CONSENT FORM

Are you participating in any other research studies? _____ yes _____no

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug or device's safety and its effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your personal doctor have a great deal of freedom in making decisions about your health care. When you are a research subject, the Protocol Director and the research staff will follow the rules of the research study as closely as possible, without compromising your health.

PURPOSE OF RESEARCH

You are invited to participate in a research study of early counseling to prevent trauma-related problems. We hope to learn how better to help trauma survivors by comparing different approaches to brief counseling. You were selected as a possible participant in this study because you experienced or witnessed a traumatic event in the last 2 years and are experiencing some distress as the result of the event.

Your participation in this study is entirely voluntary. Your decision whether or not to participate will not prejudice you or your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice to you or effect on your medical care. If you decide to terminate your participation in this study, you should notify Dr. Josef Ruzek at (650) 493-5000, extension 22977.

This research study is looking for approximately 60 trauma survivors from the San Francisco Bay Area.

DURATION OF STUDY INVOLVEMENT

You as an individual may be involved for up to approximately 6 months.

PROCEDURES

If you decide to participate, we will ask you to complete an assessment on 3 occasions, once before counseling begins, once at the end of counseling, and

once about 6 months after the initial assessment. The first and last assessments will each take about 120 minutes to complete, and will include an interview about various aspects of your medical, psychiatric, drug and alcohol use, and social history, and about your reactions to the event, and paper and pencil questionnaires measuring symptoms of traumatic stress, depression, anxiety, physical reactions, reactions to your anxiety, trauma-related beliefs, social support, trauma history, alcohol and drug use, coping, social adjustment, talking to others about what happened, daily activities, and quality of life. The assessment at the end of counseling will take about 30 minutes to complete and will include only the paper and pencil questionnaires. The interviews will be videotaped and/or audiotaped so that they can be reviewed by study staff at a later point. No one outside the project is permitted to view or listen to these tapes. If necessary, the interviews can be completed by phone and the questionnaires can be completed either by telephone or by mail.

If based on the initial interview assessment, you are judged to have concerns that would be better treated by broader mental health or substance abuse services than can be offered through our focal trauma clinic, you will be offered a referral to services in the community.

Based on the initial assessment, you may be offered from 1-20 sessions of individual counseling. The number and focus of the counseling sessions will be determined by you and the counselor you are working with, and will be based on the severity and types of difficulties you are experiencing. All counseling sessions will be videotaped and/or audiotaped. This is done to make sure all procedures are being adhered to. These tapes will be viewed only by members of the research team. No one outside the project is permitted to view these tapes. Before each counseling session, you will be asked to complete 2 brief questionnaires, which will take approximately 5 minutes. If necessary, some of the counseling sessions can be conducted by telephone.

The focus on the counseling sessions may include talking about what happened to you, learning anxiety reduction methods, reviewing your beliefs about what happened, beginning to face your memories by talking about them in counseling, making assigned trips to some of the real world situations that are now causing you anxiety in order to become less afraid, and helping you keep functioning well

by maintaining contact with other people, finding social support, participating in positive distracting activities, problem-solving difficult challenges, and reviewing your alcohol and drug use. In addition, they may focus on learning ways to maintain safety, manage anger, relax and control anxiety, and manage grief about losses you experienced.

SUBJECT'S RESPONSIBILITIES

Your responsibility is to complete the questionnaire/interview assessments and to participate in counseling sessions.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors. This is to protect you from possible distress or confusion from being involved in other kinds of treatment.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your condition and you will not lose any benefits to which you would otherwise be entitled. If you wish to withdraw from the study, you should notify Dr. Josef Ruzek at (650) 493-5000, extension 22977.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and/or study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. In the assessment process, it is possible that you may experience some distress as you are reminded of what happened to you. In counseling, the process of therapy may increase your distress over the short term, especially if your counseling involves talking in detail about your traumatic experience. The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in this consent form, we do not intend to disclose this information.

POTENTIAL BENEFITS

You may also experience some benefits from participation. You may learn to understand your stress reactions better, learn more about coping, be less isolated from others, and experience some reduction of distress.

WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

ALTERNATIVES

Your alternative to participating in this study is to not participate. Other forms of counseling and support are available in the community, although usually for a fee.

SUBJECT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You will not lose any benefits to which you would otherwise be entitled. You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Your research records may be disclosed outside of Palo Alto University/Pacific Graduate School of Psychology, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to research study personnel.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

FINANCIAL CONSIDERATIONS

You will not be paid to participate in this research study. There is no financial cost to you of participating in this project.

CONTACT INFORMATION

- Appointment Contact: If you need to change your appointment, please contact Josef Ruzek, Ph.D., at 650-493-5000, extension 22977, or Matthew Cordova, Ph.D., at 650-759-6939.
- Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this **research study**, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Josef Ruzek, Ph.D. You may contact him now or later at 650-493-5000, extension 22977.
- Emergency Contact: If you feel you have been hurt by being a part of this study, or need immediate assistance please contact Josef Ruzek, Ph.D., at 650-493-5000, extension 22977, or Matthew Cordova, Ph.D., at 650-759-6939.
- Independent of the Research Team Contact: If you are not satisfied with the manner in which this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a research study subject, please contact the IRB Chair by mail at

  Palo Alto University, Pacific Graduate School of Psychology, 1791 Arastradero Road, Palo Alto, CA 94304, or by phone at (650) 433-3827.

COMPENSATION

All forms of medical diagnosis and treatment -- whether routine or experimental -- involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. Additionally, Pacific Graduate School of Psychology is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a human subject you have the following rights. These rights include but are not limited to the subject's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;

- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- and be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

*YOUR SIGNATURE INDICATES THAT THIS STUDY HAS BEEN EXPLAINED TO YOU BY DR. RUZEK, DR. CORDOVA, OR THE RESEARCH TEAM WORKING WITH THEM, THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PERSON OBTAINING CONSENT, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU. QUESTIONS ABOUT YOUR RIGHTS AS A PARTICIPANT IN THIS STUDY MAY BE PRESENTED TO THE IRB CHAIR BY MAIL AT PALO ALTO UNIVERSITY, PACIFIC GRADUATE SCHOOL OF PSYCHOLOGY, 1791 ARASTRADERO ROAD, PALO ALTO, CA 94304, OR BY PHONE AT (650) 433-3827.

_____ _____
Signature of Adult Participant Date

_____
Social Security #

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the subject has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the subject and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the subject to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date