The creation of the Brain Inflammation Collaborative was inspired by the need for patients, researchers, and clinicians to come together to learn from each other's experiences to fuel advancements in diagnosis, treatment, and prevention of illnesses involving brain inflammation triggered as the result of autoimmune processes, infection, allergy, or injury.

Our innovative longitudinal data collection and biobank platform makes it easy for patients to contribute to research while empowering them with a tool to document and learn from their patient journey. Putting patients at the center with the ability to add demographic, health, and ongoing lifestyle related events will increase patient participation, diversity and inclusion.

We partner with patient advocacy organizations, leading expert advisors, and researchers to support us as we work to accelerate the process of uncovering solutions. As well as partnering with academic institutions and pharmaceutical companies, our own in-house research and analysis will produce original research insights and publications as we strive to make progress towards new diagnosis, treatments and methods of prevention.

About Us...

Brain Inflammation
Collaborative

Coordinated Research

We strive to assist researchers in all aspects of their research by providing the following:

- Researcher funding grants
- Use of a dynamic Research Roadmap that helps us track our brain inflammation priorities while allowing for new science and opportunities to evolve
- Researcher guidance on setting project goals
- Shared discoveries and results
- Publication support

The Unhide™ Project

This powerful and innovative platform allows for patient-generated data and bio-sample collection to be used by researchers to fuel breakthrough research in neuroinflammatory disorders.

- A clinical research project that longitudinally tracks patient history, on going symptoms and events with coordinating bio-samples
- A way to give back to the patients with tracking abilities, comparisons, and learning about brain inflammation latest developments and research

Our Focus…

Brain Inflammation
Collaborative

What We Do…

Put simply, we look to uncover the connection between brain inflammation and mental health.

We simplify and revolutionize how researchers and clinicians work to find answers. With free access to large-scale, high-quality patient data, the platform supports collaborative research to accelerate advancements in diagnosis and treatment. It's a one-stop-shop for the entire research pathway, from study design, data collection and aggregation, data analysis and publication writing - for researchers and clinicians alike.

With our research roadmap, seed grant funding, and patient driven data, we hope to create the connections needed to push the research forward.

Funding…

We have **$2.5 million dollar** grant from a family foundation to use over the next 5 years.

Additional grants from PANDAS Network and Octapharma to create 2 small seed grants.

Brain Inflammation Collaborative

What is the **Unhide™ Project**?

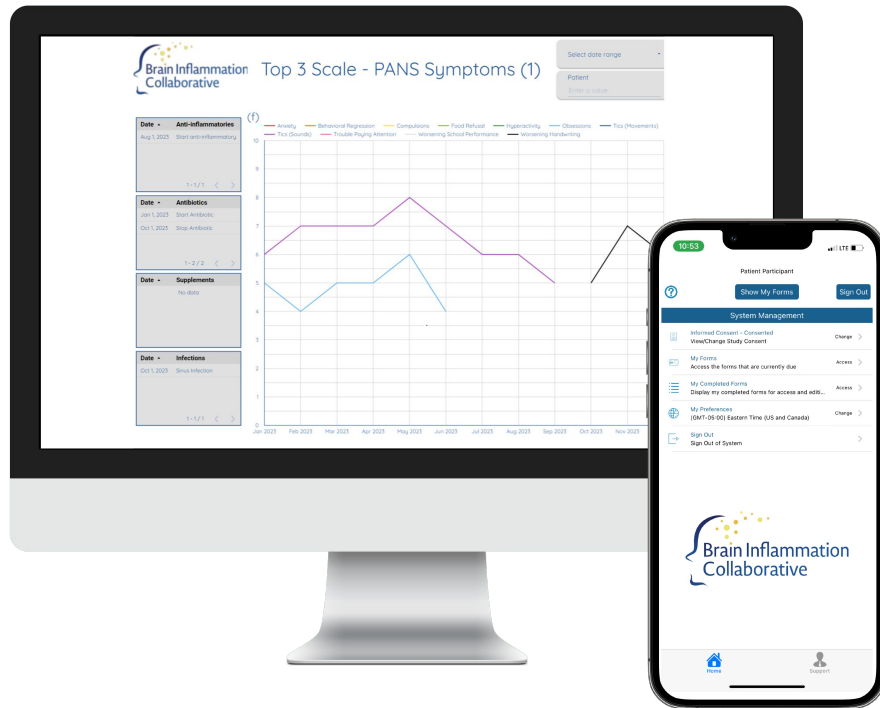## Patient Centered Clinical Research & Biobank Platform

We are changing the way research is done in the field of brain inflammation. Our cutting-edge health data platform will help researchers better understand the potential causes and treatments for neuroinflammatory illness. Our goal is to develop the world's largest patient centered health data and bio-sample repository to fuel and transform brain inflammation research.

- Online ongoing Clinical Research Study of individuals impacted by brain inflammation from autoimmune processes or infection

- Patient journey tracking tool

- Bio-samples that reflect real time life events and symptom flares

- Helping families impacted with mental health symptoms triggered by brain inflammation find better treatments

- Connecting researchers with the resources they need

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Our Clinical Research & Biobank Platform

Distinguishing Benefits and Features

- Tried-and-true, patient- and researcher- tested data capture forms and aggregation protocols used by thousands of industry leaders for data submitted to FDA and other authorities

- Patient compliance for similar longitudinal registries of ~95%

- Regulatory-grade data privacy and security: compliant with HIPAA, CFR, and all applicable global regs

- Regulatory-grade data capture and cleaning: automated edit checks, data quality SOPs, regular statistical analyses to ensure data quality, etc.

- All IRB approvals and Informed Consent/Assent obtained by BIC via central IRB – including blood, saliva collection, and biobanking storage

- BIC support and materials available for those requiring other institutional approvals

- No software needs to be installed on your institutional or home computers or servers – all web-based. Thus, no need for institutional IT support. Smartphone App use optional

- Easy to add additional forms, studies, material for optional patient participation, education, or support, either for observational or interventional studies

Patient Community Benefits
Giving Back to Our Patient Centered Community

Our insightful patient journey tracking tool is for self discovery, caregiver learning, and detail organization to share with your clinician.

- Easy to use platform through a downloadable app or computer browser on your cell, tablet, or computer

- Tracking tool for entering symptoms and other health care information to look for patterns and triggers

- Eases the overwhelming burden of patient data collection and organization

- Push notifications, patient reminders, video content, information sessions, 24/7 support, research updates

- All patient, guardian, and HCP-entered data, including bio-sample data, in organized, printable PDF reports

- Insight-generating figures & analyses relating to personal patient journey, along with lay explanations

- Compare your own data to others in the platform

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Clinician Community Benefits
Capabilities and Ease of Use

Although this in not a diagnostic or patient communication tool, conducting observational studies on a subset of your patient population can now be done with ease.

- Run observational studies of your own patients, collectively or in groups of your choosing, easily and instantly

- Push-button data analysis via Google Data Studio programs for common data analyses, including benchmarking your own patients vs. database as a whole (anonymized) or in subset (e.g., demographic, healthy controls)

- Access to BIC clinical research design & analysis expertise, as well as system-, protocol-, and HSP-trained BIC staff for additional research task support

- Live and video training available

- 24/7 system support

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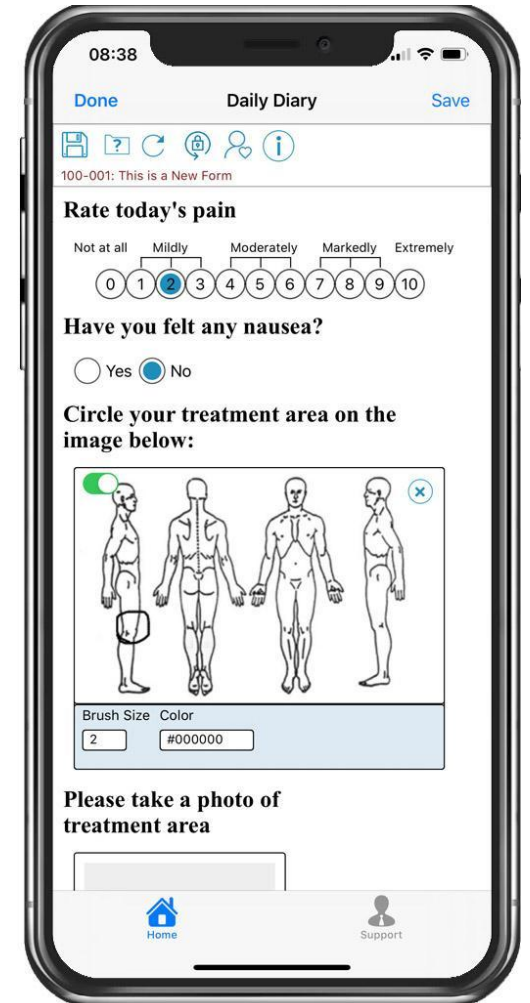# Research Community Benefits

Benefits and Features

We are providing researchers with resources to accomplish their goals. From seeds grants, use of patient data, bio-samples, and publishing help – we want researchers to succeed.

- Access to high-quality, longitudinal patient-and healthy-control generated data collected using standardized tools validated for self-report, guardian-report, and/or HCP-report, as applicable.

- Includes access to biomarker data and banked biosamples for additional laboratory analysis (with BIC approval)

- Very wide range of data capture capacity – anything that can integrate with API (all wearables, other apps); common ones already have existing, tested integrations

- Identification of patients meeting specific criteria, and interested in participating in research, for additional (external) studies

- Use existing database of patients (as a whole, by illnesses studied, or create your own co-horts)

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Integrated Data Collection

Seamlessly Connect Electronic Health Records & Wearables

- Easily enter patient historical data over time – patient/caregiver entry. No support staff needed.

- Connect and incorporate wearables into symptom tracking – sensors can detect anything from body inflammation in sweat to heart stress to sleep habits

- Strengthens ePROs with real time RWE and lesson the burden of reporting for the elderly, young children, and busy parents

- Coordinates patient health data in one easy to use platform – patients and caregivers are often overwhelmed with data organization and multiple sources

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Reporting Capabilities

Patient, Clinician and Researcher Reports

The platform has been designed to provide insights about disease symptomatology, course, severity, and treatment response directly to participating patients, caregivers, clinicians and researchers through easily generated reports.

- Reports that show trends over time
- Comparison of patient data to overall platform data trends
- Generic explanations of how to interpret tables or figures for patients and caregivers
- PDF of all forms completed are available for use in personal record-keeping or sharing with clinicians
- PDF of Casebook
- Trends over time
- Benchmarking
- Symptom vs event associations
- Scatterplots for associations between symptom scores & stress, sleep, etc.
- Export data to .csv file for other uses

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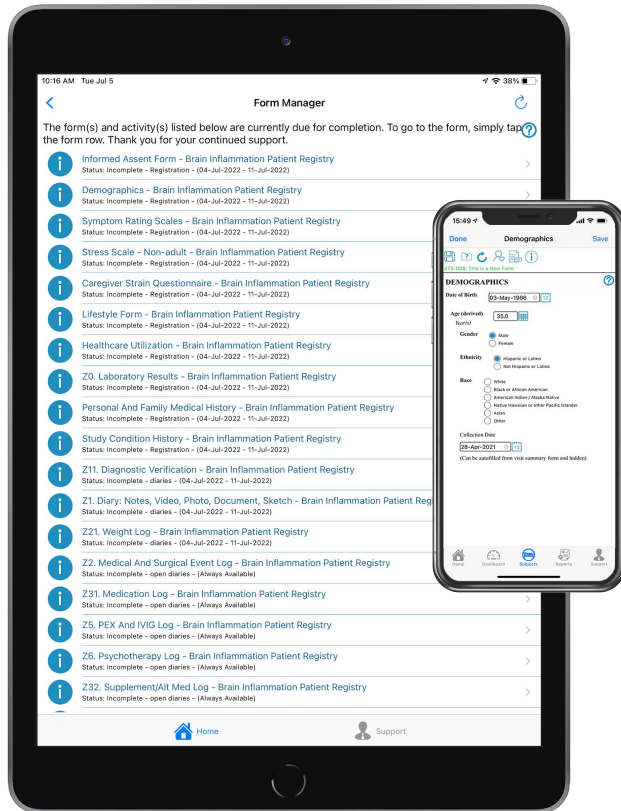
Multiple Device Support

Cell, Tablet and Computer Devices for Patient/Caregiver Data Entry

- Our web-based registry platform is easy for users to login and access from any location or device.

- Patients, Clinicians, and Researchers will have the ability to enter, analyze, or retrieve data from multiple types of devices.

- Central IRB can be used by qualifying investigators

    - Includes umbrella protocol IRB
    - Blood & Saliva Collection

- Biosample banking capabilities – including other types of fluid or body tissue

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Enrollment Forms

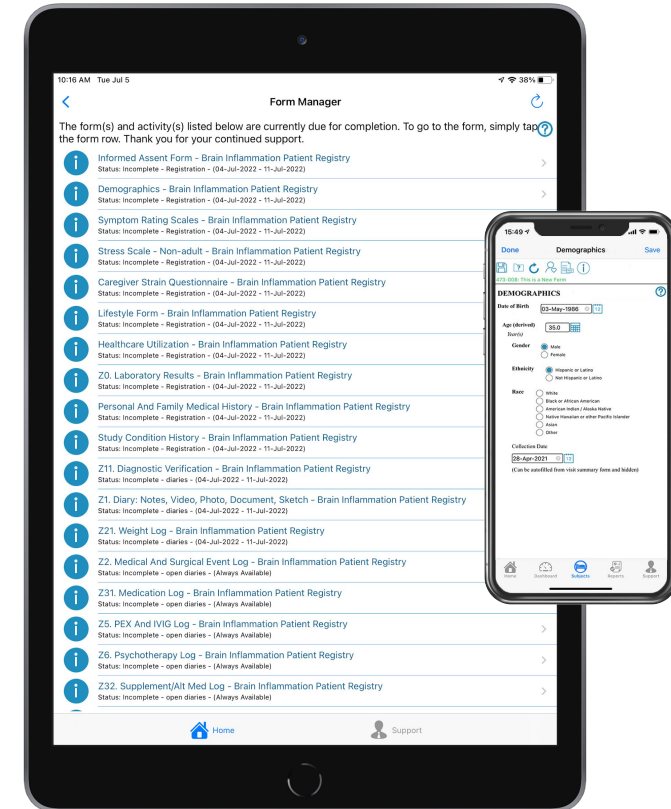Cell, Tablet and Computer Devices for Patient/Caregiver Data Entry

- We provide informed consent for patients, controls, and at-risk siblings 18 & Over. No staff required. Call in center with patient onboarding assistance as needed including diagnosis and basic medical history.

- Assent form for teens (ages 13 to 17). Call in center for onboarding assistance as needed.

- Assent form for children (age 7 to 12). Call in center for onboarding assistance as needed.

- Parents can consent for patients aged 2 to 6.

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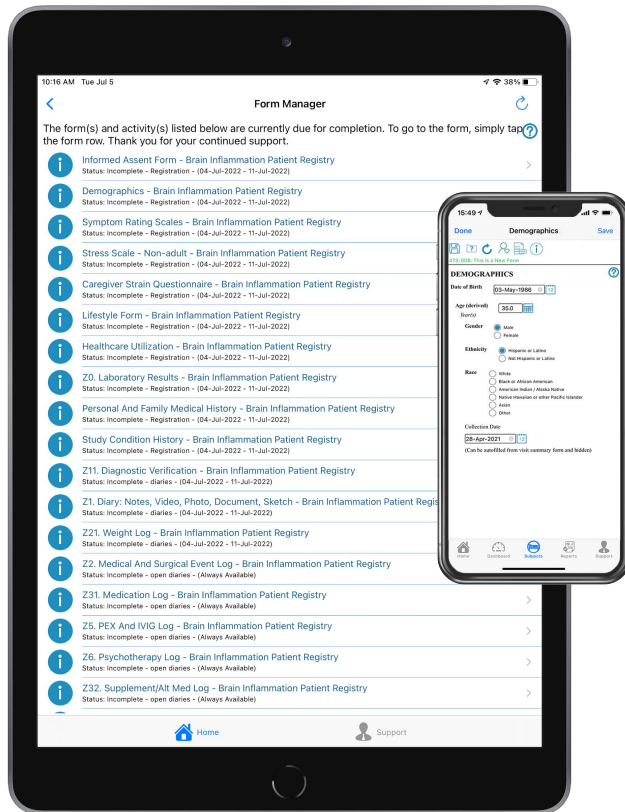Brain Inflammation Collaborative

Weekly Core Forms

Cell, Tablet and Computer Devices for Patient/Caregiver Data Entry

- Weekly welcome
  - List of what to expect for the week
  - Consent/Assent for Biosample collection
  - Option to discontinue the study

- Overall Weekly Summary
  - Flares, stress, & sleep tracking
  - Medication use
  - Infections, injuries, allergic reactions

- Weekly Symptom Update
  - Neuropsychiatric rating scale (obsessions, compulsions, anxiety, depression, irritability, depression, aggression behaviors, etc.)

- Top 3 Patient Concern Tracking

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Additional Core & Log Forms

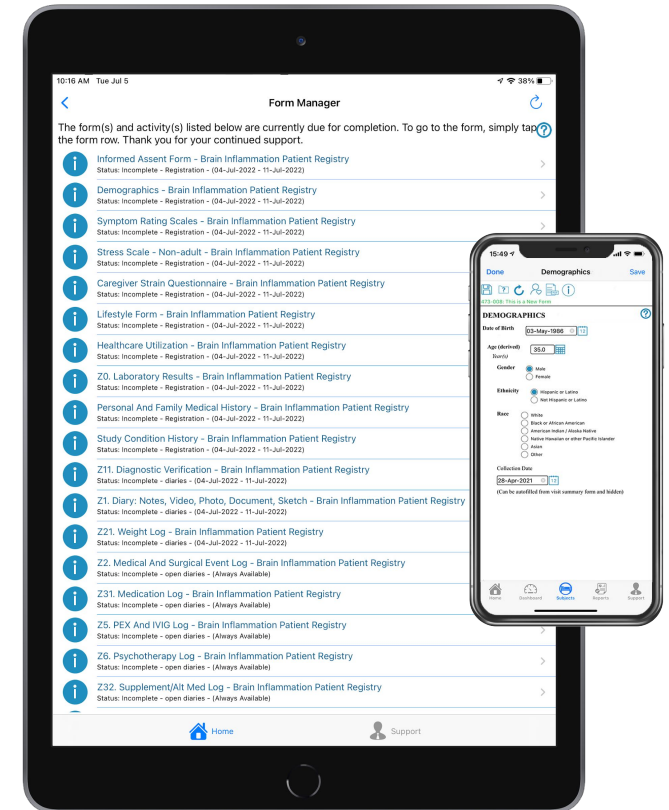Cell, Tablet and Computer Devices for Patient/Caregiver Data Entry

- Demographics & Physical Traits

- Life Events: Stress Scale - (death in the family, move, hospitalization etc)

- Life Events: Social Readjustment Rate Scale (death of spouse, marriage, divorce, move etc.)

- Family Medical History

- IVIG & Plasma Exchange

- Medical, Surgical, & Psych Events History

- Medications, Supplements, Vaccinations

- Psychotherapy & Procedures

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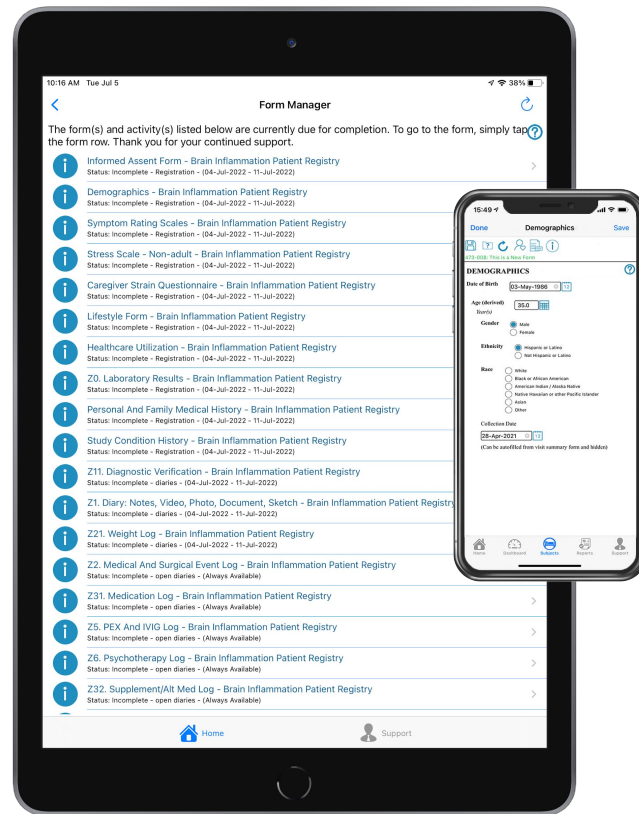# Optional Assessments (Diagnoses or Clinician Driven)

Cell, Tablet and Computer Devices for Data Entry – Patient/Caregiver Entry

- Daily Symptom Tracking

- A sample of our Standardized Neuropsychiatric Forms – Optional (Every 4 weeks)

    - Anger and Irritability Questionnaire
    - Depression and Anxiety Questionnaire
    - Adult ADHD Self-Report Scale
    - Child ADHD Rating Scale: for parents
    - Obsessive Compulsive Inventory
    - Sensory Hypersensitivity Scale
    - Tic Questionnaire
    - Eating Disorder Symptom Questionnaire
    - Family Accommodation Scale
    - Caregiver Strain
    - Fatigue Assessments
    - Other rating scales as desired by HCP (subject to permissions)

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Optional Logs & Diaries

Cell, Tablet and Computer Devices for Data Entry – Patient/Caregiver Entry

- Diary for Patient/Caregiver Notes

- Laboratory & Imaging Results

  - Routine lab work
  - Cunningham Panel
  - Immunology and cytokine testing
  - Endocrinology
  - Infections
  - Genetic Testing (our biobank also provides routine genetic testing)
  - Menstruation & Pregnancies
  - Weight
  - Cognition through Lumosity

Studied Diagnoses - Suspected Cases Included

Due to the significant impacts neuroinflammatory disorders have on patients and the lack of research relating to mental health, the Unhide™ Project will focus on the following and related symptomatology:

- Autoimmune forms of arthritis (e.g. Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis)

- Autoimmune Encephalitis

- Celiac Disease

- Chronic Sinusitis

- Ehlers Danlos Syndrome (EDS)

- Inflammatory Bowel Diseases (IBD, IBS, Crohn's & UC)

- Lupus

- Mast Cell Activation Syndrome (MCAS)

- ME/CFS

- PANDAS

- PANS

- Post-COVID syndromes marked with at least one neurological symptom

- POTS

- Psoriasis

- Sjogren's Syndrome

- Traumatic Brain Injury

- Tourette's

- Bipolar Disorder (clinical-enrolled only)

- Eating disorders involving restrictive eating and/or purging (i.e. Anorexia Nervosa, Bulimia Nervosa, ARFID)

- Major Depression

- Narcolepsy

- Obsessive Compulsive Disorder (OCD) and other anxiety disorders (exclusive of simple phobias)

- Post-Traumatic Stress Disorder (PTSD)

Thank you!

Learn more at braininflammationcollaborative.org or Unhidenow.org

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