STANFORD UNIVERSITY Research Consent Form

Protocol Director: Katie Fracalanza, PhD. EP 48109

Protocol Title: Efficacy and Feasibility of Intensive Imaginal Exposure for Hoarding Disorder

CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Katie Fracalanza at (650) 725-3438 or our research team at (650) 497-2577

PURPOSE OF RESEARCH

You are invited to participate in a research study investigating the relationship between writing and difficulties with discarding. We are interested in whether writing in a specific manner benefits people with difficulty discarding, as the writing strategy that we are investigating has benefitted people with worry about various topics in prior research.

This research study will compare two types of writing: potentially therapeutic writing and neutral writing (control group). A control group is used in research studies to see if the results are due to the strategy being examined, or other reasons. You will have a 50% chance to receive either potentially therapeutic writing or neutral writing. Whether you receive potentially therapeutic writing or neutral writing will be decided by chance (like a coin flip). After the study is completed you will receive a document describing the potentially therapeutic writing strategy, so you will have this information no matter what writing group you are in.

This research study is looking for 30 adults with hoarding disorder. You were selected as a possible participant in this study because you reported having difficulty with clutter that is affecting your life. Before you choose whether or not to participate, it is important for you to understand why this research is being done, and what it will involve. You should take time to read the following information carefully and ask the study staff any questions that you may have about this research study. This study is completed remotely, and is run by researchers at Stanford University.

If you decide to terminate your participation in this study, please notify Tatevik Avanesyan at (650) 497-2577.

The Brain and Behavior Research Foundation is providing financial support for this study.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. 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 not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

Participant ID:

STUDY

DURATION OF STUDY INVOLVEMENT

This study will take 10 days to complete. The study will involve completing questionnaires 3 times – on Day 1, Day 3, and Day 10. These questionnaires are expected to take approximately 30 minutes to 1 hour each time. The study will also involve completing a writing task on each of Day 1, Day 2, and Day 3. The writing task will take 20 minutes each time. The total time commitment is expected to be approximately 3 to 4.5 hours.

PROCEDURES

Screening To determine whether you met the eligibility criteria for this study, you already completed a screen with study staff.

Overview of Study Procedures:

Overview: You are receiving this consent form because you already completed screening procedure and you are eligible to participate in this study. If you consent to participate in the present study, you will be sent an email link to begin completing study tasks on your computer. Once you begin, there will be tasks to complete on Day 1, Day 2, Day 3, and Day 10. These tasks must be completed within 24 hours of email links being sent for our team to be able to use your data, and to be eligible for compensation for completing all study tasks.

Day 1: You will be emailed links that will guide you through completing the following tasks on your computer: (1) An assessment made up of puzzles and games (testing through WebNeuro). (2) Questionnaires about your emotional experiences. (3) A writing exercise that you will be given instructions for, and you will write for 20 minutes. Day 1 tasks will take approximately 1 to 1.5 hours to complete. The link will be available to complete for 24 hours.

Day 2: One day after Day 1, you will be emailed a link to complete a writing exercise that you will be given instructions for, and you will write for 20 minutes. This will be the same writing exercise as you completed on Day 1. Day 2 will take about 20 minutes. The link will be available to complete for 24 hours.

Day 3: One day after Day 2, you will be emailed links that will guide you through completing the following tasks on your computer: (1) A writing exercise that you will be given instructions for, and you will write for 20 minutes. This will be the same writing exercise as you completed on Days 1 and 2. (2) Questionnaires about your emotional experiences. (3) An assessment made up of puzzles and games (testing through WebNeuro). Day 3 tasks will take approximately 1 to 1.5 hours. The link will be available to complete for 24 hours.

Day 10: One-week after visit 3, you will be emailed a link that will guide you through completing questionnaires about your emotional experiences, and questions about your experience with the writing task. Day 10 tasks will take about 30 minutes to 1 hour.

Notes:

Continued Participation Depends on Your Engagement with Study Tasks: Continued eligibility in this study depends on complying with the study instructions, including completing tasks sent via email within 24 hours and following writing instructions. After a writing task is submitted, it will be reviewed by our research team to determine if it complied with the writing instructions, including factors such whether the writing met the minimum word count requirements, and whether it included the content you were asked to write about. If a participant's writing exercise complies with the instructions, they will be eligible to continue participating in this study. If a participant's writing exercise does not meet the requirements, they will not be eligible to automatically proceed with the study. Depending on the availability of study resources, a participant may be given the option to re-do the writing exercise so that it complies with the instructions if they wish to continue participation.

Similarly, because this study examines 3 days in a row of writing, the tasks in the email links must be completed within 24 hours. If a participant does not complete tasks within the timeframe specified, they will not be eligible to automatically proceed with the study. Depending on the availability of study resources, a participant may be given the option to re-start all study tasks if a part of the study is not completed within the timeframe allotted.

Test Results: The results of the study testing will be used for research purposes only and you will not be told the results of the tests.

WebNeuro: In addition to be able to proceed with the testing through Webneuro, you will have to agree to the terms and conditions of Webneuro and these terms are separate from Stanford University and this consent form. Webneuro will be collecting your date of birth. If you decide to withdraw from the study you will not be withdrawn from Webneuro.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Completing study tasks within the allotted timeframe (e.g., within 24 hours of receiving an email link). If you are unable to complete a study task within the timeframe allotted, you may not be eligible for continued participation in the study. Please contact study staff to discuss your options.
- Complete your questionnaires and writing tasks as instructed. Study tasks will be reviewed for compliance with instructions. If study tasks submitted do not comply with instructions, you may not be eligible for continued participation in the study.
- Ask questions of study staff as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

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 study staff. This includes failure to follow writing instructions or not completing tasks within the allotted timeframe.
- 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.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There is minimal risk involved if you agree to take part in this study. You understand that you may experience some negative emotions when completing the tasks. You have the right to refuse or discontinue participation at any time. You may also chose to not answer any question(s) that you do not feel comfortable answering.

Protection Against Risk
We will ask you to provide information about a friend, family member, or primary doctor who will be your emergency contact.

If at any time during the study, you develop any serious thoughts about suicide or harming yourself, you should immediately contact 911 or go to the closest emergency room.

In some cases, you may be referred for emergency psychiatric evaluation and treatment at the nearest emergency department. You may be withdrawn from the study if emergency treatment is necessary.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, serious cognitive impairment, etc.) about your health and/or safety; in such a case, the researchers may contact you (and/or your emergency contact) and provide a referral for your care.

There may be other risks associated with participating in this study that are unknown.

Other Inconveniences
There may be inconveniences of time taken to complete study procedures.

POTENTIAL BENEFITS

We cannot and do not guarantee or promise that you will receive any benefits from this study. You may derive benefit from the self-assessment as it may increase your awareness of your emotions and behaviors. You may experience benefit from learning about a writing strategy that could potentially be helpful in working with difficulties discarding. You may also develop a better understanding of research methodology and will be providing researchers with valuable insight that could benefit others with difficulty discarding.

ALTERNATIVES

You do not have to participate in this study to receive treatment for hoarding disorder. Medicines called *Serotonin Reuptake Inhibitors* (SRIs) are available for the treatment of hoarding disorder. In addition, there is a form of therapy called *Cognitive Behavior Therapy*, which has been found to be effective in treating hoarding disorder. If you decide not to participate in this study, you may choose to be treated with one or more of these therapies (on your own), or not seek further treatment. If you wish, we can provide a list of other doctors, therapists and/or treatment facilities who could help you with medication or therapy.

Talk with the study doctor if you have questions about any of these treatments or procedures.

PARTICIPANT'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 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.

ClinicalTrials.gov

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.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

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.

It is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

FINANCIAL CONSIDERATIONS

You will receive $50 for your participation in this study following the completion of all study tasks (after tasks on Day 10 of study participation are received). You will not be paid for the telephone screening that you took part in to determine eligibility.

Payments will only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You will need to provide your social security number to receive payment.

Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

COMPENSATION FOR RESEARCH-RELATED INJURY

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. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

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, Dr. Katie Fracalanza at (650) 725-3438 or the research team at (650) 497-2577. You may contact either parties now or later.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Katie Fracalanza at (650) 725-3438 or the research team at (650) 497-2577.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The goal of the study is to understand the relationship between writing and difficulties with discarding. We are interested in whether writing in a specific manner benefits people with difficulty discarding, as the writing strategy that we are investigating has benefitted people with worry about various topics. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Katie Fracalanza, PhD Department of Psychiatry, 401 Quarry Road, Stanford, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to:

- Name, address (mail and email), telephone/fax number
- Name, phone, and address of alternate contacts
- Social Security Number
- Birthdate, initials, demographics (e.g. race/ethnicity, gender)
- Research records, including clinical and research observations made during participation in the research study
- You will be assigned a unique number, which will identify you throughout the research study

The protected health information that will be collected in this study will be limited to the least amount of information needed to accomplish the purpose of the study.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Katie Fracalanza, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration
- Brain & Behavior Research Foundation
- WebNeuro

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2050 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date
(DD-MMM-YYYY)

_____
Print Name of Adult Participant

EMERGENCY PROCEDURES AND EMERGENCY CONTACT INFORMATION

Emergency Referral Procedures. It is possible that, based on information gained in this study, the investigators may have serious concerns about your health and/or safety such as severe depression, suicidality, physical abuse, etc.; in such a case, the investigators may contact you and provide a referral for your care. We will ask you to provide information about a friend, family member, or primary doctor who will be your emergency contact. We will contact your emergency contact in the event we are unable to reach you.

If at any time during the study, you develop any serious thoughts about suicide or harming yourself, you should immediately contact Tatevik Avanesyan at 650-497-2577, during business hours. Outside of business hours, please call 911. If your symptoms worsen during study, notify a member of our research staff at 650-497-2577.

If there is imminent danger of suicide, the person concerned will be sent to the emergency room on either a voluntary or (if voluntary emergency services are refused) involuntary basis to ensure safety.

In case of an emergency, call 911. Standard treatment will not be withheld. You may be withdrawn from the study if emergency treatment is necessary.

EMERGENCY RESOURCES

Should you experience increased distress, please contact our research staff at 650-497-2577. Other resources include the 24-hour Crisis Support Line of Alameda County, California 800-309-2131, National Suicide Prevention Lifeline at 800-273-8255 and local community emergency mental health contacts. **In case of an emergency, call 911.**

Please list your emergency contact information. This information will only be used under the above circumstances to learn your whereabouts and appropriately refer you to emergency mental health services

PARTICIPANT CONTACT INFORMATION

Name:_____
Phone:_____
Address:_____
(street) (city) (zip)

Please list an emergency contact (relative or friend, next of kin) that we have your permission to contact on your behalf in the event that you are judged to be suicidal, and we are unable to locate you:

NEXT OF KIN OR EMERGENCY CONTACT INFORMATION

Name:_____
Relationship to you:_____
Phone:_____
Address:_____
(street) (city) (zip)

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant, you have the following rights. These rights include but are not limited to the participant'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 signed and dated consent form for your records;
- 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.

If you have any questions about the information in this consent form or about participating in this study, please contact our lab at (650) 497-2577 or clutterhelp@stanford.edu.

Signing your name means that you have asked any questions that you may have about this study consent form.

Signing your name means you agree to be in this study and that you were given a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date (DD-MMM-YYYY)

_____

Print Name of Adult Participant