Participant Name: _____ **Date:** _____

Title of Study: Cognitive Rehabilitation for Veterans with Parkinson's Disease

Principal Investigator: [redacted]

VAMC: Edward Hines, Jr VA Hospital

SUMMARY

The research is being conducted to examine the practicality and effectiveness of an at-home cognitive training program that includes both a computer-based program with goal setting strategies for Veterans with Parkinson's Disease and mild impairment in their thinking and executive functioning. Executive function refers to problems with attention, memory, and/or problem solving.

If you agree to join the study, you will be asked to complete the following research procedures:

- Thinking and memory assessments
- questionnaires that ask about your daily functioning and mood
- 8-week at home intervention that includes computer games and goal setting strategies. You may be assigned to the real intervention, a placebo intervention or a mix of the two.

Your participation will last for approximately 3 months. This includes 8 weeks of cognitive training at home (computer games and goal setting completed 4 times per week) and a one month follow up visit. There will be four visits to Hines VAH at which you will complete testing assessments.

It is expected that the real intervention, or the mix of real and placebo intervention may improve your thinking abilities, memory, and/or daily functioning. However, we expect there will be no direct benefit to you if you receive the placebo intervention. This study will help doctors learn more about Parkinson's disease and related thinking and memory problems and it is hoped that this information will help in the treatment of future patients with conditions like yours.

The most common risks of participation are:

- Distress or anxiety related to the thinking and memory assessments
- Distress or anxiety related to maintaining the schedule for the intervention
- Loss of confidentiality

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

INTRODUCTION

You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. The sponsor of the study is VA Office of Research Development. If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at [redacted] assistance. If you have questions about this study, you may contact the Principal Investigator, [redacted].

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide.

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If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

With this research we hope to learn how practical it is to complete an at-home, computer-based program, with goal setting strategies, and determine the effectiveness for improving thinking abilities and daily function.

Sandra Kletzel, PhD is the Principal Investigator of this study. She and her team of research scientists will be conducting the study. This study is sponsored by the VA Office of Research Development.

This study is trying to find out if computer-based games, along with with goal setting strategies can improve thinking and daily functioning for people with Parkinson's disease who are experiencing mild problems with their thinking ability, memory, and solving problems. You are being asked to participate in this research study because you have been diagnosed with Parkinson's disease and are over the age of 50.

There are currently limited options to treat thinking and memory decline that may occur as Parkinson's disease progresses. This research study is trying to understand if computer-based games with goal setting plans is feasible to complete at home and whether, together they may treat a decline in thinking and memory and improve functioning in everyday routines.
45 Veterans from Edward Hines Jr. VA Hospital (Hines VAH), who have Parkinson's disease and who have mild changes in thinking and executive function will be enrolled in this study.

This research study is a *placebo-controlled trial* which means you may or may not receive the actual treatment. This will be explained more fully later in this consent form.

We will ask you to provide the name of a knowledgeable informant/caregiver who interacts with you on a weekly basis, and who may be willing to enroll in this study. A caregiver is not required for you to enroll in this study. The purpose of this caregiver is to bring additional perspective on your performance in everyday activities. Criteria for enrollment of the caregiver is 1) Interacts with you, the Veteran, on a weekly basis, 2) is 18 years or older, 3) speaks and reads English fluently, and 4) is not pregnant.

DURATION OF THE RESEARCH

This research study is expected to take approximately 2 years. Your individual participation in the project will take approximately 3 months. This includes 8 weeks of cognitive training at home and a follow up visit 1 month after completing the intervention.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen: (additional detail included below)

All research participants, regardless of group assignment, will complete the following procedures:

- At the first visit to the Hines VAH, you will complete screening tests to determine if you meet eligibility criteria. These tests will last approximately 20-30 minutes

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- At the first visit, if you are still eligible, you will complete a larger set of screening tests that will last approximately 2.5 hours.
-
- If you remain eligible, you will come to Hines VAH for a second visit and the following will happen
  - you will complete a battery, or set, of neuropsychological assessments that can take approximately 2 hours to complete
  - you will be randomized (like the flip of a coin)into one of three groups
  - You will be trained on the basic use of an iPad and taught how to access and navigate the games
  - You will be trained on goal setting strategies
- At home, for 8 weeks, you will complete games on the iPad and goal setting strategies 4 times per week.The games will take approximately 30 minutes for each day.
  - During the 8-week intervention, you will receive weekly calls from the research team's "cognitive coach". This call may last up to 20 minutes
  - At 4 weeks and 8 weeks the cognitive coach will ask you to take a short questionnaire over the phone. They will ask you questions about your perception of the computer games. This questionnaire will take approximately 5 minutes.
- When the intervention ends, you will come to Hines VAH for a third visit to compete a set of neuropsychological assessments that can take up to 3 hours to complete.
- One month later you will come to Hines VAH for a final visit to compete a set of neuropsychological assessments that can take up to 3 hours to complete..

Screening Tests

Prior to receiving this consent form, you may recall completing an initial telephone screening that included a description of the study, explanation of the time commitment required to participate and any restrictions to study participation. If you remained interested, you also provided a list of prescription and over the counter medications you are currently taking. The result of that telephone screening indicated you were eligible to move on to the consenting process and a diagnostic confirmation screening to insure you meet all eligibility criteria to participate in the study.

During diagnostic confirmation screening, you will take tests that are often used to help diagnose changes in thinking, memory, and mood. The tests are similar to ones a doctor, nurse or therapist would give to any person who may have a change in their thinking and memory ability or their mood. Results of these tests are for research purposes only. Each test will be explained to you before you start, and you may ask questions before, during or after the tests. Some of the tests are completed on a computer or on paper. Some of the tests are completed through interviews with research members or by you completing a questionnaire. You may skip any questions you prefer not to answer.

Screening Part 1: Four different questionnaires to assess your general thinking and memory ability and mood will be administered. This can take 20-30 minutes to complete.

Possible end of study participation after Screening Part 1 if your screening test results suggest

- you may have more than mild impairment in thinking and memory ability
- you may have more than mild depression

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Screening Part 2: If you remain eligible, then a larger set of thinking and memory tests will be administered. A research team member will also ask you to complete lifestyle and health questionnaires. The questions ask about your overall health, mood, how well you sleep, and how well you can do your daily activities. This will involve 15 different questionnaires.

Diagnostic confirmation screening (parts 1 and 2) will take approximately 2 to 3 hours to complete. You can take breaks between the tests if you become fatigued.

This diagnostic confirmation screening, which will be conducted by a research team member, will allow us to confirm that you remain eligible for study participation. Results from Part 1 can be determined shortly after you complete them. However, results from Part 2 will take approximately one week to score. A research team member will call you and let you know if you remain eligible to continue in the study.

- If you do not have mild cognitive impairments, you will not meet eligibility criteria, and therefore will not be able to continue in the study.
- If you do have a mild cognitive impairment, you can continue in the study.

Neuropsychological Assessments

In general, neuropsychological assessments are a series of tests that assess your mood, thinking and memory performance and other activities related to everyday living. Each test will be explained to you before you start, and you may ask questions before, during or after the tests. Some of the tests are completed on a computer or on paper. Some of the tests are completed through interviews with research members or by you completing a questionnaire. You may skip any questions you prefer not to answer.

Cognitive Training Intervention

You will be *randomly assigned* to one of three experimental groups. Randomly assigned means that you have an equal chance of being assigned to any of the groups and this is determined by a computerized procedure much like flipping a coin for heads or tails. All three groups involve playing computerized games as well as strategies for goal setting.

Computerized games: Regardless of group assignment, you will be lent an iPad to take home for use in completing the study games. You will be asked to complete 4 sessions per week for 8 weeks. Each session takes approximately 30 minutes. By the end of 8 weeks you will have completed a total of 16 hours of training. You will be taught how to access and navigate the games prior to starting the cognitive training intervention.

Goal Setting: Regardless of group assignment, you will work with a study team member to establish short term goals. You will be instructed in a verbal rehearsal of these goals. You will be asked to rate your performance on these goals initially, at the end of the intervention and then again at the one month follow up.

Before you begin the intervention at home, you will receive an instruction manual reminding you how to start a computer session and reminding you what goals you have selected.

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You will receive a weekly phone call from a study team member to check in on your progress and address any barriers to completing the training program. This call can last up to approximately 20 minutes

In this study, you and all but a few members of the research team are blind to group assignment. This means that we have taken extra steps to keep you and the select research team members unaware which experimental group you are in. For the integrity of this study, it is critical that you, the research team members providing the intervention and the research team members who conduct the testing assessments remain unaware of which treatment group you are in.

The research team will be overseeing all procedures and potential risks and benefits of the treatment, this includes determining if an adverse event results from the research and alerting you if there is a problem.

Participant responsibilities:

- Follow your treatment schedule. If you find it difficult to complete the tasks, discuss this on the weekly call with the cognitive coach.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies
- Return the loaned iPad to the research team at the end of the intervention

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

***Screening tests and the neuropsychological assessments*:** Participating in this research may cause you to experience some distress if you feel you are not performing well on the thinking and memory tests. Some questions or tasks are designed to be very easy and some are meant to be more challenging; we ask that you do the best you can. If you are having trouble with use of the paper and pencil then a study team member can assist you with any of the questionnaires. However, on paper and pencil tests that are used to assess your thinking or memory, a study team member will not be able to assist you. You can choose not to answer any question or complete any test that causes distress or discomfort. If at any time you feel fatigued, breaks of 5-10 minutes during the session can be taken. You may feel emotional distress upon learning that you have mild cognitive impairments. Assessments conducted during this study are for research purposes only. If you are concerned about the results of our assessments, you should follow-up with your doctor.

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Cognitive training: Participating in this research may cause you to experience some distress if you feel you are not performing well. Some questions or tasks are designed to be very easy and some are meant to be more challenging; we ask that you do the best you can.

You may find it difficult to complete a session in one sitting (ie. 30minutes) due to fatigue. You may choose to break the time into shorter segments which will be more easily manageable.

You may find that you require additional time to complete the required training program. A study team member will work with you to establish a feasible schedule if necessary.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

POTENTIAL BENEFITS

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include improvement in thinking ability, memory, and/or daily functioning. We expect there will be no direct benefit to you if you receive the placebo treatment. This study will help doctors learn more about Parkinson's disease and related thinking and memory problems and it is hoped that this information will help in the treatment of future patients with conditions like yours.

CONFIDENTIALITY

All individual health information is removed from data collected for this study except dates of injuries, procedures or interventions. This information is necessary in the analysis for the study.

A study number will be assigned to the iPad you will use during cognitive training. You will use this study number to login to your computer games. No personal information will be associated with the login information. Your performance on the cognitive training games will be stored on a server owned by Posit Science; the study team will be able to access the server and your game data using the study number assigned to you.

Last four digits of your Social Security numbers are required for the HIPAA form. You cannot withhold your social security on the HIPAA form and still participate.

During the conduct of this study, protected health information will be collected and reviewed for the purposes of obtaining medical history. Names, social security numbers, dates of birth, addresses and phone numbers are kept in a separate file on a VA secured computer with limited research team access. Taking part in this study will involve collecting private information about you. All information collected during the conduct of this study will be stored and analyzed at the Hines VA in research areas accessible only to authorized research personnel for this study. Study related information will be stored in locked filing cabinets in a locked office. Electronic study related information will be stored on a VA server that is safeguarded and accessible only to authorized study personnel.

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The information collected for this study will be kept confidential. If you are a Veteran who is a patient at the VA Medical Center, a copy of your signed and dated consent and HIPAA forms will be placed in your medical record(s). If you are a Veteran but do not yet have an electronic medical record at Hines VA Hospital, you are required to provide a copy of your DD214 to the eligibility office so that one may be created for you before providing your informed consent to participate.

Any information obtained about you in this study will be treated as confidential and will be safeguarded in accordance with the Privacy Act of 1974. Information published or presented about the results of the study will be in a form that does not identify any particular participant.

Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you. A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time using the study ID NCT03836963.

This informed consent form does not give the study doctor permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the VA Office of Research Development Rehabilitation Research and Development , the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), Hines VA IRB, The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran research participants. By signing this document, you consent to such inspection.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be required to pay for medical care or services received as a participant in a VA research project except as follows: some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Cost you may have to bear include transportation, time away from work and/or health cost.

Payment Offered for Participation:

You will be compensated $120 for completing all research procedures in this study. You receive $30 after completing the 2-3 hour long diagnostic confirmation screen. You will receive $30 after completing baseline neuropsychological assessments, $30 after completing endpoint neuropsychological assessments and $30 after completing the final set of follow-up neuropsychological assessments.

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You will receive a cash $30 payment for your reimbursement from the agent cashier's office at Hines VA.

If you withdraw or the PI withdraws you from the study during a visit for which a scheduled payment was planned, then you will receive the reimbursement planned for that visit.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY
According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility. This does not apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call

DURING THE DAY: [redacted]

AFTER HOURS: Please call 911 for medical emergencies. Emergency and ongoing medical treatment will be provided as needed. Veterans may also contact the crisis line at 1-800-273-8255 and Press 1 or chat online to receive confidential support 24 hours a day, 7 days a week, 365 days a year.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

PARTICIPATION IS VOLUNTARY
It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctors or other staff, and it will not affect the usual care that you receive as a patient.

If you withdraw from this study, we ask that you contact the research team so an orderly termination of participant can be conducted. Data already collected prior to your withdrawal can still be reviewed and used by the investigators. However, the investigators will no collected any additional information following withdrawal from the study.

RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION
The investigator has the right to terminate your participation, without regard to your wishes, in the research study if:

- You become uncooperative or unwilling to complete study tests
- You are experiencing undue stress from the study procedures
- You have substance abuse, mental health, or medical problem that interferes with completion of the study tests.
- The study is stopped by the sponsor, which is the VA Office of Research Development

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FUTURE USE OF DATA AND RE-CONTACT

An important part of this research is to save your research data in a secure repository/bank for other research studies in the future. The data will be stored at the Hines VA and Dr. Kletzel and her research team will have access to the data; the data are stored in the Parkinson's disease Cognition Data Repository at Hines VA.

You may be eligible to participate in future research. Future studies may use some of the same information that you provide today, but may also involve additional assessments. If you would be interested in hearing about future research opportunities both within the VA or outside the VA, please indicate your interest below:

☐ I agree to be contacted for future research. _____(Initials)

☐ I do not wish to be contacted about future research. _____(Initials)

You may discuss these options with your usual doctor.

ADDITIONAL CONTACT INFORMATION

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who is not part of the study team, you can contact the Hines VA IRB Administrator [redacted].

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

_____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

_____ / /

Signature of Participant Date Written by Participant