CONSENT FORM

Are you participating in any other research studies? ___ Yes ____No

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Dr. Carolyn Rodriguez at (650) 723-6158

PURPOSE OF RESEARCH

You are invited to participate in a research study investigating whether a facilitated self-help support group called Buried in Treasures (BIT) and an in-home declutter practice can help individuals with hoarding disorder. We hope to understand the changes in the brain that go hand in hand with successful treatment of hoarding disorder. You were selected as a possible participant in this study because you have difficulty with clutter that is affecting your life. Before you choose whether or not to take part, 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 doctor any questions that you may have about this research study. This research study is looking for 58 participants with hoarding disorder and 12 healthy participants.

This research study will compare BIT group therapy with in home declutter practice to wait-list (control). A control is used in research studies to see if the results are due to the treatment or other reasons. You will be assigned to receive BIT group therapy with in home declutter practice immediately or after being on the waitlist for 18-20 weeks. Whether you get the therapy immediately or after the waitlist will be decided by chance (like a coin flip). You will have equal chance you will get therapy immediately than being on the waitlist first (1:1). Individuals randomized to the immediate treatment will have neuroimaging before and after the therapy.

To measure brain changes that may take place during therapy, we will take a "picture" of your brain before and after treatment using a Magnetic Resonance Imaging (MRI), which is a standard clinical test approved by the FDA for the diagnosis of disease. MRI methods use a magnet and radio-waves. The MRI camera uses no x-rays or other radioactivity. To measure changes in circuits, you will do games while in the MRI.

If you decide to terminate your participation in this study, you should notify Dr. Carolyn Rodriguez at (650) 723-6158.

This research study is looking for 58 adults with hoarding disorder and 12 healthy controls. All enrollment will take place at Stanford University.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. 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.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 2 years to complete. Each individual participant will contribute 29 2 hour visits in 18 weeks of active participation (total time 63-64 hours in 18 weeks). Additional visits may be requested to monitor your symptoms and will be recommended as needed by your study physician.

PROCEDURES

Screening As part of the routine screening done in our lab (IRB#35150), you have already met with staff of our lab to discuss your present and past medical and psychiatric condition. You were given an interview to assess your eligibility for this study.

Overview of Study Procedures (Baseline – Week 18) for individuals randomized to immediate treatment:
Overview: After completing screening, you will participate in a weekly facilitated self-help support group that follows a model laid out in the Buried In Treasures book and the facilitator's guide, which has been shown to work well for individuals with hoarding disorder. You will also have ten 2-hour sessions of individual in-home decluttering practice that are tailored for the treatment of your hoarding disorder. Two members of the research staff will visit your home during the initial evaluation, at week 8 and 18 and also during the in-home decluttering practice. To better understand the activity of your brain before and after treatment, we will take a "picture" of your brain using a Magnetic Resonance Imaging (MRI) camera while you play games. This camera has no x-rays or radioactivity. You will also play games outside of the camera. You have the right to refuse to answer particular questions.

Baseline
This visit will take about 4-5 hours.
At this visit:

- We will have you talk with study physician or psychologist to answer questions about your symptoms, mood and well being
- We will test your urine for pregnancy, if you are a female
- We will give you some questionnaires to fill out about your general health and well-being, quality of life, mental health, emotional health, and mood
- You will complete puzzles and games on a computer
- You will have an MRI scan that will take a picture of your brain

Week 1
This visit will take about 2.5 hours.
At this visit:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms
- We will collect baseline vitals

Weeks 2-7
These visits will take about 2 hours each.
At these visits, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Week 8
This week you will have three visits that will take about 4.5 hours in total.
At these visits:

- You will meet with your BIT group and participate in activities (2 hours)
- You will be given homework to complete and return at the next session
- We will meet you at your home for independent in home evaluation (30min)
- We will meet at a store of your choice to do support your non-acquiring efforts (2 hours)
- We will have you talk with a study physician or psychologist to answer questions about your symptoms, mood and well being

Week 9
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet at a store of your choice to do support your non-acquiring efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 10
This visit will take about 2 hours.
At this visit, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Week 11
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet come to your home and support your decluttering efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 12
This visit will take about 2 hours.
At this visit, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Weeks 13-16
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet come to your home and support your decluttering efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 17

This week you will have two visits that will take about 2 hours each:
At this visits:

- We will meet come to your home and support your decluttering efforts (2 visits)
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 18

This week will include three visits that will take about 2-4 hours each.
At two visits (2 hours each):

- We will meet come to your home and support your decluttering efforts (2 visits)
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

At the third visit (4 hours) you will come at our center and we will:

- Have you talk with a study physician or psychologist to answer questions about your symptoms, mood and well being
- Give you some questionnaires to fill out about your general health and well-being, quality of life, mental health, emotional health, and mood
- Complete puzzles and games on a computer
- Test your urine for pregnancy, if you are a female
- Have an MRI scan that will take a picture of your brain

Overview of Study Procedures (Baseline – Week 36) for individuals randomized to waitlist and then treatment:

Overview: After completing screening, you will have a baseline evaluation before and after your time on the wait list (approximately 18 weeks). Then, you will participate in a weekly facilitated self-help support group that follows a model laid out in the Buried In Treasures book and the facilitator's guide, which has been shown to work well for individuals with hoarding disorder. You will also have ten 2-hour sessions of individual in-home decluttering practice that are tailored for the treatment of your hoarding disorder. Two members of the research staff will visit your home during the initial evaluation, at week 26 and 36 and also during the in-home decluttering practice.

Baseline
This visit will take about 4-5 hours.
At this visit:

- We will have you talk with study physician or psychologist to answer questions about your symptoms, mood and well being
- We will test your urine for pregnancy, if you are a female
- We will give you some questionnaires to fill out about your general health and well-being, quality of life, mental health, emotional health, and mood
- You will complete puzzles and games on a computer

Weeks 1-18

- Wait-list

Week 19
This visit will take about 2.5 hours.
At this visit:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms
- We will collect baseline vitals

Weeks 20-25
These visits will take about 2 hours each.
At these visits, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Week 26
This week you will have three visits that will take about 4.5 hours in total.
At these visits:

- You will meet with your BIT group and participate in activities (2 hours)
- You will be given homework to complete and return at the next session
- We will meet you at your home for independent in home evaluation (30min)
- We will meet at a store of your choice to do support your non-acquiring efforts (2 hours)
- We will have you talk with a study physician or psychologist to answer questions about your symptoms, mood and well being

Week 27
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet at a store of your choice to do support your non-acquiring efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 28
This visit will take about 2 hours.
At this visit, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Week 29
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet come to your home and support your decluttering efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 30
This visit will take about 2 hours.
At this visit, you will:

- Meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session

Weeks 31-34
This week you will have two visits that will take about 2 hours each:
At this visits:

- You will meet with your BIT group and participate in activities
- You will be given homework to complete and return at the next session
- We will meet come to your home and support your decluttering efforts
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 35
This week you will have two visits that will take about 2 hours each:
At this visits:

- We will meet come to your home and support your decluttering efforts (2 visits)
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

Week 36
This week will include three visits that will take about 2-3 hours each.
At two visits (2 hours each):

- We will meet come to your home and support your decluttering efforts (2 visits)
- We will ask you questions about your symptoms
- We will give you some questionnaires to fill out about your symptoms

At the third visit (3 hours) you will come at our center and we will:

- Have you talk with a study physician or psychologist to answer questions about your symptoms, mood and well being
- Give you some questionnaires to fill out about your general health and well-being, quality of life, mental health, emotional health, and mood
- Complete puzzles and games on a computer

Optional Photography/Videotaping: You will be asked to have your home photographed/videotaped 3 times over the course of this study (at baseline, week 8 and week 18). You do not have to agree to have your home photographed/videotaped to participate in this study.

Aftercare: At the end of the study you will have the option to receive 10 weeks of follow up support at no cost to participants and referrals for outside care.

<u>MRI (Magnetic Resonance Imaging) ONLY IF RANDOMIZED TO IMMEDIATE TREATMENT</u>
MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for approximately 30 minutes while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. You will, however, hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs or headphones that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any doctor visits or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

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 disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Carolyn Rodriguez at (650) 723-6158.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 1 hour.

At this visit, we will:

- Have you talk with an independent doctor or specialist over the telephone to answer questions about your mood and well being
- Give you some questionnaires to fill out

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

- Failure to follow the instructions of the Protocol Director and study staff
- The Protocol Director decides that continuing your participation could be harmful to you
- Pregnancy
- You need treatment not allowed in the study
- The Sponsor decides to stop the study
- Other administrative reasons
- Unanticipated circumstances
- Your hoarding symptoms worsen
- Your depression symptoms worsen and/or you have suicidal thoughts

If this happens, the study doctor will explain why you need to stop taking part in the study. We will ask you to come in for a final study visit as described above. You may choose to stop taking part in the study at any time.

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.

Distress During Interviews

The interviews are time consuming and about personal matters. It is possible that you will feel upset, tired or anxious. You can choose not to answer specific questions or ask to have the interview stopped at any time.

Distress during the Cognitive Tasks

The cognitive tasks are time consuming. It is possible that you will feel tired or anxious. You can choose to take breaks or stop at any time.

Distress during the In-home Decluttering Practice

The intervention is time consuming and involves de-cluttering, which is a personal matter. It is possible that you will feel upset, tired, or anxious. You can choose to stop at any time.

Risks Associated with MRI

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches and credit cards should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is expected and should not be painful.

Some of the radio frequency imaging coils, imaging software and devices being used in your scan are not approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a risk of heating from radiofrequency imaging coils and their cables, button response boxes and their cables, and the cables from monitoring devices that record physiologic processes such as heart beats per minute or electrical activity of the brain. Please report any heating sensation immediately. You may have the scan stopped at any time

if this occurs. Dizziness or nausea may occur if you move your head rapidly within the magnet.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and Stanford are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and Stanford are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

Lack of Benefit from Study Treatment

You may not experience any symptom relief. In addition, your symptoms may worsen.

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 Dr. Rodriguez at (650) 723-6158 or any of the study doctors and call 911.

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.

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

Other Inconveniences

There may be inconveniences of travel and time to complete study procedures.

POTENTIAL BENEFITS

Your symptoms of hoarding disorder may improve while in this study. The study may benefit other people with hoarding disorder by furthering our understanding of what treatments work best for hoarding disorder and how they work in the brain.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

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.

If information is revealed about child abuse or neglect, elder abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

FINANCIAL CONSIDERATIONS

Payment

ONLY IF RANDOMIZED TO IMMEDIATE TREATMENT

You will play 2 games during the MRI and based on your performance you will be able to win up to $200 ($100 at baseline and $100 at 18 weeks). If you get randomized to delayed therapy you will not receive any payment.

Details of the compensation only if randomized to immediate treatment: You will be paid up to $100 in cash for the fMRI reward task that is variable depending on your performance during baseline and at 18 weeks (total up to $200). In case of you voluntarily withdrawal from the study, you will get compensated based on your level of participation as detailed above.

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

Costs

If you participate in this study, there may be additional costs to you. These include the personal time it will take to come to all of the study visits and the cost of purchasing the Buried In Treasures book. The study will pay for all other services, supplies, procedures, and care associated with this study that are not a part of your routine medical care.

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.

Sponsor

The Stanford Department of Psychiatry is providing financial support and/or material for this study, some financial support for the facility and staff where part or all of the study is taking place.

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. Carolyn Rodriguez. You may contact her now or later at (650) 723-6158.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Carolyn Rodriguez at (650) 723-6158.
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, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact the Rodriguez Lab at (650) 724-8912.

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 whether and how facilitated group therapy and in home decluttering provide relieve for hoarding disorder, and this information may in some form by submitted to the Stanford Department of Psychiatry and/or the FDA. 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: Carolyn Rodriguez, MD, 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
- Birthdate, initials, demographics (e.g. race/ethnicity, gender)
- Research records, including clinical and research observations made during participation in the research study
- Supporting information from your medical records (medical history, medication history)
- Physical examination (e.g. height, weight)
- Laboratory test results (e.g. urine) and medical record number
- MRI data and results
- You will be assigned a 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 Carolyn Rodriguez, MD, PhD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- Laboratory Staff

- MRI 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
- Consultant for ensuring reliability of independent evaluation
- Data Safety Monitoring Board

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, 2045 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

_____

Print Name of Adult Participant

EXPERIMENTAL SUBJECT'S 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 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.

Photography, Audio and/or Videotaping Consent

You have been asked, as part of your evaluation at our lab, to be photographed, audio recorded and/or videotaped during your evaluation visits with the raters. Some of the interviews and rating forms with clinic staff will be digitally recorded.

The purpose of these photographs is to record changes in the level of clutter in your home and other living spaces as you progress through the study. These photographs may be used for professional or educational purposes including presentations, meetings, or publications. Your name will not be used in any of these presentations and the photographs will not include your image.

The purpose of audio recording is to allow you to record a description of your home that accompanies the photograph.

The purpose of videotaping sessions is to supervise and improve the evaluation.

You may participate in the evaluation even if you do not agree to be photographed, audio recorded and/or videotaped. Also, you may refuse to have the photography, recording and/or videotaping done without affecting your treatment in our lab.

All photographs, audio recordings and/or videotapes will be labeled using ID numbers of the participants and will be stored on a secure server accessible only to authorized lab personnel.

You have the right to withdraw consent for photography, audio recording and/or videotaping at any time without affecting your participation. You may also request that these recordings be erased at any time during or after the interview.

I give consent for my home to be photographed during this study:

Please initial:____Yes____No Date:_____

I give consent to be audio recorded during this study:

Please initial:____Yes____No Date:_____

I give consent to be video recorded during this study:

Please initial:____Yes____No Date:_____

**The studies that our lab participates in constantly change, if you want to be contacted in the future about new studies, please check and initial the box below.

I consent to being contacting in the future.

Please initial:____Yes____No Date:_____

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

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent