Parkinson's Progression Markers Initiative

Study Overview

About PPMI and Its Purpose

The Parkinson's Progression Markers Initiative (PPMI) seeks to uncover insights into Parkinson's disease (PD) onset and progression that could transform how we diagnose, treat, and potentially prevent PD.

PPMI has already contributed to new understanding around disease biology and experience, and its findings and design have led to more efficient clinical research.

Now PPMI is looking to bring together a larger and more diverse group of individuals—both with and without PD—who can help contribute to a more detailed look into the way the disease develops and changes over time.

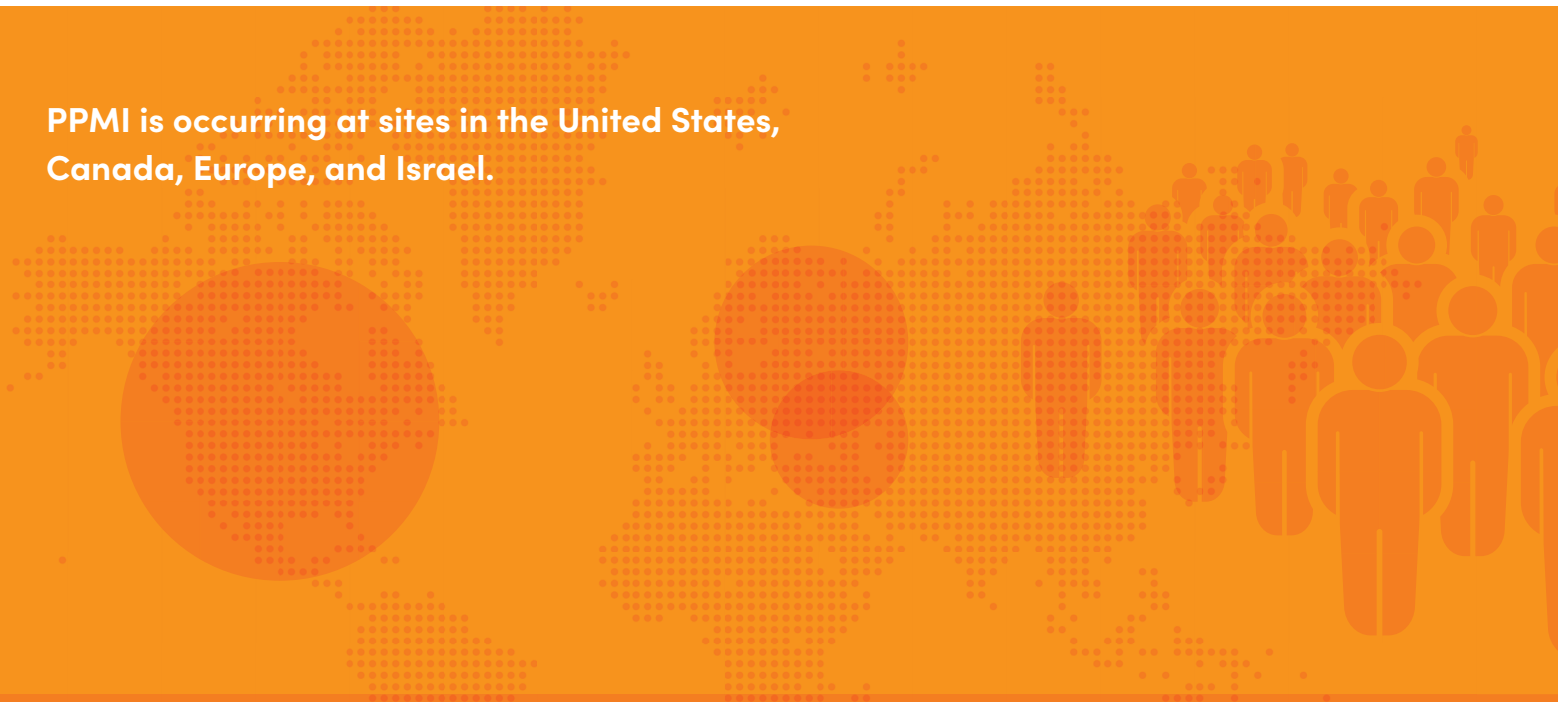
To date, PPMI has taken place at 33 clinical sites around the world, following nearly 1,400 participants for at least five years. As part of PPMI's expansion, the study will now include 50+ sites and follow up to 4,000 participants.

PPMI is sponsored by the Michael J. Fox Foundation for Parkinson's Research and funded by a consortium of industry partners, nonprofit organizations, and individual donors.

These key insights could help lead to critical advancements across the spectrum of care: from the earlier identification of people who may be at risk for developing PD to innovative new treatments that could improve quality of life and slow disease progression.

The study team includes many clinicians and scientists who conduct research in Parkinson's disease. It is led by principal investigator Kenneth Marek, MD, President and Senior Scientist of the Institute for Neurodegenerative Disorders in New Haven, Connecticut.

PPMI is occurring at sites in the United States, Canada, Europe, and Israel.



5+
Years

Up to
4,000
Participants

50+
Sites

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Frequently Asked Questions (FAQs)

Who is eligible to enroll?

Participants must be at least 30 years of age.
PPMI seeks the participation of:

People with Parkinson's who have been diagnosed within the last two years and are not currently taking standard PD medications

First-degree family members (parent, child, sibling) of a person with Parkinson's

People who have risk factors for the development of PD (known genetic mutation, loss of smell, history of physically acting out dreams during sleep, and others)

People without Parkinson's and no known risk to act as a comparison group

If you are interested in enrolling, your eligibility will be determined by staff at the study site during your screening visit.

How long will the study last?

PPMI would like to follow participants for at least five years to gather information on disease progression and natural aging. You may be asked to continue beyond five years based on the status of the study. Participation in any study is completely voluntary, and your PPMI study coordinator will work with you to consider modifications or to withdraw you from the study if you no longer want to or are unable to participate.

What will happen at the first visit?

The first—or screening—visit will be conducted by the study coordinator and study doctor. Those who consent will be screened for eligibility. The screening visit length varies by participant and will be explained by study staff in more detail prior to attending.

1. First there will be a comprehensive review of study details and a consent form. The consent form is a document you will be asked to sign if you are interested in participating in the study. This review is an opportunity to ask questions and address any concerns about participating. A copy of the consent form will be provided for your review well in advance of the date of your first appointment.

2. Once you provide consent, evaluations and assessments will be conducted to determine your eligibility to participate in PPMI. This could include a medical history, medication review, neurological tests, a physical exam, cognitive assessments, blood collection, and a brain scan that measures dopamine activity (DaTscan™). Consult the PPMI Imaging Procedures and Blood Sampling Overview/FAQs sections enclosed for more information about these procedures.

The nearest PPMI site is far from where I live. Can I be part of the study but attend visits at a medical facility closer to my home?

Unfortunately, no. Every PPMI site has been carefully selected for its ability to adhere to strict processes and procedures. This is because sample acquisition, handling, and storage must be standardized so that results from all sites can be compared—critical for maximizing what researchers are able to learn from this and other studies.

Will I be paid for my time and travel?

Yes. The study will cover the cost of PPMI-related travel, and you will be paid a set amount at each visit to compensate you for your time and completion of study-related procedures. Additional details can be provided by your local study coordinator.

Can I choose to do only some of the study activities?

We ask PPMI participants to complete all study activities and assessments. Parkinson's disease involves multiple systems and processes in the body, requiring many tests. Additionally, it is important to gather the same information over time to compare results and understand how the disease changes.

If you would like to skip an assessment, your study coordinator may be able to discuss modifications or adjustments that could help you feel more comfortable or address certain needs.

Will my personal information and medical data be kept confidential?

Your privacy is very important. All data collected in PPMI will remain anonymous. The data is "de-identified," meaning your name and other identifying details will never be tied to your data. Significant measures have been taken in designing the study to ensure that your identity remains completely private. Additional information on privacy policies and procedures can be found in the Informed Consent Form.

What will happen to the biological samples you collect?

The samples collected in PPMI will also be de-identified (stripped of your personal information to ensure your privacy) and sent to a central storage facility. De-identified samples will be analyzed for study-relevant characteristics using state-of-the-art lab procedures. The data from this analysis will be entered in a database maintained by the Laboratory of NeuroImaging (LONI) at the University of Southern California. Samples will be banked in a central repository. The de-identified data, and the samples themselves, will be available to qualified Parkinson's researchers on request for use in other studies.

Can I participate in other trials while I am enrolled in PPMI?

Yes, but we ask that you wait one year to enroll in any trial testing an intervention. The effects of the drug or therapy in testing may alter the data and biosamples that you contribute to PPMI. After you have been enrolled in PPMI for one year, you may enroll in other trials. You are welcome to enroll in other observational studies at any time, including PPMI Online (our web-based companion study).

If I enroll, do I have to stop seeing my current physician?

No, you are encouraged to maintain your relationship with your doctor. When you come for study visits as a PPMI participant, you will be evaluated by an experienced clinical research team, but they may not have the time or background to discuss all the details of your care. PPMI participants may elect to have the PPMI study site share test results and clinically relevant findings with their personal physician.

What if a PPMI test reveals that I have an unexpected illness or medical problem?

The PPMI clinical team will report any unexpected results of this nature to you and, if given your permission, share this information with your physician.

What if my doctor suggests that I take medication for Parkinson's after I enroll?

Your health is of the utmost importance. While we hope that participants will not begin taking Parkinson's disease medications for at least their first six months in the study, physicians and patients should make the decision to begin a new medication regimen independent of participation in PPMI. Please inform your study coordinator if any changes are required, such that the information can be recorded in your research chart.

Where is PPMI being conducted?

PPMI will be following participants at approximately 50 sites in at least 12 countries across three continents. Not all sites may be recruiting at the same time, however. Visit www.michaeljfox.org/ppmi for more information.

Who is sponsoring this research?

PPMI is sponsored by the Michael J. Fox Foundation for Parkinson's Research, the largest nonprofit funder of Parkinson's research. Visit www.michaeljfox.org to learn more about the Foundation.

THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

www.michaeljfox.org/PPMI

I don't qualify for PPMI, but I still want to help. What can I do?

Please help us spread the word to people who might be interested in participating. If you know someone recently diagnosed with PD or someone who is a first-degree family member of a person with PD, please refer them to michaeljfox.org/ppmi.

In addition, all individuals, with and without PD, are eligible to participate in Fox Insight (foxinsight.org), an online study that captures information about physical and emotional health, PD treatment, and quality of life. You can also contact your nearest study site, as they very likely are conducting other studies for which you may be eligible. And look for recruiting studies in the Fox Trial Finder (michaeljfox.org/trial-finder).

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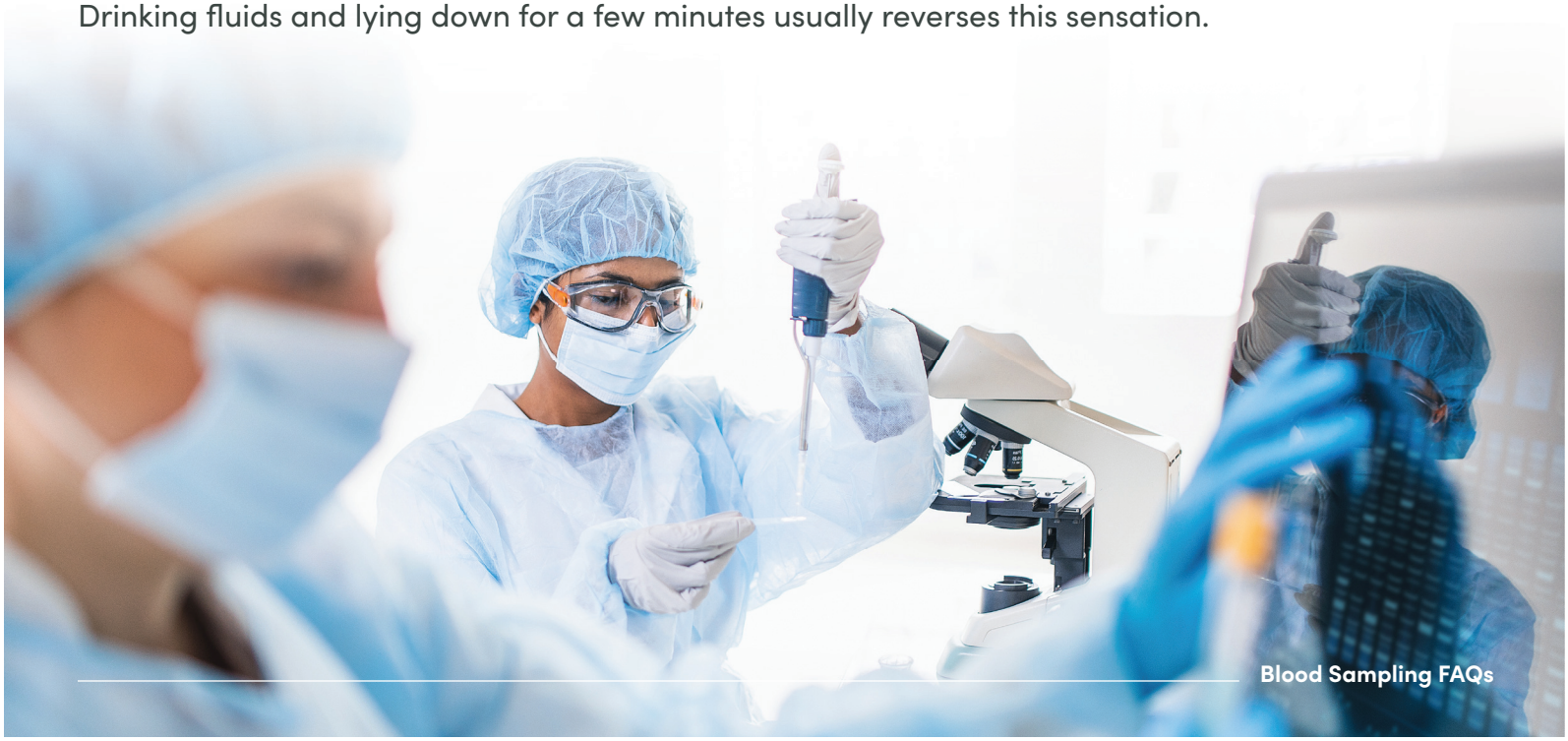
Blood Sampling (FAQs)

What is the purpose of collecting blood in this study?

Blood is collected from each participant at regular intervals. The blood is analyzed for genes, proteins, and other chemicals that may differ or change at different rates in people with PD, at-risk volunteers, and control participants.

Are there any side effects from blood sampling?

You may experience bruising at the site where the blood was drawn, which is usually minor. In addition, you may feel lightheaded during or following the procedure. Drinking fluids and lying down for a few minutes usually reverses this sensation.



Will I get results from the blood sample collection?

No, you will not learn anything directly about your personal health from the blood testing. The purpose of obtaining blood samples in PPMI is to learn as much as possible about changes that may occur in the blood of people with Parkinson's.

Will the researchers analyzing my blood know that it is mine?

No. As with all samples in the trial, your personal information will be removed to "de-identify" the sample. Any analysis will not be associated with you as an individual. Any results from the testing, including genetic findings, will not be able to be linked back to you as an individual.

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Imaging Procedures (FAQs)

What is MRI?

MRI is short for magnetic resonance imaging. An MRI machine uses a magnetic field and radio waves to create detailed images of structures inside the body.

Why is a brain MRI important for this study?

An MRI enables us to take pictures of basic brain structures. For PPMI, this is important for all enrolled participants:

- In early Parkinson's disease, MRI of the brain is usually normal, so we would like to check that there is no other reason for your symptoms. Using special analysis techniques, researchers may also obtain useful information about PD and assess how MRI results in individuals with Parkinson's disease change over time.

In individuals who may be at risk for developing Parkinson's disease, researchers are assessing differences and changes on MRI scans that may help predict PD:

- It is also important that researchers obtain similar imaging data from control participants so that we can learn which changes are unique to Parkinson's disease and which are associated with normal aging.

Will I be exposed to radiation during the MRI?

No. There is no radiation exposure in an MRI.

Will I get claustrophobia during the MRI?

Most individuals tolerate the MRI procedure quite well. If you are concerned about claustrophobia, speak to your study doctor before the procedure. The study team will make their best effort to make the process as comfortable for you as possible.

What should I do to prepare for an MRI?

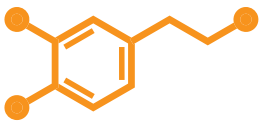
Little to no preparation is required before an MRI. When you arrive at the clinic, you will be asked to remove all accessories such as jewelry, credit cards, and any metallic objects. This is because MRIs involve magnets, which may interact with objects in your possession and could affect the image quality.

What is DAT imaging?

DAT imaging is a specialized technique that allows doctors to capture detailed pictures of dopamine transporters in your brain. This technique involves the use of a chemical compound (DaTscan™) containing a radioactive element. The compound is injected into a vein and taken up by the proteins that transport the brain chemical dopamine. A SPECT (single photon emission computed tomography) brain scan can detect the radioactive element and show the dopamine transporters. In this way, it is possible to determine whether there is a reduction in dopamine activity, which happens in Parkinson's disease.

Why is DAT imaging important for this study?

DAT imaging allows researchers to take detailed pictures of dopamine activity in the brain. This is important for two reasons in PPMI:



For PPMI volunteers with Parkinson's or risk factors for the development of PD, the DAT data will be crucial to understanding the neurologic changes associated with the onset and progression of PD. It is also required to determine your eligibility for enrollment.

For control participants, the data ensure that brain function is normal, which is a required element to confirm your eligibility for enrollment. This scan also provides researchers with an age- and gender-matched image that can be compared to images of PD participants enrolled in the study.

What does DAT imaging offer that MRI does not?

DAT imaging provides a more detailed picture of the dopamine system of the brain and richer information about how the brain is functioning. This is critical because degeneration of the dopamine system is the pathological hallmark of Parkinson's disease.

Why haven't I had DAT imaging before?

The DaTscan™ radioactive compound was approved by the FDA in 2011, and the imaging scan is prescribed by doctors on a case-by-case basis. In clinical care, the DAT imaging may not change diagnosis or treatment recommendations.

Will I be exposed to radiation during DAT imaging?

There is a small amount of radiation exposure from the injected chemical compound. The amount of radiation exposure is in the range between a chest X-ray and a chest and abdominal CT scan. The level of exposure from this study is well within the limits specified by the US Food and Drug Administration (FDA) in its guidelines for acceptable radiation exposure for research participants.

What if DAT imaging shows something unexpected?

The information obtained in this procedure will be used primarily for the purposes of research. If a medically significant abnormality is observed on your scan, study personnel will inform you of that finding. If given your permission, your study doctor will contact your primary physician to discuss the results and treatment recommendations.

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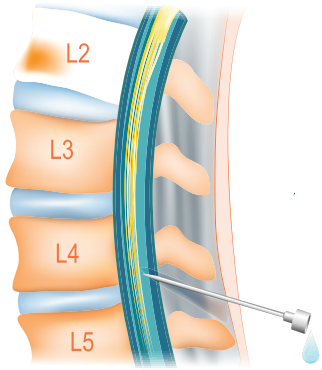
Lumbar Puncture (FAQs)

What is a Lumbar Puncture (LP)?

An LP is an outpatient procedure where a small needle is inserted between the vertebrae (bones) of the lower back at a level well below the spinal cord to collect spinal fluid, which bathes the brain and spinal cord.

What is the purpose of the LP in this study?

The purpose of obtaining spinal fluid is to learn as much as possible about changes in proteins and other neurochemicals that may occur in individuals with Parkinson's disease. Spinal fluid is useful because it bathes the brain and spinal cord, making it a great source of information about neurochemical changes that may be occurring in the brain. Being able to measure changes in specific proteins or neurochemicals in spinal fluid may provide a way to measure progression of Parkinson's disease or monitor whether medications are slowing progression of the disease.



As a control participant, why do I need an LP?

In addition to what we can learn from spinal fluid from participants with PD, we can learn a lot from the spinal fluid of control participants who are about the same age as people with PD in the study. By comparing these samples, researchers can determine which changes are unique to Parkinson's disease and which are associated with normal aging.

Is an LP painful?

An anesthetic medication is administered to help minimize the amount of discomfort that occurs during LP. The anesthetic may burn or sting for a few seconds. You will feel a pressure sensation when the needle is inserted, and there is usually some brief pain when the needle goes through the tissue surrounding the spinal cord. This pain should stop in a few seconds. In most cases, discomfort is minimal to moderate.

What are the risks of LP?

When performed by an experienced doctor, as in PPMI, LP is safe and involves minimal discomfort. There is a small chance of developing a headache after the procedure. This usually gets better with rest and drinking plenty of fluids. Rarely, the headache may continue for more than 24 hours after the procedure and require additional treatment. LPs for PPMI will be performed using a special needle designed especially for this procedure. This needle causes less pain at the site where the needle goes in and brings less risk for headache after the LP.

There is no risk of paralysis with an LP.

Will I get results from the spinal fluid testing?

Spinal fluid collected during the LP will be tested using standard clinical tests. You will be notified by your study doctor at your study site if there is any reason for concern from the results of these tests. Otherwise, you will not learn anything directly about the results of spinal fluid testing.

Will the researchers analyzing my spinal fluid know that it is mine?

No. Like all samples in the PPMI study, spinal fluid samples will be de-identified, which means that they will be stripped of any information that could link the samples to you as an individual.

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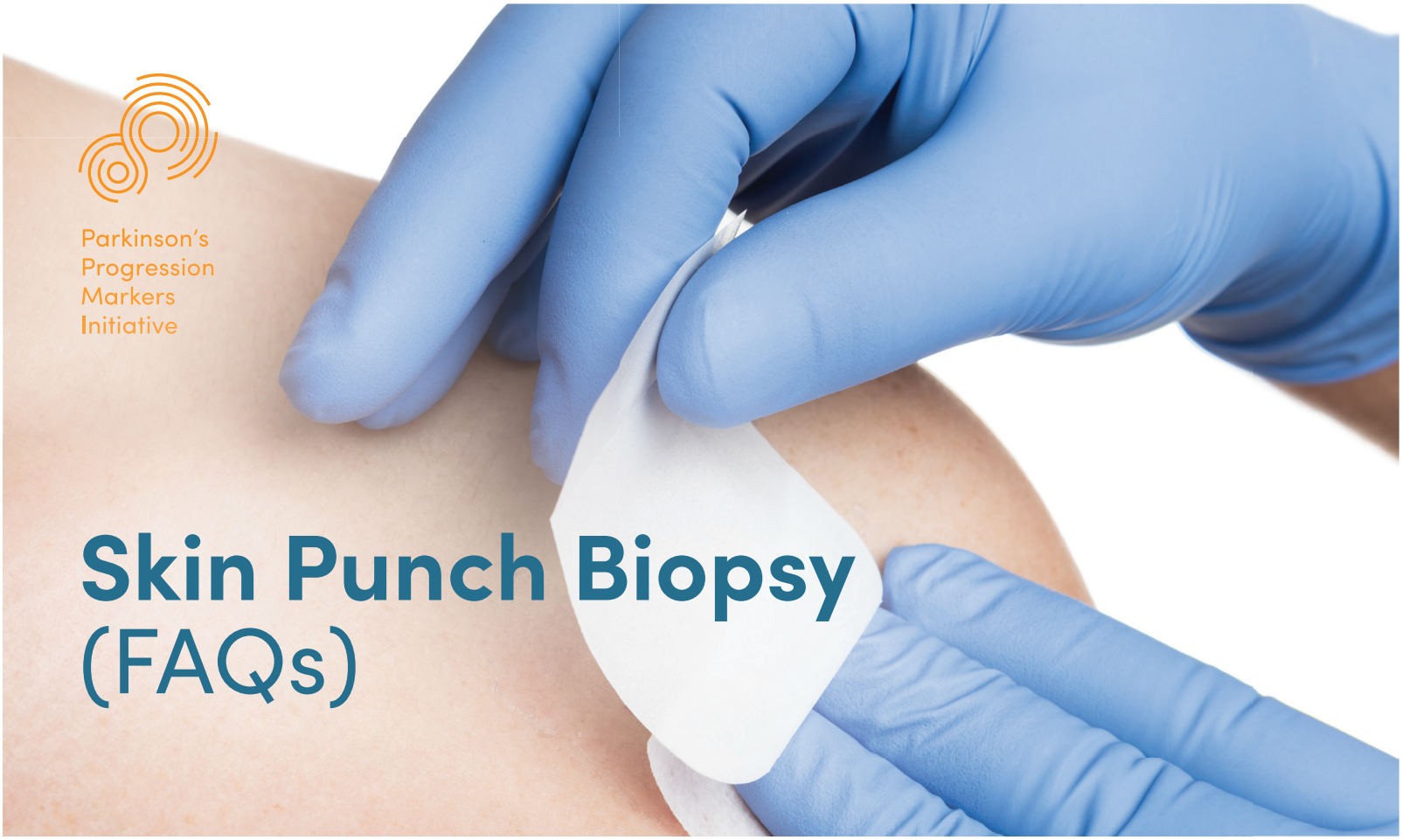


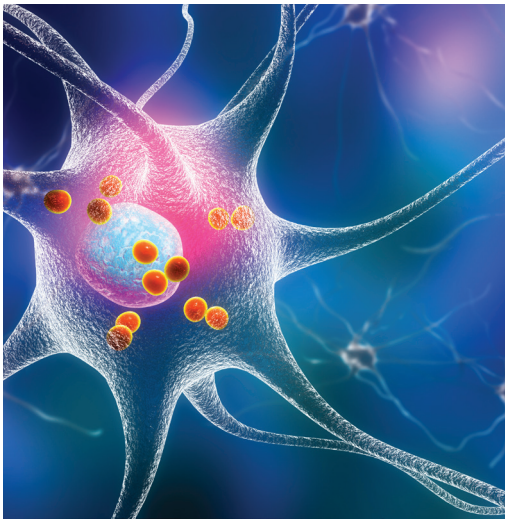
Skin Punch Biopsy (FAQs)

What is a skin punch biopsy?

A skin punch biopsy is a procedure to remove cells or skin samples from the surface of your skin for analysis. A doctor uses a circular tool to remove a small section on your skin that includes some of the deeper layers.

What is the purpose of the skin biopsies in this study?

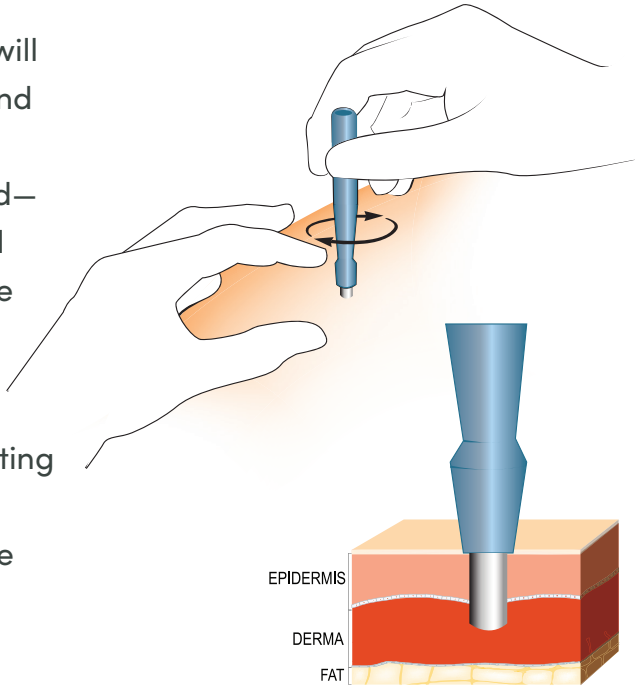
Alpha-synuclein, the sticky protein that clumps up in the brains of people with Parkinson's, has also been found in the skin samples of individuals with PD. The purpose of obtaining skin biopsies in this study is to analyze the amount of alpha-synuclein protein found in the skin of people with and without PD. This will help researchers to learn if alpha-synuclein found in the skin may be a good biomarker for PD diagnosis or future use in clinical trials.



What happens during the skin punch biopsies?

A doctor who has been trained in skin punch biopsies will perform the procedure. You will be asked to undress and change into a clean gown. The doctor performing the procedure will then clean the area that will be biopsied—on your back in between your shoulder blades. You will then receive a local anesthetic to numb the area where the biopsy will be taken.

A pencil-like, sterilized instrument is used to perform the skin punch. The doctor will apply pressure in a twisting motion and will remove a small, thin cylinder of tissue. A stitch may be needed to close the small hole after the biopsy, and a bandage will be placed over the biopsy site to prevent bleeding.



What are the risks with skin punch biopsies?

You may experience bleeding, bruising, or pain at the site where the biopsy was taken. You will also have a small scar at the biopsy site, though the scar may fade gradually. There is a small risk of infection, but this risk is very minimal if the biopsy site is kept clean and the bandages are changed daily.

Will I get results from the analysis of my skin punch biopsy?

You will be notified by the study staff at your study site if there is any reason for concern after the skin biopsy procedure. Otherwise, you will not learn anything directly about the results of the analysis of the skin biopsy.