

# ImPatient Empowered™ Project: Informed Consent Form

**Protocol Title:** The ImPatient EmPowered™ Project: A Longitudinal Natural History Study of Symptoms, Course, Comorbidities, and Biomarkers, in Children and Adults with Possible Inflammatory Neurological Syndromes and At-Risk Siblings

**Protocol Number:** BIC-2022-01

**Sponsor Name:** Brain Inflammation Collaborative (BIC)

**Legal Registered Address:** 925 Genesee St, #180440  
Delafield, WI 53018

**BIC Research Team Contact:** Dr. Denise Calaprice-Whitty  
1-833-286-4433 or 1-833-2UNHIDE

## KEY INFORMATION ABOUT THIS STUDY

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your physician. If you agree to take part in this research study, you must sign this consent form.

You have been invited to participate in the ImPatient EmPowered™ Project because you or your minor child have been identified as probably or definitely having PANDAS (Pediatric Acute-Onset Neuropsychiatric Disorder Associated with Strep), PANS (Pediatric Acute-onset Neuropsychiatric Syndrome), Autoimmune Encephalitis, post-Covid mental health or neurological symptoms, Obsessive Compulsive Disorder (OCD), Anorexia Nervosa, or Tourette's. You may also be participating because you have volunteered yourself or your child as a sibling of a patient with one of these diagnoses, or as part of a healthy comparison group ("healthy control").

### **Purpose and Design of Study:**

The Brain Inflammation Collaborative (BIC) is conducting this study to collect "naturalistic data" (see **Observational**, below) and "biosamples" over time from people with neurological conditions that may be caused or worsened by inflammation, such as PANDAS, PANS, Autoimmune Encephalitis, post-Covid syndromes, OCD, Anorexia Nervosa, and Tourette's, as well as from their unaffected siblings under age 18 and healthy controls. The goal is to better understand the characteristics of these conditions, what causes them, who develops them, and

## **ImPatient Empowered™ Project: Informed Consent Form**

how they can best be treated and prevented. In the meantime, the ImPatient Empowered™ Project will also directly benefit participants by providing an easy but thorough system for tracking and understanding each person's symptoms, laboratory results, treatments, and life and health-related situations that might impact symptoms. BIC plans to continue the Impatient EmPowered™ Project for a minimum of 5 years. Up to 1000 participants are expected to enroll during year 1 and 10,000 by year 5.

### **Observational:**

Collecting “naturalistic data” means that the study will collect information about (“observe”) people's symptoms, treatments, and life events (such as infections or stressful occasions), without interfering. You will not need to make any changes to how you manage your/your child's condition or live your lives, and you will not receive any medical care as part of participation. The data collection relies on your reporting of information about your/your child's medical conditions, and what symptoms, life events, and feelings you experience, into our highly secure, private online database. You may do this using either a computer and/or a mobile device with internet access.

### **Your Participation:**

Your participation in this study is voluntary; you have the right to choose not to participate. If you decide to participate, your involvement is expected to last at least 1 year if you/your child are a patient or patient's sibling, and at least 3 months if you/your child are a healthy control. You will be able to participate for longer if you wish, as long as you continue to enter requested data and the Project is still ongoing. Your level of participation is also up to you. You may decide not to answer certain questions and you will still be able to continue participation. (Even if the system tells you that a question is “required,” this only means that it's required for e.g. rating-scale scoring purposes; it never means that you won't be able to continue in the study if you don't answer.) However, the more information you put into the system, the more insight you may be able to gain from the reports that will be generated for you by the system (see later section)! You can also choose to stop at any time. If you decide to stop, you will be asked to complete a Registry Exit form giving the reason(s). There will be no penalty for withdrawing participation.

To participate in this study as an “Adult” you must have been identified as probably or definitely being a “Patient” with PANDAS (Pediatric Acute-Onset Neuropsychiatric Disorder Associated

## ImPatient Empowered™ Project: Informed Consent Form

with Strep), PANS (Pediatric Acute-onset Neuropsychiatric Syndrome), Autoimmune Encephalitis, post-Covid mental health or neurological symptoms, Obsessive Compulsive Disorder (OCD), Anorexia Nervosa, or Tourette's, OR you must be volunteering yourself as a "Healthy Control" with no neurological, psychiatric, or autoimmune conditions (other than allergies). To participate in this study as a Parent/Legal Guardian, your minor child must have been identified as probably or definitely being a "Patient" with one of the above diagnoses, OR you must be volunteering your child as a sibling of a "Patient" (but who does not have such a condition himself/herself), OR as a "Healthy Control" with no neurological, psychiatric, or autoimmune conditions (other than allergies). Participating as a Patient does not require that you/your child have any symptoms at the time of enrollment. Even a long-ago diagnosis qualifies a person to participate as a Patient.

In addition, you must:

- Be between 18 and 89 years of age
- Be a US Resident
- Be fluent in English
- Have consistent access to a computer and/or smartphone and the internet
- Have a good knowledge of how to log onto a website or app and how to type information into it.

Only one parent/legal guardian may participate per child. If you are participating as the parent/legal guardian of a child, that child must be at least 2 years old and less than 18 years old. If your child is between 13 and 17 years old, he or she must also assent (agree) to participation in this study or else neither of you will be able to participate. Parents/guardians must not coerce adolescents into agreeing to study participation.

Your participation in this study may be stopped without your consent at any time and for any reason by the BIC Study Team. You may be withdrawn from the study if you do not follow the study instructions, the study is stopped, or for other administrative reasons. As part of your study participation, you will be asked to review and approve "informed consent forms" such as this one on at least an annual basis. If you do not provide ongoing consent in this manner, your study participation will end.

### **Participant Responsibilities:**

## ImPatient Empowered™ Project: Informed Consent Form

Participants will be expected to complete online questionnaires at weekly intervals. The system will send you reminders by push notification and/or email and will keep track of what information is needed. This way, you just have to look out for the reminders, log into the system, and complete the questionnaires that the system asks you to complete within 2 days of when you receive the reminder. Overall, you may be asked to provide information about:

- your/your child's medical and family history, demographic and physical characteristics (for example, age, weight, occupation)
- treatments and/or medications you/your child are currently taking
- you/your child's vaccination history
- how your/your child's condition is impacting your/your child's life
- past and current diagnoses and emotional and physical symptoms.

For participants aged 2-5, only parents/legal guardians will provide information. For participants aged 6-17, both the child and the parent/legal guardian will be requested to complete electronic questionnaires. All information collected directly from children will be collected using very brief questionnaires designed by research experts for that age group. Children may complete these with parental/guardian assistance, if needed. Parents/guardians must not coerce children into completing forms against their will.

You will be asked to provide some information about every 3 months, some every 4 weeks, some every 2 weeks, and some every week.

- The information you will be asked about **weekly** includes quick ratings of how bad the three more concerning symptoms were in the past week, as well as simple information about any infection, allergy, or injury that happened. If a new treatment or supplement or a new medical condition has started, or if one has stopped, you will also be asked to provide this information. Altogether, the weekly updates should take only a couple of minutes.
- The additional information you will be asked about **every two weeks** includes more details about symptoms and how they impact your/your child's life. This update will take about **4-20 additional minutes** to provide, depending on how much information you want to provide.
- Right after you enroll, and then again **every 3 months**, you will be asked about life events that may have been stressful for you/your child, lifestyle changes that you/your child may have undergone that could have impacted your/your child's condition, how often you/your child has used medical services and what type of services have been used, and any

## ImPatient Empowered™ Project: Informed Consent Form

updates to the family history. This information will take about **2 to 12 additional minutes** to provide, depending again on how much you want to share.

- In addition, the system has places where you can write in or upload notes, videos, photos, or sketches that you feel would be useful in tracking your/your child's condition. These will be available to you at any time that you have access to a computer or smartphone and the internet, to make it easy for you to track these things.
- Finally, you may allow the study database to collect information from your/your child's "wearable device" (AppleWatch, FitBit, etc.). This is optional but could provide you and the research scientists with valuable information about the impact of your/your child's condition on sleep, heart rate, and activity, among other things.

It is important to know that no-one will be actively monitoring the information you enter to make sure that you're okay. If you are having troublesome symptoms or thoughts, you must contact your healthcare providers directly with your concerns.

For some participants, "noninvasive biosamples" will also be requested to identify biological traits associated with aspects of your/your child's condition. A "noninvasive biosample" is a sample that comes from your/your child's body but that does not involve any kind of puncture to your skin. Samples to be collected may include urine, saliva, cheek swabs, and/or stool. Whether you are asked to provide biosamples will depend on how your/your child's characteristics compare to those needed for the biosample research. If you are asked to provide a sample and you say "yes," a kit will be sent to you, with instructions for sample collection and return. These bio-samples will be sent to the biobank and/or research labs that collaborate with BIC with only your Study ID number on them (see below), and no information that could identify who you are. **IMPORTANT: YOU CAN REFUSE TO PROVIDE ANY OF THESE SAMPLES AND STILL PARTICIPATE IN THE REST OF THE STUDY.**

### **Risks:**

The risks or discomforts associated with this study are minimal. It is possible that recalling or writing about the symptoms or circumstances that the study asks about may make you

## ImPatient Empowered™ Project: Informed Consent Form

uncomfortable. If this happens, you may choose not to provide information that disturbs you, or you may end your participation altogether as described above.

### **Benefits:**

You will not receive monetary compensation or any medical care for your participation. We cannot guarantee any benefits from participating. However, it is possible that this research may benefit you, your child, and/or others in the future by helping identify effective treatments and other actions people can take to manage or prevent the conditions being studied.

While you are participating, you will have access to the information you have entered in an organized way, which may help you track and understand how your/your child's condition develops and changes over time, and which may help you communicate this information to others in an organized way.

In addition, by participating in the ImPatient EmPowered™ Project, you may have the opportunity to participate in additional research studies of patients with your/your child's condition. After you enroll, you will be asked if you are interested in this. It is possible that participation in other studies could benefit you directly, and it is also possible they could involve risk. If you are interested, you will be provided with more information about those studies, including the potential benefits and risks, and you will have (an) additional Consent Form(s) to complete. Any information that researchers may gain from your participation in these studies may be combined with the information you enter into the ImPatient EmPowered™ database to better achieve the same goals. Whether or not you would like to participate in additional studies has no impact on your ability to continue participation in the ImPatient EmPowered™ Project.

The ImPatient EmPowered™ Project will be conducted in compliance with all applicable regulations. The ImPatient EmPowered™ Project platform is not a medical device, and is not intended to diagnose, treat, cure, monitor, or prevent medical conditions or illnesses. Do not make any major health changes without consulting your doctor or medical professional.

# ImPatient Empowered™ Project: Informed Consent Form

**Costs:** There is no cost to participate in this study.

## **Privacy Protection Measures and Confidentiality:**

We prioritize and protect your privacy by ensuring that all responses to this survey are protected in multiple ways. First, the technology platform that is being used for this study meets very high standards for the protection of personal health information. To maintain this security, you are responsible for not sharing your access information/PIN number with anyone else.

Second, if you take part in this study, you will be assigned a unique Subject ID code to help protect your privacy. Your study records and study samples will be labeled with this code that does not directly identify you. The ImPatient EmPowered™ platform securely stores the linking code between your email address and other study information.

The data may be analyzed and published by researchers who are employees of BIC, or Collaborators with BIC. All of the information you enter will be “de-identified” prior to any data analysis so that your answers to questions cannot be associated with your/your child’s name, your IP address, your email address, or any other “identifying information.” So, although the results of this research project may be presented at meetings or in publications, you cannot be identified in these presentations and/ or publications.

## **Authorization to Use and Disclose Personal Health Information:**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The BIC Research Team must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the BIC Research Team will get any personal information about you that you provide. This may include information that might identify you. They will also get any information about your health that you provide. This information may include:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Information obtained during this research about laboratory test results

## ImPatient Empowered™ Project: Informed Consent Form

- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records.

Only the BIC Research Team members directly involved in enrolling you and in ensuring the quality of the data will have access to identifying information. These people have all been carefully trained and certificated in Human Subjects Protection and in privacy requirements and fully understand the importance of keeping your information private.

By signing this consent form, you are giving permission to use and give out the health information listed above, in the ways described above, for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely. However, you may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the BIC Research Team contact at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

### **Genetic Research:**

Your genes are in the cells in your body. Genes make you different from anyone else. Some genes are responsible for inherited traits like hair and eye color. Some genes affect the chances that a person will get a certain disease or how their body responds to drugs. If you choose to provide a bio-sample or to upload you genetic data from a service like 23andMe® or Ancestry®, these may be used for genetic research that will help understand why some people are more vulnerable to symptoms associated with neuro-inflammation than others. As described before, many steps have been taken to safeguard your information, so the risk of loss of confidentiality is small. However, if confidentiality is broken (for example by a hacker), results of genetic testing may become available to insurance carriers or employers. The knowledge of this



## **ImPatient Empowered™ Project: Informed Consent Form**

information has the potential to lead to discrimination in employment or insurance. Someone with a known genetic condition indicating a susceptibility to develop a disease or condition might be denied a job or a promotion, or denied health or life insurance, because they are regarded as a health risk and therefore an economic risk. Carriers for a genetic disorder might be discriminated against and viewed as having the potential to have a child with a genetic condition.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

You may choose to obtain a copy of the raw genetic data generated from your biosample. Although we will not interpret information for you, we will make every reasonable effort to direct you to products and services by others who can support the interpretation of genomic data.

If you elect to receive a copy of your genetic data, you might discover information that you find distressing or uncomfortable. For example, you may discover that you are not of a particular ethnic group, casting doubt on who your biological parents really are. Such surprising disclosures are rare in genetic research, but they are known to happen.

### **Contact for questions, concerns, complaints:**

If you have questions or concerns about the study, please contact the BIC Research Team at 1-833-286-4433 or 1-833-2UNHIDE. The Principal Investigator (main researcher) in charge of this study is Dr. Denise Calaprice-Whitty. She can be reached at [denise@braininflammationcollaborative.org](mailto:denise@braininflammationcollaborative.org).

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at [www.branyirb.com/concerns-about-research](http://www.branyirb.com/concerns-about-research). The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

# ImPatient Empowered™ Project: Informed Consent Form

On behalf of the Brain Inflammation Collaborative (BIC), we thank you for your interest in the **ImPatient Empowered™ Project!**

## Eligibility and Consent

**By providing my Consent below, I confirm that I:**

### STATEMENT OF CONSENT - SIGNATURES

By signing this form, I confirm the following:

- I have opened, read fully, and understand the Informed Consent Form
  - All of my questions about the study have been answered to my satisfaction
  - I understand that this study is only observational, and provides no clinical care
  - I understand that this study platform is not to serve as a means of communication with my doctor for the purpose of clinical care
  - I am age 18 - 89 and a resident of the United States
  - I have a confirmed or suspected diagnosis of PANDAS, PANS, Anorexia Nervosa, Obsessive Compulsive Disorder, Autoimmune Encephalitis, post-Covid mental health or neurological symptoms, or Tourette's, AND/OR am the legal guardian of a minor who is at least 2 years old and who has a confirmed or suspected diagnosis of one of these conditions, AND/OR am participating as or representing a Healthy Control (no significant mental health, neurological, or autoimmune conditions) or minor sibling of a patient with one of the above diagnoses.
  - I am fluent in English
  - I have consistent access to a computer and/or smartphone and the internet, and know how to log onto a website or app and how to type information into it.
  - I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by BIC and other authorized persons as described in this form.
  - I will be given an electronic copy of this signed and dated consent form to keep.
  - I do not give up any legal rights that I would otherwise have if I were not in this study.
  - If I am participating as a parent or legal guardian, I understand the importance of not pressuring or coercing my child into assenting for the study or into completing any forms or procedures against his or her will.
  - I understand that I may ask questions at any time and can withdraw my participation without prejudice regarding any future treatment or other opportunities.
- 
- I consent to participating in this study
  - I do not consent to participating in this study

(ICF time and date automatically captured by the system.)

## ImPatient Empowered™ Project: Informed Consent Form

If “I do not consent...” is selected, candidate cannot move any further in the system.