completion of the study visit. You will also be provided with parking validation.

RESEARCH INJURY
If you think you have been hurt by taking part in this study, tell the doctor in charge of this research study as soon as possible. The study doctor's name and phone number are provided in this consent form. CHLA will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer.

CONFIDENTIALITY
The data collected as part of this study will be "coded." Coded means that the data will be assigned a unique code or study ID. Your research data will not include your name or any other identifying information about you. The code that could be linked back to your identifying information will be kept separate from your research data.

People on the research team will know that you are a research subject. All results will be kept confidential.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you. Your private information, data and medical records will be shared with individuals and organizations that oversee this research, including:

- The CHLA Institutional Review Board (IRB) reviewed this research, and authorized representatives of CHLA.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

FUTURE RESEARCH USE OF DATA
Your data collected as part of this study may be used by the researcher conducting this study or by other researchers (at CHLA or elsewhere) for future research projects that are related or unrelated to the purpose of this study. The data will be labeled with a unique code or Study ID. The link connecting your identity to your study ID will be kept by the research team at CHLA. This future research may be done without consulting you or obtaining consent (permission) for this additional use.

STUDY WITHDRAWAL
The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected from you up to that point will remain part of the study and may not be removed from the study database.

QUESTIONS ABOUT THE STUDY
If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team:

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call the CHLA Principal Investigator, Dr. Bradley Peterson, at 323-361-6456 or email at brainimaginglab@chla.usc.edu

Evenings, nights, weekends or holidays you may call 323-660-2450 ask for the Psychiatry Service doctor on-call.

ClinicalTrials.gov is a Web site that provides information about federally and privately supported clinical trials. 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.

This research is being overseen by the CHLA Institutional Review Board ("IRB"). An IRB is a group of people who perform ethical review of research studies. You may talk to them at (323) 361-2265, or hspp@chla.usc.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

RIGHTS OF RESEARCH SUBJECTS
You can agree to take part in this study and stop your participation in the study anytime. You should not sign this form if you have any questions that have not been answered or if you are unclear about any information in this form.

Your participation in the study is entirely voluntary. If you choose not to take part in the study or decide to stop your participation in this study at any time, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to leave the study after agreeing to participate, you should let the Principal Investigator know.

You will be told about any new information found during the course of the study that may affect your health, welfare, or choice to stay in the research. If this happens, you might be asked to sign a new consent form.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from CHLA.
- If you decide not to take part, you can still receive medical care from CHLA.
- You will be given a copy of this signed and dated consent form and the "Experimental Subject's Bill of Rights" to keep.
- You will be asked to sign a separate CHLA HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information.

OPTIONAL PROCEDURES

Would you like to be provided with the results of your research MRI scan? Please provide your initials beside your decision.

_____Yes _____No [Subject]

SIGNATURE OF RESEARCH SUBJECT

Your signature below indicates:

- You have read this document and understand its meaning;
- You have had a chance to ask questions and have had these questions answered to your satisfaction;
- You consent to your participation in this research study; and
- You will be given a signed copy of this form.

_____
Print Name of Subject

_____ _____
Signature of Subject Date

SIGNATURE OF INDIVIDUAL OBTAINING CONSENT

I have explained the research to the subject and have answered all of their questions. I believe that they understand all of the information described in this document and freely give consent to participate.

_____
Print Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date

SIGNATURE OF WITNESS (if applicable)

Your signature below indicates:

- You were present for the entire consent conference;
- The information in the consent document and any other written information was accurately explained to the subject;
- The subject had an opportunity to ask questions and those questions were answered; and
- The subject voluntarily signed the consent form in your presence.

_____
Print Name of Witness

_____ _____
Signature of Witness Date