

**Partners HealthCare System
Research Consent Form**

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Functional Assessment of the Melanopsin-Containing Retinal Ganglion Cells in Progressive Supranuclear Palsy Using Chromatic Pupillometry

Principal Investigator: Shirley H. Wray, MD, PhD, FRCP

Site Principal Investigator: Shirley H. Wray, MD, PhD, FRCP

Description of Subject Population: Subjects with or without Progressive Supranuclear Palsy (PSP) or other neurodegenerative disorders

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

This study is being done to learn more about how bright white or blue light stimulates changes in the pupil of the eye. The test is called the pupillary light reflex response. We hope that studying how your pupil responds to different colors of light (white, red, and blue) will better help us understand the changes that occur in the eyes and brains of individuals with Progressive Supranuclear Palsy (PSP) or other diseases.

This study involves the use of the DP-2000 Pupillometer that will be used to scan the eyes of enrolled subjects. The DP-2000 Pupillometer is not FDA approved. However, pupillometers are often used by ophthalmologists (eye doctors) to evaluate patients with night blindness and for other diseases of the retina.

We are asking you to take part in this study because you have either been diagnosed with Progressive Supranuclear Palsy (PSP); you have been diagnosed with another neurodegenerative disease (for example, Parkinson's Disease), or you are a healthy volunteer.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful.

About 52 subjects will take part in this study at the Massachusetts General Hospital.

How long will I take part in this research study?

It will take you about 12 months to complete this study. During that time, we will ask you to make 2 study visits to the MGH. We may also call you during the study to schedule your Study Visits.

What will happen in this research study?

If you decide to take part in the study, a Research Assistant will contact you to schedule your Study Visit. The study Principal Investigator (Dr. Shirley Wray) and the Research Assistant are both available to answer any questions you may have throughout the study.

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Before the Study Visit begins, we will tell you a few things about the pupillometer device ('DP-2000 Pupillometer') that will be used to scan your eyes. A pupillometer is an instrument used to measure the size of your eyes' pupils with the use of different colored lights. The DP-2000 Pupillometer consists of 2 cameras and is secured on a desk. We will scan one eye at a time.

The entire test will take place in a darkened room. The study Research Assistant will be present throughout the Study Visit. You may also have your caregiver or a study partner with you at all times throughout the test. You or your caregiver/study partner may choose to stop the test at any time for any reason.

You will be assigned an identification number when you enroll in the study and the ID number and date of test will be recorded with each test scan. To protect your privacy and to ensure data confidentiality, your name and other personal identifiers (e.g., date of birth) will not be recorded on the DP-2000 Pupillometer and will only be known to authorized study staff and research collaborators.

Before testing begins, we will first ensure that both cameras are safe and clean. The test will proceed with both of your eyes open, and you will be asked to focus on the camera that is placed directly in front of each eye. The test will be done monocularly (one eye at a time). If both eyes are eligible, only one eye will be randomly selected to be tested and the non-tested eye will be covered by an eye-patch. You will be asked to focus on the camera that is placed directly in front of the eye that is being tested. A bright light that lasts no more than 1 second will shine into your eye and your pupil will naturally shrink in response. We will repeat the bright light procedure for a maximum of 4 times and the entire procedure will last about 1 minute.

We will contact you again to schedule a similar follow-up test at about 12 months after the initial testing session.

The results from this study will only be used for research and will not be kept as part of your medical records.

The study doctor may have to take you out of the study. This may happen because you may experience a feeling of stress, anxiety, discomfort or fatigue during the study.

What are the risks and possible discomforts from being in this research study?

The bright lights may be uncomfortable or unpleasant.

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You may have some anxiety while undergoing the tests for the first time while sitting in the dark and you may choose to have your caregiver or study partner be with you at all time during the test.

You may stop the test procedure if it causes you anxiety or discomfort at any time.

There are no health risks associated with the test procedure and it does not provoke headaches, dizziness, syncope ('fainting') or seizures.

What are the possible benefits from being in this research study?

You will not benefit from taking part in this research study.

We hope that what we learn in this study may help doctors better identify and diagnose patients with PSP or other brain disorders in the future.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

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Will I be paid to take part in this research study?

You will not be paid to take part in this research study.

What will I have to pay for if I take part in this research study?

You do not have to pay anything to be in this study. Study funds will pay for all study-related procedures.

Charges for any ongoing or routine medical care you receive outside this study will be billed to you or to your insurance company in the usual way. You will be responsible for any deductibles or co-payments required by your insurer for your routine medical care.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

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Shirley H. Wray, MD, PhD, FRCP is the person in charge of this research study. You can call her at 617-726-5539 from 9AM-5PM, Monday-Friday. You may also call Dr. Wray's assistant at the same number with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

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- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: Dr. Shaobo Lei of the University of Toronto (Department of Ophthalmology & Vision Sciences) & Dr. Claudio Privitera of NeurOptics, Inc.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

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You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject

Date

Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

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Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent

Date

Time (optional)

Consent of Non-English Speaking Subjects Using the “Short Form” in the Subject’s Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter

Date

Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

Name

Date

Time (optional)

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Witness to Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

Making his/her mark above

Other means _____
(fill in above)

Witness

Date

Time (optional)

Consent Form Version: September 18, 2017