

## **Appendix 7a1: Consent Form CG MCI**

**Project Title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigator:** Dr. Andrew Frank

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics approval:** 11 Sept 2017

Thank you for your interest in this study. This document will help you understand the study and provide you with the information you need in order to decide if you would like to participate. We kindly ask that you read this information and prepare any questions that you may have before signing the consent form.

### **What is this study about?**

In this study, we want to observe how well a computer game works in detecting memory and intellectual difficulties, and predicting future decline in the mental functions.

### **How is the computer game?**

The computer game is has four different tasks. In each task, one card will appear at the center of a screen. You will be asked to answer different questions in each task, for example "has the card turned face up?" To answer, you will have to press the "D" key (representing YES) or the "K" key (representing NO). The game does not need you to be experienced with computers. It takes around 15 minutes to complete.



Example of one of the tasks in the computer game: you will be asked to press the D key as soon as the card has turned face up.

### **Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9

### **How long is the study?**

This is a 3-year study. If you decide to participate, you will have to visit the Bruyère Hospital once every 3 months during the first year. Then, you will have to come once at the end of the second year, and again at the end of the third year. We will cover your parking costs, if needed.

### **What will I do in the visits if I choose to participate?**

- You will need to answer a brief paper-and-pencil memory test that takes around 10 minutes to complete
- You will play the computer game that takes around 15 minutes to complete
- You will have to complete a set of tests that measure your memory, language, and other mental functions. This should take you around 60 minutes to complete.
- You will need to answer a questionnaire about your perception of memory difficulties. This takes around 5 minutes to complete.
- You will be given breaks between-tasks to reduce fatigue. If during the longer sessions you feel very fatigued and need to stop the testing, please advise the experimenter and you will continue the session in another day.

On some sessions, you will need to complete all the tasks described above; on other sessions, only some. Below is a chart showing every visit with the tasks included in them.

	<b>Visit 1 (baseline)</b>	<b>Visit 2 (3 months)</b>	<b>Visit 3 (6 months)</b>	<b>Visit 4 (9 months)</b>	<b>Visit 5 (12 months)</b>	<b>Visit 6 (24 months)</b>	<b>Visit 7 (36 months)</b>
<b>Tasks</b>	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires
<b>Total Time</b>	90 minutes (105 with breaks)	30 minutes	30 minutes	30 minutes	90 minutes (105 with breaks)	65 minutes (75 with breaks)	65 minutes (75 with breaks)

### **Where and how will I complete these tasks?**

All the tasks will be performed in a private room in the hospital. A research assistant will administer the tasks.

### **How will my privacy be protected?**

All of your answers to the tasks will be saved using a study number, and will be kept in a password-protected file in our office's computer. No one will be able to identify you from the study results. Everyone in the research team has signed a pledge committing to respect your privacy. We will share your results within the team to analyze the study results. Your results in the computer game will also be shared with the manufacturer of the game (Cogstate, USA). Again the results will not have your name on them, and there will be no way of identifying you from them.

### **What is a study partner and will I need one?**

A study partner is a an adult that knows you well, for at least 5 years, and with whom you have frequent contact (at least twice a week). This person will answer some questions about your functioning in daily life. Specifically, they will be asked if you need assistance with daily life activities such as shopping, travelling out your neighbourhood, and paying bills. They will also be asked if they notice that you are having more memory difficulties compared to years or months ago, for example if they have noticed that you are repeating questions more frequently or having more difficulties remembering recent conversations.

You will need to have a study partner to join this study. If you decide to participate, we will ask you to identify a person who you believe could act as your study partner and we will ask you to obtain his/her authorization for having us contacting him/her.

### **What happens if I can't find a study partner, or if my study partner decides to stop participating?**

Unfortunately, having a study partner is a requirement. If you can't find a study partner, we will not be able to include you in the study. If during the study, your study partner decides to stop participating, we will ask you to find another person who could act as your study partner for the remaining part of the study. If you can't find someone else, we will have to withdraw you from the study.

### **Do I have the right to refuse and to decide not to participate?**

You have the right to refuse, and to decide not to take part in this study. Your regular care will not be affected by this decision. We will not tell your physicians if you are or are not participating in the study.

### **What do I need to do in order to be included in the study?**

You will need to answer a short questionnaire to ensure that you have understood the study. You will need to find a study partner. Finally, your diagnosis of mild cognitive impairment will need to be confirmed in the first testing session. If any of the former is not met, we will not be able to include you in the study. If the former happens, all data collected during the baseline testing will be destroyed. This will allow us to protect your privacy.

Since there are other medical conditions that can affect the brain, we will need to ask you if you have received a diagnosis of epilepsy, stroke, traumatic brain injury, substance abuse, seizures, or active major depression. If you have any of these diagnoses, we will not be able to include you in the study.

**Once I am in, can I withdraw at any point?**

You are free to drop out from the study at any time. You will not need to give any explanations. If you chose to drop out of the study, this will not affect your future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, you can advise the research team.

**Are there any benefits to me if I participate in this study?**

There are no direct benefits from participating in this study. You are benefitting science by helping grow knowledge about memory impairment. During the study we will be continuously testing your memory: if we detect a significant change, we will let you and your study partner know. You can always ask for a copy of your results in the set of paper-and-pencil tests. You can ask the research assistant for the results at any point during the study. The research assistant will give you a written copy of your results in-person, at the hospital. The copy will only include the test results and will not have any diagnosis. Your study partner can also receive a copy if you assent this.

**Are there any potential risks to me if I participate in this study?**

There are no significant risks for you. You may not enjoy the computer game, or any of the tasks. It may happen that it might inconvenience you having to visit the hospital. If any of these happens, remember that you are free to drop out from the study at any point.

**What happens if during the study my memory difficulties increase?**

If we detect that your difficulties have significantly increased, we will let you and your study partner know and ask you to notify your doctor. We will share with you and your study partner a report with the test results, so you can show it to your doctor if wanted. Also, because the difficulties might affect your capacity to understand and/or remember the study details, we will ask you and your study partner to identify someone who could act as a Substitute Decision Maker (SDM). The SDM can be the same person than your study partner or a different person, depending on your particular circumstances. The SDM will be asked to decide whether you continue to participate or not in the study, and will be asked to sign a consent form on your behalf. The SDM can discuss this decision with you.

**Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Andrew Frank  
613-562-6262 extension 1078

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board  
613-562-6262 extension 4003

We thank you for your time reading this information. A Research Assistant will call you and answer any questions you might have about the study.

**Participant Consent- Signature Page**

**THIS PAPER WILL BE SIGNED IN PERSON AT THE BASELINE SESSION, BEFORE INITIATING THE TESTING AND AFTER CONSENT REVIEW.**

**Study title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigator:** Dr. Andrew Frank

**Please check as appropriate:**

I read the information sheet

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study

YES [ ] NO [ ]

I received satisfactory answers to all my questions

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop out of the study:

- At any time
- Without having to give a reason
- Without affecting my future care

YES [ ] NO [ ]

I understand that this is my choice to consent and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to play a computer game, undergo memory tests, and answer – together with my study partner- questions about memory difficulties

YES [ ] NO [ ]

I give my consent for the research team to include me in the study

YES [ ] NO [ ]

By signing below, I understand what my participation in this study means and I agree to participate in this study.

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Your name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

## **Appendix 7a2: Consent Form CG CN**

**Project Title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigator:** Dr. Andrew Frank

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics approval:** 11 Sept 2017

Thank you for your interest in this study. This document will help you understand the study and provide you with the information you need in order to decide if you would like to participate. We kindly ask that you read this information and prepare any questions that you may have before signing the consent form.

### **What is this study about?**

In this study, we want to observe how well a computer game works in detecting memory and intellectual difficulties, and predicting future decline in the mental functions.

### **How is the computer game?**

The computer game is has four different tasks. In each task, one card will appear at the center of a screen. You will be asked to answer different questions in each task, for example “has the card turned face up?” To answer, you will have to press the “D” key (representing YES) or the “K” key (representing NO). The game does not need you to be experienced with computers. It takes around 15 minutes to complete.



Example of one of the tasks in the computer game: you will be asked to press the D key as soon as the card has turned face up.

### **Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9

### **How long is the study?**

This is a 3-year study. If you decide to participate, you will have to visit the Bruyère Hospital once every 3 months during the first year. Then, you will have to come once at the end of the second year, and again at the end of the third year. We will cover your parking costs, if needed.

### **What will I do in the visits if I choose to participate?**

- You will need to answer a brief paper-and-pencil memory test that takes around 10 minutes to complete
- You will play the computer game that takes around 15 minutes to complete
- You will have to complete a set of tests that measure your memory, language, and other mental functions. This should take you around 60 minutes to complete.
- You will need to answer a questionnaire about your perception of memory difficulties. This takes around 5 minutes to complete.
- You will be given breaks between-tasks to reduce fatigue. If during the longer sessions you feel very fatigued and need to stop the testing, please advise the experimenter and you will continue the session in another day.

On some sessions, you will need to complete all the tasks described above; on other sessions, only some. Below is a chart showing every visit with the tasks included in them.

	<b>Visit 1 (baseline)</b>	<b>Visit 2 (3 months)</b>	<b>Visit 3 (6 months)</b>	<b>Visit 4 (9 months)</b>	<b>Visit 5 (12 months)</b>	<b>Visit 6 (24 months)</b>	<b>Visit 7 (36 months)</b>
<b>Tasks</b>	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires
<b>Total Time</b>	90 minutes (105 with breaks)	30 minutes	30 minutes	30 minutes	90 minutes (105 with breaks)	65 minutes (75 with breaks)	65 minutes (75 with breaks)

### **Where and how will I complete these tasks?**

All the tasks will be performed in a private room in the hospital. A research assistant will administer the tasks.

### **How will my privacy be protected?**

All of your answers to the tasks will be saved using a study number, and will be kept in a password-protected file in our office's computer. No one will be able to identify you from the study results. Everyone in the research team has signed a pledge committing to respect your privacy. We will share your results within the team to analyze the study results. Your results in the computer game will also be shared with the manufacturer of the game (Cogstate, USA). Again the results will not have your name on them, and there will be no way of identifying you from them.

### **Do I have the right to refuse and to decide not to participate?**

You have the right to refuse, and to decide not to take part in this study. Your regular care will not be affected by this decision. We will not tell your physicians if you are or are not participating in the study.

### **What do I need to do in order to be included in the study?**

To participate, you need to be cognitively healthy. This means that you cannot have received a diagnosis of mild cognitive impairment or dementia. Also, we will need to confirm that you are cognitively healthy using a set of memory and cognitive tests in the first session. If the results suggest that you might have a minor or major cognitive impairment, we will not be able to include you in the study. If this is the case, we will let you know and ask you to notify your doctor. If the former happens, all data collected during the baseline testing will be destroyed. This will allow us to protect your privacy. Since there are other medical conditions that can affect the brain, we will need to ask you if you have received a diagnosis of epilepsy, stroke, traumatic brain injury, substance abuse, seizures, or active major depression. If you have any of these diagnoses, we will not be able to include you in the study.

### **Once I am in, can I withdraw at any point?**

You are free to drop out from the study at any time. You will not need to give any explanations. If you chose to drop out of the study, this will not affect your future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, you can advise the research team.

### **Are there any benefits to me if I participate in this study?**

There are no direct benefits from participating in this study. You are benefitting science by helping grow knowledge about memory impairment. During the study we will be continuously testing your memory: if we detect a significant change, we will let you know. You can always ask for a copy of your results in the set of paper-and-pencil tests. You can ask the research assistant for the results at any point during the study. The research assistant will give you a written copy of your results in-person, at the hospital. The copy will only include the test results and will not have any diagnosis.

**Are there any potential risks to me if I participate in this study?**

There are no significant risks for you. You may not enjoy the computer game, or any of the tasks. It may happen that it might inconvenience you having to visit the hospital. If any of these happens, remember that you are free to drop out from the study at any point.

**What happens if during the study I start showing memory difficulties?**

If we detect that you start showing memory difficulties, we will let you and know and ask you to notify your doctor. We will share with you a report with the test results, so you can show it to your doctor if wanted. Also, because the difficulties might affect your capacity to understand and/or remember the study details, we will administer a questionnaire to make sure if you are still capable of giving consent. If you don't, we will ask you to find a person who could act as a Substitute Decision Maker (SDM). This person will be asked to decide whether you continue to participate or not in the study, and will be asked to sign a consent form on your behalf. S/he can discuss this information with you. Also, if you continue to participate, we will need to ask you to find a study partner (who could be the same than the substitute decision maker). A study partner is a person who knows you well, for at least the last 5 years, and with whom you have frequent contact. The SDM can be the same person than your study partner or a different person, depending on your particular circumstances. The study person will be asked to complete two brief questionnaires about your memory difficulties. This information is needed to better understand your memory difficulties. Specifically, they will be asked if you need assistance with daily life activities such as shopping, travelling out your neighbourhood, and paying bills. They will also be asked if they notice that you are having more memory difficulties compared to years or months ago, for example if they have noticed that you are repeating questions more frequently or having more difficulties remembering recent conversations. If you do not find a study partner, we will need to withdraw you from the study.

**Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Andrew Frank  
613-562-6262 extension 1078

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board  
613-562-6262 extension 4003

We thank you for your time reading this information. A Research Assistant will call you and answer any questions you might have about the study.

### Participant Consent- Signature Page

**THIS PAPER WILL BE SIGNED IN PERSON AT THE BASELINE SESSION, BEFORE INITIATING THE TESTING AND AFTER CONSENT REVIEW.**

**Study title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigator:** Dr. Andrew Frank

**Please check as appropriate:**

I read the information sheet

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study

YES [ ] NO [ ]

I received satisfactory answers to all my questions

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop out of the study:

- At any time
- Without having to give a reason
- Without affecting my future care

YES [ ] NO [ ]

I understand that this is my choice to consent and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to play a computer game, undergo memory tests, and answer questions about memory difficulties

YES [ ] NO [ ]

I give my consent for the research team to include me in the study

YES [ ] NO [ ]

By signing below, I understand what my participation in this study means and I agree to participate in this study.

---

Your name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

**Appendix 7b1: Consent Form NCP MCI**

**Project Title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer’s disease

**Qualified Investigator:** Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics Clearance:** TBD

Thank you for your interest in this study. This document will help you understand the study and provide you with the information you need in order to decide if you would like to participate. We kindly ask that you read this information and prepare any questions that you may have.

**What is this study about?**

The purpose of this study is to explore brain responses to specific sounds. Brain responses are obtained through an Electroencephalogram (EEG), which is a machine that records the electrical activity of the brain. We want to compare the brain responses of subjects with mild cognitive impairment with that of cognitively healthy subjects. We also want to explore if changes in the brain responses of a subject over time are related to a worsening of his/her cognition.

**Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9. We will cover your parking costs, if needed.

**How long is the study?**

This is a 3-year study. If you decide to participate, you will have to visit the Hospital every 6 months during the first year. Then, you will have to come once at the end of the second year, and again at the end of the third year.

**What will I do in the visits if I choose to participate?**

- You will need to answer a brief paper-and-pencil memory test that takes around 10 minutes to complete.
- You will undergo an EEG testing which will take around 25 minutes.
- You will have to complete a set of tests that measure your memory, language, and other mental functions. This should take you around 60 minutes to complete.
- You will need to answer a questionnaire about your perception of memory difficulties. This takes around 5 minutes to complete.
- You will be given breaks between-tasks to reduce fatigue. If during the longer sessions you feel very fatigued and need to stop the testing, please advise the research assistant and you will continue the session in another day.

On some sessions, you will need to complete all the tasks described; on other sessions, only some. Below is a chart showing every visit with the tasks included in them:

	<b>Visit 1 (baseline)</b>	<b>Visit 2 (6 months)</b>	<b>Visit 3 (12 months)</b>	<b>Visit 4 (24 months)</b>	<b>Visit 5 (36 months)</b>
<b>Tests</b>	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG 3. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires
<b>Time (approx.)</b>	100 minutes (115 with breaks)	40 minutes	100 minutes (115 with breaks)	100 minutes (115 with breaks)	100 minutes (115 with breaks)

### **How is the EEG testing?**

For the EEG, a cap containing small sensors will be placed on your head. Sensors are small metal discs that record the activity of the brain. To place the sensors, the scalp area underneath them will be lightly rubbed with gel. Placing the cap should take around 10 minutes. Once placed, the testing will begin. In the testing, you will listen to sounds or words for 12 minutes, separated in two blocks. You will be asked to simply listen. The computer will record your brain's response to each sound. Because medications can affect brain responses, we will need to ask you and your study partner for the list of medications that you are taking. To respect your privacy, we will write down the list in a sheet of paper using a study number, and keep this sheet in a locked cabinet.

### **Where and how will I complete these tasks?**

All the tasks will be performed in a private room in the hospital. A research assistant will administer the tasks.

### **How will my privacy be protected?**

All of your answers to the tasks will be saved using a study number, and will be kept in a password-protected file in our office's computer. No one will be able to identify you from the study results. Everyone in the research team has signed a pledge committing to respect your privacy. We will share your results within the team to analyze the study results. Your results in the EEG will also be shared with the manufacturer of device (HealthTech Connex, Vancouver). Again the results will not have your name on them, and there will be no way of identifying you from them.

### **What is a study partner and will I need one?**

A study partner is a an adult that knows you well, for at least 5 years, and with whom you have frequent contact (at least twice a week). This person will answer some questions about your functioning in daily life. Specifically, they will be asked if you need assistance with daily life activities such as shopping, travelling out your neighbourhood, and paying bills. They will also be asked if they notice that you are having more memory difficulties compared to years or months ago, for example if they have noticed that you are repeating questions more frequently or having more difficulties remembering recent conversations. This information is needed to better understand your memory difficulties. You will need to have a study partner to join this study. If you decide to participate, we will ask you to identify a person who you believe could act as your study partner and we will ask you to obtain his/her authorization for having us contacting him/her.

### **What happens if I can't find a study partner, or if my study partner decides to stop participating?**

Unfortunately, having a study partner is a requirement. If you can't find a study partner, we will not be able to include you in the study. If during the study, your study partner decides to stop participating, we will ask you to find another person who could act as your study partner for the remaining part of the study. If you can't find someone else, we will have to withdraw you from the study.

### **What do I need to do in order to be included in the study?**

You will need to answer a short questionnaire to ensure that you have understood the study. You will need to find a study partner. Finally, your diagnosis of mild cognitive impairment will need to be confirmed in the first testing session. If any of the former is not met, we will not be able to include you in the study. If the former happens, all data collected during the baseline testing will be destroyed. This will allow us to protect your privacy. Since there are other medical conditions that can affect the brain, we will need to ask you if you have received a diagnosis of epilepsy, stroke, traumatic brain injury, substance abuse, seizures, or active major depression. If you have any of these diagnoses, we will not be able to include you in the study. Also, to make sure the EEG will work and be safe on you, you cannot participate in the study if you have an in-ear hearing aid, an implanted pacemaker, metal or plastic implants in skull, allergy to rubbing alcohol, or an unhealthy scalp (open wounds).

### **Do I have the right to refuse and to decide not to participate?**

You have the right to refuse, and to decide not to take part in this study. Your regular care will not be affected by this decision. We will not tell your physicians if you are or are not participating in the study.

### **Once I am in, can I withdraw at any point?**

You are free to drop out from the study at any time. You will not need to give any explanations. If you chose to drop out of the study, this will not affect your future care in any way. The information collected

up to this point will still be used in the study. If you prefer that none of your information be used in the study, you can advise the research team.

**Are there any benefits to me if I participate in this study?**

There are no direct benefits from participating in this study. You are benefitting science by helping grow knowledge about memory impairment. During the study we will be continuously testing your memory: if we detect a significant change, we will let you and your study partner know. You can always ask for a copy of your results in the set of paper-and-pencil tests. You can ask the research assistant for the results at any point during the study. The research assistant will give you a written copy of your results in-person, at the hospital. The copy will only include the test results and will not have any diagnosis. Your study partner can also receive a copy if you assent this.

**What are the risks if I participate in the study?**

Preparation of the EEG requires skin scraping and cleansing. You may experience mild skin irritation or discomfort from this preparation. You will be encouraged to tell the experimenter whether you are experiencing any discomfort. The elastic cap and sensors are placed in a disinfectant. The risks of contamination are about the same as in a hair salon. The risks of being connected to the EEG are minimal. The cap includes safety measures that prevent excessive charge. The amplifier uses a battery, so it will not be connected to the power while testing. The cap can be easily removed should the need arise. The experimenter has been trained in proper application of the device.

**What happens if during the study my memory difficulties increase?**

If we detect that your difficulties have significantly increased, we will let you and your study partner know and ask you to notify your doctor. We will share with you and your study partner a report with the test results, so you can show it to your doctor if wanted. Also, because the difficulties might affect your capacity to understand and/or remember the study details, we will ask you and your study partner to identify someone who could act as a Substitute Decision Maker (SDM). The SDM can be the same person than your study partner or a different person, depending on your particular circumstances. The SDM will be asked to decide whether you continue to participate or not in the study, and will be asked to sign a consent form on your behalf. The SDM can discuss this decision with you.

**Who are the contact persons?**

If you have any questions about this study, you can call the researcher coordinator:

Natalia Valech

613-562-6262 extension 1677

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board

613-562-6262 extension 4003

We thank you for your time reading this information. A Research Assistant will call you and answer any questions you might have about the study.

**Participant Consent- Signature Page**

**THIS PAPER WILL BE SIGNED IN PERSON AT THE BASELINE SESSION, BEFORE INITIATING THE TESTING AND AFTER CONSENT REVIEW.**

**Study title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Qualified Investigator:** Frank Knoefel

**Please check as appropriate:**

I read the information sheet.

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study.

YES [ ] NO [ ]

I received satisfactory answers to all my questions.

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop out of the study:

- At any time
- Without having to give a reason
- Without affecting my future care

YES [ ] NO [ ]

I understand that this is my choice to consent and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to undergo memory tests, an EEG testing, and answer –together with my study partner- questions about memory difficulties

YES [ ] NO [ ]

I give my consent for the research team to include me in the study

YES [ ] NO [ ]

By signing below, I understand what my participation in this study means and I agree to participate in this study.

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Your name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

**Appendix 7b2: Consent Form NCP CN**

**Project Title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer’s disease

**Qualified Investigator:** Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics Clearance:** TBD

Thank you for your interest in this study. This document will help you understand the study and provide you with the information you need in order to decide if you would like to participate. We kindly ask that you read this information and prepare any questions that you may have before signing the consent form.

**What is this study about?**

The purpose of this study is to explore brain responses to specific sounds. Brain responses are obtained through an Electroencephalogram (EEG), which is a machine that records the electrical activity of the brain. We want to compare the brain responses of subjects with mild cognitive impairment with that of cognitively healthy subjects. We also want to explore if changes in the brain responses of a subject over time are related to a worsening of his/her cognition.

**Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9. We will cover your parking costs, if needed.

**How long is the study?**

This is a 3-year study. If you decide to participate, you will have to visit the Hospital every 6 months during the first year. Then, you will have to come once at the end of the second year, and again at the end of the third year.

**What will I do in the visits if I choose to participate?**

-You will need to answer a brief paper-and-pencil memory test that takes around 10 minutes to complete.

-You will undergo an EEG testing which will take around 25 minutes.

-You will have to complete a set of tests that measure your memory, language, and other mental functions. This should take you around 60 minutes to complete.

-You will need to answer a questionnaire about your perception of memory difficulties. This takes around 5 minutes to complete.

-You will be given breaks between-tasks to reduce fatigue. If during the longer sessions you feel very fatigued and need to stop the testing, please advise the research assistant and you will continue the session in another day.

On some sessions, you will need to complete all the tasks described; on other sessions, only some. Below is a chart showing every visit with the tasks included in them:

	<b>Visit 1 (baseline)</b>	<b>Visit 2 (6 months)</b>	<b>Visit 3 (12 months)</b>	<b>Visit 4 (24 months)</b>	<b>Visit 5 (36 months)</b>
<b>Tests</b>	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG 3. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires
<b>Time (approx.)</b>	100 minutes (115 with breaks)	40 minutes	100 minutes (115 with breaks)	100 minutes (115 with breaks)	100 minutes (115 with breaks)

**How is the EEG testing?**

For the EEG, a cap containing small sensors will be placed on your head. Sensors are small metal discs that record the activity of the brain. To place the sensors, the scalp area underneath them will be lightly rubbed with gel. Placing the cap should take around 10 minutes. Once placed, the testing will begin. In the testing, you will listen to sounds or words for 12 minutes, separated in two blocks. You will be asked to simply listen. The computer will record your brain's response to each sound. Because medications can affect brain responses, we will need to ask you and your study partner for the list of medications that you are taking. To respect your privacy, we will write down the list in a sheet of paper using a study number, and keep this sheet in a locked cabinet.

**Where and how will I complete these tasks?**

All the tasks will be performed in a private room in the hospital. A research assistant will administer the tasks.

**How will my privacy be protected?**

All of your answers to the tasks will be saved using a study number, and will be kept in a password-protected file in our office's computer. No one will be able to identify you from the study results. Everyone in the research team has signed a pledge committing to respect your privacy. We will share your results within the team to analyze the study results. Your results in the EEG will also be shared with the manufacturer of device (HealthTech Connex, Vancouver). Again the results will not have your name on them, and there will be no way of identifying you from them.

**What do I need to do in order to be included in the study?**

The study results of the first testing session will need to confirm that you do not have memory difficulties. If the results suggest that you might have memory difficulties, we will need to withdraw you from the study. All data collected during the baseline testing will be destroyed. This will allow us to protect your privacy. Since there are other medical conditions that can affect the brain, we will need to ask you if you have received a diagnosis of epilepsy, stroke, traumatic brain injury, substance abuse, seizures, or active major depression. If you have any of these diagnoses, we will not be able to include you in the study. Also, to make sure the EEG will work and be safe on you, you cannot participate in the study if you have an in-ear hearing aid, an implanted pacemaker, metal or plastic implants in skull, allergy to rubbing alcohol, or an unhealthy scalp (open wounds).

**Do I have the right to refuse and to decide not to participate?**

You have the right to refuse, and to decide not to take part in this study. Your regular care will not be affected by this decision. We will not tell your physicians if you are or are not participating in the study.

**Once I am in, can I withdraw at any point?**

You are free to drop out from the study at any time. You will not need to give any explanations. If you chose to drop out of the study, this will not affect your future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, you can advise the research team.

**Are there any benefits to me if I participate in this study?**

There are no direct benefits from participating in this study. You are benefitting science by helping grow knowledge about memory impairment. During the study we will be continuously testing your memory: if we detect a significant change, we will let you and your study partner know. You can always ask for a copy of your results in the set of paper-and-pencil tests. You can ask the research assistant for the results at any point during the study. The research assistant will give you a written copy of your results in-person, at the hospital. The copy will only include the test results and will not have any diagnosis.

**What are the risks if I participate in the study?**

Preparation of the EEG requires skin scraping and cleansing. You may experience mild skin irritation or discomfort from this preparation. You will be encouraged to tell the experimenter whether you are experiencing any discomfort. The elastic cap and sensors are placed in a disinfectant. The risks of contamination are about the same as in a hair salon. The risks of being connected to the EEG are minimal. The cap includes safety measures that prevent excessive charge. The amplifier uses a battery, so it will not be connected to the power while testing. The cap can be easily removed should the need arise. The experimenter has been trained in proper application of the device.

**What happens if during the study I start showing memory difficulties?**

If we detect that you start showing memory difficulties, we will let you and know and ask you to notify your doctor. We will share with you a report with the test results, so you can show it to your doctor if wanted. Also, because the difficulties might affect your capacity to understand and/or remember the study details, we will administer a questionnaire to make sure if you are still capable of giving consent. If you don't, we will ask you to find a person who could act as a Substitute Decision Maker. This person will be asked to decide whether you continue to participate or not in the study, and will be asked to sign a consent form on your behalf. S/he can discuss this information with you. Also, if you continue to participate, we will need to ask you to find a study partner (who could be the same than the substitute decision maker). A study partner is a person who knows you well, for at least the last 5 years, and with whom you have frequent contact. The SDM can be the same person than your study partner or a different person, depending on your particular circumstances. The study person will be asked to complete two brief questionnaires about your memory difficulties. Specifically, they will be asked if you need assistance with daily life activities such as shopping, travelling out your neighbourhood, and paying bills. They will also be asked if they notice that you are having more memory difficulties compared to years or months ago, for example if they have noticed that you are repeating questions more frequently or having more difficulties remembering recent conversations. This information is needed to better understand your memory difficulties. If you do not find a study partner, we will need to withdraw you from the study.

**Who are the contact persons?**

If you have any questions about this study, you can call the researcher coordinator:

Natalia

613-562-6262 extension 1677

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board

613-562-6262 extension 4003

We thank you for your time reading this information. A Research Assistant will call you and answer any questions you might have about the study.

**Participant Consent- Signature Page**

**THIS PAPER WILL BE SIGNED IN PERSON AT THE BASELINE SESSION, BEFORE INITIATING THE TESTING AND AFTER CONSENT REVIEW.**

**Study title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Qualified Investigator:** Frank Knoefel

**Please check as appropriate:**

I read the information sheet.

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study.

YES [ ] NO [ ]

I received satisfactory answers to all my questions.

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop out of the study:

- At any time
- Without having to give a reason
- Without affecting my future care

YES [ ] NO [ ]

I understand that this is my choice to consent and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to undergo memory tests, an EEG testing, and answer questions about memory difficulties

YES [ ] NO [ ]

I give my consent for the research team to include me in the study

YES [ ] NO [ ]

By signing below, I understand what my participation in this study means and I agree to participate in this study.

---

Your name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

### **Appendix 11a: Study Partner Consent Form CG only**

**Project Title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigator:** Dr. Andrew Frank

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext.1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics approval:** 11 Sept 2017

This document explains a research project of the Bruyère hospital, in which your relative/acquaintance is interested in participating. S/he needs a study partner to participate in this study, and s/he would like you to act as his/her study partner. You have the right to decide whether or not to participate. Participation is voluntary. We kindly ask that you read this information and prepare any questions that you may have before completing the signature page. A research assistant will contact you to answer your questions.

#### **What is this study about?**

In this study, we want to observe how well a computer game works in detecting memory and cognitive difficulties, and predicting future cognitive decline.

#### **What is a study partner?**

Study partner is a person who knows the participant well, for at least 5 years, and interacts with him/her in a regular basis (at least twice a week).

#### **Why do participants need a study partner?**

Participants need to have a study partner in order to be included in this study. The study partner's perception of the difficulties that the participant may have in performing daily life activities is crucial for defining the participant's cognitive health. Although participants will be asked about their own perception of difficulties, given that cognitive impairment may affect the person's level of awareness and capacity to remember, it is important to have an additional source of reporting.

#### **What do I have to do if I choose to act as the study partner?**

If you decide to act as his/her study partner, you will need to answer the following two questionnaires:

- **Functional Activities Questionnaire:** in this questionnaire, you will have to rate the level of dependence of your relative/acquaintance in different activities of daily living. For example, we will ask you if s/he is able to do shopping alone or requires assistance. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.
- **General Practitioner Assessment of Cognition:** in this questionnaire, you will be asked if you have perceived that your relative/acquaintance has more memory difficulties compared to before. For example, we will ask you if you perceive s/he has more troubles recalling conversations compared to one year ago. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.

#### **How many times will I need to answer these questionnaires?**

This is a 3-year study. During this time, you will need to answer the questionnaires at every testing session. There are 7 testing sessions:

1. First session
2. 3 months session
3. 6 months session
4. 9 months session
5. 12 months session
6. 24 months session
7. 36 months session

As you can see, you will need to answer these questionnaires every three months for the first year, and two additional times at the end of the second and third year.

**How will I answer these questionnaires?**

A research assistant will administer these questionnaires to you. You will be able to choose between:

- **Answering the questions in person:** at the Bruyère Hospital. For example, if you come with the participant to the testing sessions, you will complete the questionnaires while waiting for him/her to complete the tasks. We will cover your parking cost, if needed.
- **Answering the questions by phone:** the research assistant will call you,

**How will my answers be recorded?**

The research assistant will record your answers in a piece of paper using an anonymized study number. The paper will not have your name, the participant's name, or any personal identifier. There will be no way of identifying you from the questionnaires.

**How will my confidentiality be protected?**

All study team members have signed a confidentiality pledge committing to respect the privacy of the participants. As mentioned before, your answers to the questionnaires will be recorded in paper sheets that will not contain your name or personal identifiers. These paper sheets will be stored in a locked cabinet inside the team's office.

**Will my answers to the questionnaires be shared?**

Your answers will be shared between the members of the team, using a password-protected Excel file, in order to analyze the study results. The file will not contain your name, the participant's name, or any personal identifier. There will be no way of identifying you from them.

We will not share your answers with anyone outside the study team. We will not share your answers with the participant. However, you are free to comment your answers with him/her if you wish to.

**Do I have the right to refuse to act as the Study Partner?**

You have the right to refuse to act as the Study Partner. If your relative/acquaintance does not find another Study Partner, s/he will be withdrawn from the study. His/her regular care at the Bruyère Memory Program clinic will not be affected by this decision. His/her care staff is not notified of his/her participation in the study.

**Once I start acting as the study partner, can I withdraw?**

You are free to drop out from the study at any time without giving any explanations. If you choose to do so, your relative/acquaintance must find another study partner to continue in the study. The information collected up to this point will still be used in the study. If you prefer that none of the information be used in the study, you can advise the research assistant.

**Are there any benefits to you if you participate in this study?**

There are no direct benefits from participating in this study.

**Are there any potential risks for me if I act as a Study Partner in this study?**

There are no significant risks for you if you decide to act as a Study Partner in this study. It may happen that you feel uncomfortable answering some of the questions. If this is the case, please notify the research assistant and the question will be omitted.

**Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Frank Knoefel: 613-562-6262 extension 1357

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board: 613-562-6262 extension 4003

We thank you for your time for reviewing this material. Our Research Assistant will review it with you and answer any questions. A signature page denoting consent acting as a Study Partner is attached below. Please do not complete it until after your questions have been answered.

**Study Partner Consent- Signature Page**

**Project Title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigator:** Dr. Andrew Frank

**Please check as appropriate:**

I read the consent form

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study

YES [ ] NO [ ]

I received satisfactory answers to all my questions

YES [ ] NO [ ]

I understand that I am free to withdraw consent and stop acting as a Study Partner:

- At any time
- Without having to give a reason
- Without affecting my relative/acquaintance's future care

YES [ ] NO [ ]

I understand that this is my choice to consent, and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to answer two questionnaires about my relative/acquaintance's memory and cognitive difficulties, and level of independence in daily life activities

YES [ ] NO [ ]

By signing below, I understand what the participation as a Study Partner means and I agree to participate as such in this study.

---

Your name: \_\_\_\_\_

Relative/acquaintance name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

### **Appendix 11b: Study Partner Consent Form NCP only**

**Project Title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Qualified Investigator:** Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech (research assistant)

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics Clearance:** TBD

This document explains a research project of the Bruyère hospital, in which your relative/acquaintance is interested in participating. S/he needs a study partner to participate in this study, and s/he would like you to act as his/her study partner. You have the right to decide whether or not to participate. Participation is voluntary. We kindly ask that you read this information and prepare any questions that you may have before completing the signature page. A research assistant will contact you to answer your questions.

#### **What is this study about?**

The purpose of this study is to explore brain responses to specific sounds in subjects with mild cognitive impairment. Brain responses are obtained through an Electroencephalogram (EEG), which is a test that records the electrical activity of the brain. The brain activity of subjects with mild cognitive impairment will be compared to that of cognitively healthy subjects. We will also explore if over time the changes in the brain responses of a subject are related to a worsening of his/her cognition.

#### **What is a study partner?**

Study partner is a person who knows the participant well, for at least the last 5 years, and interacts with them in a regular basis (at least twice a week).

#### **Why do participants need a study partner?**

Participants need to have a study partner in order to be included in this study. The study partner's perception of the difficulties that the participant may have in performing daily life activities is crucial for defining the participant's cognitive health. Although participants will be asked about their own perception of difficulties, given that cognitive impairment may affect the person's level of awareness and capacity to remember, it is important to have an additional source of reporting.

#### **What do I have to do if I choose to act as the study partner?**

If you decide to act as his/her study partner, you will need to answer the following two questionnaires:

- Functional Activities Questionnaire: in this questionnaire, you will have to rate the level of dependence of your relative/acquaintance in different activities of daily living. For example, we will ask you if s/he is able to do shopping alone or requires assistance. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.
- General Practitioner Assessment of Cognition: in this questionnaire, you will be asked if you have perceived that your relative/acquaintance has more memory difficulties compared to before. For example, we will ask you if you perceive s/he has more troubles recalling conversations compared to one year ago. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.

After completing the questionnaires, we will ask you about the medications that the participant is taking. We also ask this information to the participant, but given that cognitive impairment can affect memory we would need to confirm this information with you.

#### **How many times will I need to answer these questionnaires?**

This is a 3-year study. During this time, you will need to answer the questionnaires at every testing session. There are 5 testing sessions:

1. First session
2. 6 months session
3. 12 months session
4. 24 months session
5. 36 months session

As you can see, you will need to answer these questionnaires every six months for the first year, and two additional times at the end of the second and third year.

### **How will I answer these questionnaires?**

A research assistant will administer these questionnaires to you. You will be able to choose between:

- **Answering the questions in person:** at the Bruyère Hospital. For example, if you come with the participant to the testing sessions, you will complete the questionnaires while waiting for him/her to complete the tasks. We will cover your parking cost, if needed.
- **Answering the questions by phone:** the research assistant will call you,

### **How will my answers be recorded?**

The research assistant will record your answers in a piece of paper using an anonymized study number. The paper will not have your name, the participant's name, or any personal identifier. There will be no way of identifying you from the questionnaires.

### **How will my confidentiality be protected?**

All study team members have signed a confidentiality pledge committing to respect the privacy of the participants. As mentioned before, your answers to the questionnaires will be recorded in paper sheets that will not contain your name or personal identifiers. These paper sheets will be stored in a locked cabinet inside the team's office.

### **Will my answers to the questionnaires be shared?**

Your answers will be shared between the members of the team, using a password-protected Excel file, in order to analyze the study results. The file will not contain your name, the participant's name, or any personal identifier. There will be no way of identifying you from them.

We will not share your answers with anyone outside the study team. We will not share your answers with the participant. However, you are free to comment your answers with him/her if you wish to.

### **Do I have the right to refuse to act as the Study Partner?**

You have the right to refuse to act as the Study Partner. If your relative/acquaintance does not find another Study Partner, s/he will be withdrawn from the study. His/her regular care at the Bruyère Memory Program clinic will not be affected by this decision. His/her care staff is not notified of his/her participation in the study.

### **Once I start acting as the study partner, can I withdraw?**

You are free to drop out from the study at any time without giving any explanations. If you choose to do so, your relative/acquaintance must find another study partner to continue in the study. The information collected up to this point will still be used in the study. If you prefer that none of the information be used in the study, you can advise the research assistant.

### **Are there any benefits to you if you participate in this study?**

There are no direct benefits from participating in this study.

### **Are there any potential risks for me if I act as a Study Partner in this study?**

There are no significant risks for you if you decide to act as a Study Partner in this study. It may happen that you feel uncomfortable answering some of the questions. If this is the case, please notify the research assistant and the question will be omitted.

### **Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Frank Knoefel: 613-562-6262 extension 1357

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board: 613-562-6262 extension 4003

Version n°8: August 29, 2018

We thank you for your time for reviewing this material. Our Research Assistant will review it with you and answer any questions. A signature page denoting consent acting as a Study Partner is attached below. Please do not complete it until after your questions have been answered.

**Study Partner Consent- Signature Page**

**Study title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigator:** Dr. Frank Knoefel

**Please check as appropriate:**

I read the consent form

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study

YES [ ] NO [ ]

I received satisfactory answers to all my questions

YES [ ] NO [ ]

I understand that I am free to withdraw consent and stop acting as a Study Partner:

- At any time
- Without having to give a reason
- Without affecting my relative/acquaintance's future care

YES [ ] NO [ ]

I understand that this is my choice to consent, and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to answer two questionnaires about my relative/acquaintance's memory and cognitive difficulties, and level of independence in daily life activities

YES [ ] NO [ ]

By signing below, I understand what the participation as a Study Partner means and I agree to participate as such in this study.

---

Your name: \_\_\_\_\_

Relative/acquaintance name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

### **Appendix 11c: Study Partner Consent Form CN and NCP**

**Project Title:** Validation of new technologies in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigators:** Dr. Andrew Frank and Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext 1677

**E-mail Address:** tafeta@bruyere.org

**Date of Ethics approval:** TBD

This document explains a research project of the Bruyère hospital, in which your relative/acquaintance is interested in participating. S/he needs a study partner to participate in this study, and s/he would like you to act as his/her study partner. You will find below a detailed description of what your role will be if you choose to act as his/her study partner. Participation is voluntary. We kindly ask that you read this information and prepare any questions that you may have before signing the form.

#### **What is this study about?**

The purpose of this study is to explore new technologies and their capacity to detect memory and cognitive difficulties. One of the technologies is a computer game, and the other one is a new Electroencephalogram (EEG) machine. EEG is a test that records the electrical activity of the brain. We want to explore if changes in the EEG and in the computer game's performance of a subject over time are related to a worsening of his/her condition.

#### **What is a study partner?**

Study partner is a person who knows the participant well, for at least the last 5 years, and interacts with them in a regular basis (at least twice a week).

#### **Why do participants need a study partner?**

Participants need to have a study partner in order to be included in this study. The study partner's perception of the difficulties that the participant may have in performing daily life activities is crucial for defining the participant's cognitive health. Although participants will be asked about their own perception of difficulties, given that cognitive impairment may affect the person's level of awareness and capacity to remember, it is important to have an additional source of reporting.

#### **What do I have to do if I choose to act as the study partner?**

If you decide to act as his/her study partner, you will need to answer the following two questionnaires:

- Functional Activities Questionnaire: in this questionnaire, you will have to rate the level of dependence of your relative/acquaintance in different activities of daily living. For example, we will ask you if s/he is able to do shopping alone or requires assistance. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.
- General Practitioner Assessment of Cognition: in this questionnaire, you will be asked if you have perceived that your relative/acquaintance has more memory difficulties compared to before. For example, we will ask you if you perceive s/he has more troubles recalling conversations compared to one year ago. This questionnaire takes around 5 minutes to be completed. Please find the questionnaire attached at the end of this form for more details.

After completing the questionnaires, we will ask you about the medications that the participant is taking. We also ask this information to the participant, but given that cognitive impairment can affect memory we would need to confirm this information with you.

#### **How many times will I need to answer these questionnaires?**

This is a 3-year study. During this time, you will need to answer the questionnaires at every testing session. There are 7 testing sessions:

1. First session
2. 3 months session

3. 6 months session
4. 9 months session
5. 12 months session
6. 24 months session
7. 36 months session

As you can see, you will need to answer these questionnaires every three months for the first year, and two additional times at the end of the second and third year.

### **How will I answer these questionnaires?**

A research assistant will administer these questionnaires to you. You will be able to choose between:

- **Answering the questions in person:** at the Bruyère Hospital. For example, if you come with the participant to the testing sessions, you will complete the questionnaires while waiting for him/her to complete the tasks. We will cover your parking cost, if needed.
- **Answering the questions by phone:** the research assistant will call you,

### **How will my answers be recorded?**

The research assistant will record your answers in a piece of paper using an anonymized study number. The paper will not have your name, the participant's name, or any personal identifier. There will be no way of identifying you from the questionnaires.

### **How will my confidentiality be protected?**

All study team members have signed a confidentiality pledge committing to respect the privacy of the participants. As mentioned before, your answers to the questionnaires will be recorded in paper sheets that will not contain your name or personal identifiers. These paper sheets will be stored in a locked cabinet inside the team's office.

### **Will my answers to the questionnaires be shared?**

Your answers will be shared between the members of the team, using a password-protected Excel file, in order to analyze the study results. The file will not contain your name, the participant's name, or any personal identifier. There will be no way of identifying you from them.

We will not share your answers with anyone outside the study team. We will not share your answers with the participant. However, you are free to comment your answers with him/her if you wish to.

### **Do I have the right to refuse to act as the Study Partner?**

You have the right to refuse to act as the Study Partner. If your relative/acquaintance does not find another Study Partner, s/he will be withdrawn from the study. His/her regular care at the Bruyère Memory Program clinic will not be affected by this decision. His/her care staff is not notified of his/her participation in the study.

### **Once I start acting as the study partner, can I withdraw?**

You are free to drop out from the study at any time without giving any explanations. If you choose to do so, your relative/acquaintance must find another study partner to continue in the study. The information collected up to this point will still be used in the study. If you prefer that none of the information be used in the study, you can advise the research assistant.

### **Are there any benefits to you if you participate in this study?**

There are no direct benefits from participating in this study.

### **Are there any potential risks for me if I act as a Study Partner in this study?**

There are no significant risks for you if you decide to act as a Study Partner in this study. It may happen that you feel uncomfortable answering some of the questions. If this is the case, please notify the research assistant and the question will be omitted.

### **Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Frank Knoefel: 613-562-6262 extension 1357

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board: 613-562-6262 extension 4003

Version n°8: August 29, 2018

We thank you for your time for reviewing this material. Our Research Assistant will review it with you and answer any questions. A signature page denoting consent acting as a Study Partner is attached below. Please do not complete it until after your questions have been answered.

**Study Partner Consent- Signature Page**

**Project Title:** Validation of new technologies in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigators:** Dr. Andrew Frank, Dr. Frank Knoefel

**Please check as appropriate:**

I read the consent form

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study

YES [ ] NO [ ]

I received satisfactory answers to all my questions

YES [ ] NO [ ]

I understand that I am free to withdraw consent and stop acting as a Study Partner:

- At any time
- Without having to give a reason
- Without affecting my relative/acquaintance's future care

YES [ ] NO [ ]

I understand that this is my choice to consent, and that I will not benefit directly from this research.

YES [ ] NO [ ]

I understand that I will be asked to answer two questionnaires about my relative/acquaintance's memory and cognitive difficulties, and level of independence in daily life activities

YES [ ] NO [ ]

By signing below, I understand what the participation as a Study Partner means and I agree to participate as such in this study.

---

Your name: \_\_\_\_\_

Relative/acquaintance name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Your signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

## **Appendix 13a : SDM Consent Form for CG study**

**Project Title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigator:** Dr. Andrew Frank

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext 1677

**E-mail Address:** nvalech@bruyere.org

**Date of Ethics approval:** 11 Sept 2017

This document explains a research project of the Bruyère Research Institute, in which the person whom you are representing has been participating so far. Because the cognitive impairment of the participant has progressed, we need you to act as his/her Substitute Decision Maker and decide whether the participant continues in this study or not. Participation is voluntary.

### **What is this study about?**

In this study, we want to observe how well a computer game works in detecting memory difficulties, and predicting future decline in mental functions.

### **How is the computer game?**

The computer game is has four different tasks. In each task, one card appears at the center of a computer screen. The participant is asked to answer different questions in each task, for example "has the card turned face up?" To answer, s/he has to press the "D" key (representing YES) or the "K" key (representing NO). The game does not need participants to be experienced with computers. It takes around 15 minutes to complete.



Example of one of the tasks in the computer game: you will be asked to press the D key as soon as the card has turned face up.

### **Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9. We cover parking costs, if needed.

### **How long is the study?**

This is a 3-year study. The participant needs to come once every 3 months during the first year. Then, s/he needs to come once at the end of the second year, and again at the end of the third year. Please ask the research assistant which sessions are remaining for the participant.

### **What does the participant in the visits?**

- The participant plays the computer game described above (15 minutes)
- The participant answers a brief paper-and-pencil memory test that takes around 10 minutes to complete
- The participant answers a questionnaire about his/her perception of memory difficulties. This takes around 5 minutes to complete.
- In some sessions, the participant will need to complete a set of tests that measure his/her memory, language, and other mental functions. This takes around 50-60 minutes to complete.
- The participant will be given breaks between-tasks to reduce fatigue. If during the longer sessions the participant feels very fatigued and needs to stop the testing, the experimenter will suspend the testing and continue with the session in another day.

Below is a chart showing every visit with the tasks included in them:

	<b>Visit 1 (baseline)</b>	<b>Visit 2 (3 months)</b>	<b>Visit 3 (6 months)</b>	<b>Visit 4 (9 months)</b>	<b>Visit 5 (12 months)</b>	<b>Visit 6 (24 months)</b>	<b>Visit 7 (36 months)</b>
<b>Tasks</b>	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game Questionnaires	Brief memory test Computer game -5 minutes break- Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires	Set of tests part I -10 min break- Set of tests part II Questionnaires
<b>Total Time</b>	90 minutes (105 with breaks)	30 minutes	30 minutes	30 minutes	90 minutes (105 with breaks)	65 minutes (75 with breaks)	65 minutes (75 with breaks)

**Where and how does the participant complete these tasks?**

All the tasks are performed in a private room in the hospital. A research assistant administers the tasks.

**How is the participant’s privacy protected?**

All the answers to the tasks are saved using a study number, and are kept in a password-protected file in our office’s computer. No one will be able to identify the participant from the study results. Everyone in the research team has signed a pledge committing to respect the participant’s privacy. We will share the results within the team to analyze the study results. The participant’s results in the computer game will also be shared with the manufacturer of the game (Cogstate, USA). Again the results will not have the participant’s name on them, and there will be no way of identifying his/her.

**Do I have the right to refuse and to decide not to continue participation?**

You have the right to refuse on behalf of the participant, and to decide to discontinue his/her participation. The participant’s regular care will not be affected by this decision.

**Can I withdraw participation at any point in the future?**

You are free to drop out the participant from the study at any time. You will not need to give any explanations. If you chose to drop him/her out of the study, this will not affect his/her future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, please advise the research assistant.

**Are there any benefits to the participant in this study?**

There are no direct benefits from participating in this study. Participants are benefitting science by helping grow knowledge about cognitive impairment and dementia.

**Are there any potential risks to the participant in this study?**

There are no significant risks for participants. Participants not enjoy the computer game, or any of the paper and pencil tasks. It may happen, also, that it might inconvenience the participant having to visit the hospital. If any of these happens, remember that you are free to drop him/her out and of the study at any point.

**Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher. That person is:

Dr. Andrew Frank

613-562-6262 extension 1078

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board

613-562-6262 extension 4003

We thank you for your time reviewing this material. Our Research Assistant will review it with you and answer any questions.

**Participant Consent- SDM Signature Page**

**Study title:** Validation of a computer game in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigator:**

Dr. Andrew Frank

**Please check as appropriate:**

I read the information and consent sheet.

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study.

YES [ ] NO [ ]

I received satisfactory answers to all my questions.

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop the participant out of the study:

- Without having to give a reason
- Without affecting his/her future care
- At any time

YES [ ] NO [ ]

I understand that this is my choice to consent on behalf of the participant, and that he/she will not benefit directly from this research.

YES [ ] NO [ ]

I understand that the participant will be asked to play a computer game, undergo memory and cognitive tests, and answer –together with a study partner- questions about daily life difficulties

YES [ ] NO [ ]

I give my consent for the research team to continue including the participant in the study

YES [ ] NO [ ]

By signing below, I understand what the participation in this study means and I Agree to consent on behalf of the PWD for his continuance in this study.

---

Your name: \_\_\_\_\_

Participant's name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

### Appendix 13b: SDM Consent Form for NCP study

**Project Title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Qualified Investigator:** Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech (research assistant)

**Telephone number:** 613-562-6262 ext. 1677

**E-mail Address:** nvalech@bruyere.org

**Date of Ethics Clearance:** TBD

This document explains a research project of the Bruyère Research Institute, in which the person whom you are representing has been participating so far. Because the cognitive impairment of the participant has progressed, we need you to act as his/her Substitute Decision Maker and decide whether the participant continues in this study or not. Participation is voluntary.

#### **What is this study about?**

The purpose of this study is to explore brain responses to specific sounds in subjects with mild cognitive impairment. Brain responses are obtained through an Electroencephalogram (EEG), which is a test that records the electrical activity of the brain. The brain activity of subjects with mild cognitive impairment will be compared to that of cognitively healthy subjects. We will also explore if over time the changes in the brain responses of a subject are related to a worsening of his/her cognition.

#### **Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9. We cover parking costs, if needed.

#### **How long is the study?**

This is a 3-year study. The participant needs to come once every 6 months during the first year. Then, s/he needs to come once at the end of the second year, and again at the end of the third year. Please ask the research assistant which sessions are remaining for the participant.

#### **What does the participant in the visits?**

-The participant answers a brief paper-and-pencil memory test (screening test) that takes around 10 minutes to complete

-The participant undergoes an EEG testing which will take around 25 minutes. This is explained with more detail below.

-The participant answers a questionnaire about his/her perception of memory and cognitive difficulties. This takes around 5 minutes to complete

-In some visits, the participant also completes a set of cognitive tests that measure your memory, language, and other functions. This takes around 50-60 minutes to complete.

-The participant will be given breaks between-tasks to reduce fatigue. If during the longer sessions the participant feels very fatigued and needs to stop the testing, the experimenter will suspend the testing and continue with the session in another day.

On some sessions, you will need to complete all the tasks described above; on other sessions, only some. Below is a chart showing every visit with the tasks included in them.

	Visit 1 (baseline)	Visit 2 (6 months)	Visit 3 (12 months)	Visit 4 (24 months)	Visit 5 (36 months)
<b>Tests</b>	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG 3. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires	1. Memory test 2. EEG -5 min break- 3. Set of tests part I -10 min break- Set if tests part II 4. Questionnaires
<b>Time (approx.)</b>	100 minutes (115 with breaks)	40 minutes	100 minutes (115 with breaks)	100 minutes (115 with breaks)	100 minutes (115 with breaks)

### **How is the EEG testing?**

For the EEG, a nylon cap containing small sensors is placed on the participant's head. Sensors are small metal discs with thin wires that record the activity of the brain. To place the sensors, the scalp area underneath them will be lightly rubbed with gel. Placing the cap takes around 10 minutes. Once correctly placed, the testing begins. In the testing, the participant listens to sounds or words through computer speakers for 12 minutes separated in two blocks. The participant is asked to simply listen, without making any specific action. Because medications can affect brain responses, we ask the participant and his/her study partner for the list of medications that the participant is taking in each session. To respect the participant's privacy, we write down the list of medications in a sheet of paper using an anonymized study number, and keep this sheet of paper in a locked cabinet inside an office at the hospital.

### **Where and how does the participant complete these tasks?**

All the tasks are performed in a private room in the hospital. A research assistant administers the tasks.

### **How is the participant's privacy protected?**

All the answers to the tasks are saved using a study number, and are kept in a password-protected file in our office's computer. No one will be able to identify the participant from the study results. Everyone in the research team has signed a pledge committing to respect the participant's privacy. We will share the results within the team to analyze the study results. The results will be shared with the manufacturer of the machine (HealthTech, Vancouver). Again the results will not have the participant's name on them, and there will be no way of identifying his/her.

### **Do I have the right to refuse and to decide not to continue participation?**

You have the right to refuse on behalf of the participant, and to decide to discontinue his/her participation. The participant's regular care will not be affected by this decision.

### **Can I withdraw participation at any point in the future?**

You are free to drop out the participant from the study at any time. You will not need to give any explanations. If you chose to drop him/her out of the study, this will not affect his/her future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, please advise the research assistant.

### **Are there any benefits to the participant in this study?**

There are no direct benefits from participating in this study. Participants are benefitting science by helping grow knowledge about cognitive impairment and dementia.

### **Are there any potential risks to the participant in this study?**

There are no significant risks for participants. Preparation of the EEG requires skin scraping and cleansing (with alcohol pads and scrubs). The participant may experience mild skin irritation or discomfort from this preparation. The participant is encouraged to tell the experimenter whether s/he is experiencing any discomfort. The elastic cap and sensors are placed in a disinfectant that kills viruses, bacteria, and fungi. The risks of contamination are about the same as in a hair salon. The risks of being connected to the EEG are minimal. The cap includes safety measures that prevent excessive static charge. The amplifier uses a battery, so it will not be connected to the power while testing. The cap can be easily removed should the need arise. The experimenter has been trained in proper application of the EEG.

### **Who are the contact persons?**

If you have any questions about this study, you can call the lead researcher: Dr. Frank Knoefel, 613-562-6262 extension 1357

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at: Bruyère Research Ethics Board, 613-562-6262 extension 4003.

We thank you for your time reviewing this material. Our Research Assistant will review it with you and answer any questions.

**Participant Consent- SDM Signature Page**

**Study title:** Validation of event-related potentials in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigator:**  
Dr. Frank Knoefel

**Please check as appropriate:**

I read the information and consent sheet.

YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study.

YES [ ] NO [ ]

I received satisfactory answers to all my questions.

YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop the participant out of the study:

- Without having to give a reason
- Without affecting his/her future care
- At any time

YES [ ] NO [ ]

I understand that this is my choice to consent on behalf of the participant, and that he/she will not benefit directly from this research.

YES [ ] NO [ ]

I understand that the participant will undergo EEG testing, complete memory and cognitive tests, and answer –together with a study partner- questions about daily life difficulties

YES [ ] NO [ ]

I give my consent for the research team to continue including the participant in the study

YES [ ] NO [ ]

By signing below, I understand what the participation in this study means and I Agree to consent on behalf of the PWD for his continuance in this study.

---

Your name: \_\_\_\_\_

Participant's name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_

### **Appendix 13c: SDM Consent Form for CG and NCP study**

**Project Title:** Validation of new technologies in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Principal Investigators:** Dr. Andrew Frank and Dr. Frank Knoefel

**Affiliation:** Bruyère Continuing Care

**Contact Person:** Natalia Valech

**Telephone number:** 613-562-6262 ext 1677

**E-mail Address:** nvalech@bruyere.org

**Date of Ethics approval:** TBD

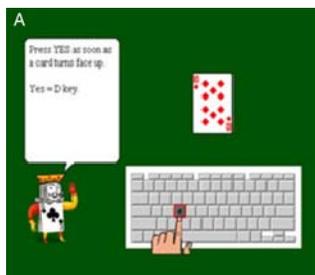
This document explains a research project of the Bruyère Research Institute, in which the person whom you are representing has been participating so far. Because the cognitive impairment of the participant has progressed, we need you to act as his/her Substitute Decision Maker and decide whether the participant continues in this study or not. Participation is voluntary.

#### **What is this study about?**

The purpose of this study is to explore new technologies and their capacity to detect memory difficulties. One of the technologies is a computer game, and the other one is an Electroencephalogram (EEG). The EEG is a test that records the electrical activity of the brain. We want to explore if changes in the EEG and in the computer game's performance of a subject over time are related to a worsening of his/her condition.

#### **How is the computer game?**

The computer game is has four different tasks. In each task, one card appears at the center of a computer screen. The participant is asked to answer different questions in each task, for example "has the card turned face up?" To answer, s/he has to press the "D" key (representing YES) or the "K" key (representing NO). The game does not need participants to be experienced with computers. It takes around 15 minutes to complete.



Example of one of the tasks in the computer game: you will be asked to press the D key as soon as the card has turned face up.

#### **How is the EEG testing?**

For the EEG, a nylon cap containing small sensors is placed on the participant's head. Sensors are small metal discs with thin wires that record the activity of the brain. To place the sensors, the scalp area underneath them will be lightly rubbed with gel. Placing the cap takes around 10 minutes. Once correctly placed, the testing begins. In the testing, the participant listens to sounds or words through computer speakers for 12 minutes separated in two blocks. The participant is asked to simply listen, without making any specific action. Because medications can affect brain responses, we ask the participant and his/her study partner for the list of medications that the participant is taking in each session. To respect the participant's privacy, we write down the list of medications in a sheet of paper using a study number, and keep this sheet of paper in a locked cabinet inside an office at the hospital.

#### **Where is the study?**

The study is done at the Bruyère Hospital, in Ottawa. Address is: 75 Bruyère St., K1N 5C9. We cover parking costs, if needed.

#### **How long is the study?**

This is a 3-year study. The participant needs to come once every 3 months during the first year. Then, s/he needs to come once at the end of the second year, and again at the end of the third year. Please ask the research assistant which sessions are remaining for the participant.

**What does the participant in the visits?**

- The participant answers a brief paper-and-pencil memory test that takes around 10 minutes to complete.
- The participant plays the computer game described above.
- The participant undergoes an EEG testing session. It takes 25 minutes to complete.
- The participant completes a set of tests that measure his/her memory, language, and mental functions. This takes around 50-60 minutes to complete.
- The participant answers a questionnaire about his/her perception of memory difficulties. This takes around 5 minutes to complete.

The participant will be given breaks between-tasks to reduce fatigue. If during the longer sessions the participant feels very fatigued and needs to stop the testing, the experimenter will suspend the testing and continue with the session in another day.

On some sessions, you will need to complete all the tasks described above; on other sessions, only some. Below is a chart showing every visit with the tasks included in them:

	Visit 1 (baseline)	Visit 2 (3 months)	Visit 3 (6 months)	Visit 4 (9 months)	Visit 5 (12 months)	Visit 6 (24 months)	Visit 7 (36 months)
<b>Tests</b>	1. Memory test 2. Computer game <i>5' break</i> 3. EEG <i>5' break</i> 4. Set of tests part I <i>10' break</i> 5. <i>Set of tests part II</i> 5. Questionnaires	1. Memory test 2. Computer game 3. Questionnaires	1. Memory test 2. Computer game <i>5' break</i> 3. EEG 4. Questionnaires	1. Memory test 2. Computer game 3. Questionnaires	1. Memory test 2. Computer game <i>5' break</i> 3. EEG <i>5' break</i> 4. Set of tests part I <i>10' break</i> 5. <i>Set of tests part II</i> 6. Questionnaires	1. Memory test 2. EEG <i>5' break</i> 3. Set of test part I <i>10' break</i> 4. <i>Set of tests part II</i> 4. Questionnaires	1. Memory test 2. EEG <i>5' break</i> 3. Set of test part I <i>10' break</i> 4. <i>Set of tests part II</i> 4. Questionnaires
<b>Time</b>	115 minutes (135 with breaks)	30 minutes	55 minutes (60 with break)	30 minutes	115 minutes (135 with breaks)	100 minutes (115 with breaks)	100 minutes (115 with breaks)

**Where and how does the participant complete these tasks?**

All the tasks are performed in a private room in the hospital. A research assistant administers the tasks.

**How is the participant’s privacy protected?**

All the answers to the tasks are saved using a study number, and are kept in a password-protected file in our office’s computer. No one will be able to identify the participant from the study results. Everyone in the research team has signed a pledge committing to respect the participant’s privacy. We will share the results within the team to analyze the study results. The computer game’s results will also be shared with the manufacturer of the game (Cogstate, USA) and manufacturer of the EEG (Healthtech, Vancouver). Again the results will not have the participant’s name on them, and there will be no way of identifying his/her.

**Do I have the right to refuse and to decide not to continue participation?**

You have the right to refuse on behalf of the participant, and to decide to discontinue his/her participation. The participant’s regular care will not be affected by this decision. You also have the option to choose the participant to remain in the study but only for one of the technologies: for example, you might prefer to continue the computer game but discontinue the EEG testing sessions, or vice versa.

**Can I withdraw participation at any point in the future?**

You are free to drop out the participant from the study at any time. You will not need to give any explanations. If you chose to drop him/her out of the study, this will not affect his/her future care in any way. The information collected up to this point will still be used in the study. If you prefer that none of your information be used in the study, please advise the research assistant. You are also free to

withdraw participation at any point from one of the two technologies, for example discontinue only the computer game sessions or the EEG testing sessions.

**Are there any benefits to the participant in this study?**

There are no direct benefits from participating in this study. Participants are benefitting science by helping grow knowledge about cognitive impairment and dementia.

**Are there any potential risks to the participant in this study?**

There are no significant risks for participants. Preparation of the EEG requires skin scraping and cleansing (with alcohol pads and scrubs). The participant may experience mild skin irritation or discomfort from this preparation. The participant is encouraged to tell the experimenter whether s/he is experiencing any discomfort. The elastic cap and sensors are placed in a disinfectant that kills viruses, bacteria, and fungi. The risks of contamination are about the same as in a hair salon. The risks of being connected to the EEG are minimal. The cap includes safety measures that prevent excessive static charge. The amplifier uses a battery, so it will not be connected to the power while testing. The cap can be easily removed should the need arise. The experimenter has been trained in proper application of the EEG.

**Who are the contact persons?**

If you have any questions about this study, you can call the lead researchers:

Dr. Andrew Frank, 613-562-6262 extension 1078 (for Computer game)

Dr. Frank Knoefel, 613-562-6262 extension 1357 (for the EEG)

Or you can talk to someone who is not involved in the study at all, but can tell you about your right as a participant in a research study at:

Bruyère Research Ethics Board, 613-562-6262 extension 4003.

We thank you for your time reviewing this material. Our Research Assistant will review it with you and answer any questions.

**Participant Consent- SDM Signature Page**

**Study title:** Validation of new technologies in the diagnosis of mild cognitive impairment and Alzheimer's disease

**Name of Principal Investigators:**  
Dr. Frank Knoefel and Dr. Andrew Frank

**Please check as appropriate:**

I read the information and consent sheet.  
YES [ ] NO [ ]

I had the chance to ask questions/to discuss this study.  
YES [ ] NO [ ]

I received satisfactory answers to all my questions.  
YES [ ] NO [ ]

I understand that I am free to withdraw consent and drop the participant out of the study:

- Without having to give a reason
- Without affecting his/her future care
- At any time

YES [ ] NO [ ]

I understand that this is my choice to consent on behalf of the participant, and that he/she will not benefit directly from this research.

YES [ ] NO [ ]

I understand that the participant will undergo EEG testing, complete memory and cognitive tests, play a computer game, and answer –together with a study partner- questions about daily life difficulties

YES [ ] NO [ ]

I give my consent for the research team to continue including the participant in the study

YES [ ] NO [ ]

By signing below, I understand what the participation in this study means and I Agree to consent on behalf of the PWD for his continuance in this study.

---

Your name: \_\_\_\_\_

Participant's name: \_\_\_\_\_

Date (DD/MM/YYYY): \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature: \_\_\_\_\_

Qualified investigator signature (do not complete): \_\_\_\_\_