

# George T. Gitchel, Ph. D.

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## Expert Witness and Subject Matter Expert for Traumatic Brain Injury Litigation

Passionate researcher with more than 17 years' experience in patient centered clinical research, neurological disorder biomarker development, human factors engineering and innovative leadership positions. Evidence-based with a thorough knowledge of clinical trial project management; strong background in developing protocols for biomarker development and quantitative assessment of traumatic brain injury (TBI). Expertise in biotech applied research, development, and inventing a new class of neurodiagnostic test from inception through completion. Record of device development across the entire lifecycle of a product from conceptual theory through translational medicine, translational research, and regulatory approval, to international implementation, commercialization, and international sales.

### AREAS OF EXPERTISE

- Recognized as an authority in the field of eye tracking development, design, use, analysis, and interpretation.
- Ability to translate quantified eye movements to specific loci of neurological damage or disease. Specifically, oculomotor analysis and quantification for the assessment of TBI, Parkinson's, Stroke, and 30 other disorders.
- Expert in the field of repetitive transcranial magnetic stimulation (rTMS) use, intervention, and analysis.
- Extensive experience with FDA submissions ranging from initial registration, Q-submission, breakthrough device status, qualified biomarker status, and approval.
- Lead projects from initial study conceptualization and design, IRB approval, subject enrollment and data collection, complex novel data analysis, interpretation, publication, formalizing Intellectual Property, licensing to a company for development, and international patent submission and litigation.
- Design, develop, interpret, integrate, and deliver multiple movement quantification devices for complex, multidimensional analysis of movement disorders.
- Strong problem-solving abilities-led a design project that resulted in a superior piece of new lab equipment and objective diagnostic test for clinicians that affects the healthcare of millions.
- Exceptional organizational, prioritization, attention to detail, communication, and time management skills.

### PROFESSIONAL EXPERIENCE

|   |                           |
|---|---------------------------|
| <b>TBI Litigation Support, LLC</b>  | <b>07/2024 to Present</b> |
| <b>Founder and Owner</b>  |                           |
| <ul style="list-style-type: none"><li>• Provide expert witness testimony for litigation involving Traumatic Brain Injury (TBI)</li><li>• Utilizes a nation-wide network of eye tracking devices to provide quantitative reliable data to support or refute a claim of TBI, as well as stratifying the injury into none, concussion, or mild/moderate/severe TBI.</li><li>• Expert witness is blinded to the client/claimant, thereby minimizing any potential bias in the report.</li><li>• Provides clear, easy to understand results with high jury impact.</li></ul>   |                           |
| <b>RightEye LLC</b>   | <b>1/2017 to 05/2024</b>  |
| <b>Expert Witness, Traumatic Brain Injury Consultant and Neurological Disease Specialist</b>  |                           |
| <ul style="list-style-type: none"><li>• Subject Matter Expert in traumatic brain injury and associated eye movements to support or refute diagnoses for legal cases for both plaintiff and defense clients.</li><li>• External scientific consultant in development of a clinical tool for physicians and navigating it through the FDA breakthrough device regulatory pathway.</li><li>• Subject matter expert in eye movements in TBI subjects for numerous litigation cases from personal liability to worker's comp, slip and fall, and more.</li><li>• Licensed a personally developed intellectual property to RightEye through the tech transfer offices of VCU and the VA for commercial development.</li></ul> |                           |

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## **Multidisciplinary Association for Psychedelic Studies (MAPS) Public Benefit Corporation**

**10/2022 to 9/2023**

### **Program and Development Team Leader-Phase 2 Studies and Pipeline Development**

- Developed, organized, and managed a cross-functional team of patient centered outcome research professionals to execute multiple sponsored Phase 2 studies for a first-in-class pharmaceutical.
- Created and refined study startup and progression plans. Independently identified and delivered solutions to routine and complex research issues.
- Strategically planned pipeline and drug development strategies for future indications and compounds focusing on regulatory and timelines both domestically and globally.

## **U. S. Department of Veterans Affairs-Richmond, VA**

**8/2007 to 10/2022**

### **Senior Advisor, Innovation Ecosystem (10/2020 to 10/2022)**

Led the strategic development, integration, and coordination of 5 National Centers of Innovation across the US within the Veterans Health Administration: Innovation Ecosystem.

- Identified emerging trends and technologies to deliver cutting edge care to Veterans. Coordinated efforts with the FDA and outside agencies to establish new healthcare possibilities across five clinical service lines: bio-printing, orthotics & prosthetics, assistive technology, dental, and AI or machine learning.
- Strategically planned and implemented a systematic mechanism by which VHA Innovation Ecosystem enables co-development of emerging technology solutions through collaborative relationships with internal and external partners.

### **Director of Clinical Research (1/2011 to 10/2022)**

Directed the conception, research, development, licensing, regulatory approval, and international sales success of a novel biomarker and diagnostic test for Parkinson's disease and over 28 other neurological disorders. Created strategic plan to build a coalition and create a world-class, multidiscipline research center.

- Invented a breakthrough test for diagnosis of Parkinson's, patented and licensed to industry and used by over 2,500 medical clinics, NFL, NHL, MLB, US Olympics, and others to improve clinical care of neurology patients.
- Independently conducted the development, management, and strategic planning of a robust complex multidisciplinary research program for the Veterans Affairs Parkinson's disease specialty clinic.
- Planned, executed, and conducted applied research for multiple clinical trials at the VA Southeast Regional Parkinson's Disease Research, Education, and Clinical Center. Managed protocol development process; conducted and oversaw data generation and validation, and clinical data review/query resolution.
- Interpreted and translated complex technical neurological R&D, diagnosis, clinical knowledge, and algorithms to layman's terms for engineers, lawyers, and physicians.
- Extensively researched, discovered, and invented a novel and digital health method to differentially diagnose numerous neurological diseases with high accuracy, some of which can be detected >10 years preclinically.

### **Research Assistant (8/2007 to 12/2010)**

- Collected data, completed regulatory paperwork, and interviewed patients as a graduate student.

## **EDUCATION**

### **Virginia Commonwealth University-Richmond, VA**

#### **Ph.D. Biomedical Engineering, 2016**

Concentration areas: Neuroscience, human factors engineering, signal analysis.

Dissertation title: Development of an accurate differential diagnostic tool for neurological movement disorders utilizing eye movements.

#### **M.S. Biomedical Engineering, 2010**

Thesis: Oculomotor Functions in Patients with Parkinson's Disease.

#### **B.S. Biomedical Engineering, 2006**

Concentration areas: Biomechanics and Biomaterials.

## AWARDS AND RECOGNITION

**Federal Labs Consortium Impact Award, 2022.** Personal research was the first within Veterans Affairs to ever be honored with an award from Federal Lab Consortium, which oversees all laboratories within the US federal government.

**Virginia Commonwealth University Inventor of the Year, 2019**

**Innovator's Award in Technology for a Better World, 2018.** Received prestigious award for the product resulting from invention licensed to RightEye, announced at the Consumer Electronics Show (CES) in Las Vegas.

## INTELLECTUAL PROPERTY

- US patent # 10,575,726: Automated analysis system for the detection and screening of neurological disorders and defects, Published March 3, 2020
- International Patent pending: PCT/US2014/023923; Automated Analysis System for the Detection and Screening of Neurological Disorders and Deficits.
- Resulting product, the RightEye Vision System, achieved FDA Clearance for a Class 2 Medical Device. 510k Number: K181771.
- RightEye Vision system granted FDA breakthrough device designation for a Parkinson's disease screening tool.

## FUNDING

- \$1 Million grant awarded from Michael J Fox Foundation investigating the eye movements as a clinical and pre-clinical biomarker in diagnosing Parkinson's disease. Principle Investigator at the McGuire VAMC.
- \$480,000 DARS CNI grant, Principal Investigator, utilizing TMS to study cognition in a TBI population.
- Co-investigator and subject matter expert on the 2 largest grants ever received at Virginia Commonwealth University. CENC and LIMBIC (Combined value of \$112 million).
- DARPA funded study - Investigational study on the effects of hyperbaric oxygen therapy for the improvement of mild traumatic brain injury (HBOT); Sub-investigator.

## TECHNOLOGY EXPERTISE

- Experienced with a broad spectrum of specialty engineering, lab, and design software including SolidWorks, MATLAB, LabVIEW, AutoCAD, SPSS, SigmaPlot, ANSI C/C++, and other general lab equipment.
- Proficient user of Neurocom SMART Balance Master Computed Posturography.
- Proficient in the use of MTS and Instron materials testing load frames and computer control software.

## PUBLICATIONS AND SPEAKING ENGAGEMENTS

See addendum