

OhioHealth Research Institute

2024

New Provider Orientation

What is Research?

The National Institutes of Health (NIH) on Aging describe clinical research as the study of health and illness in people. There are two main types of clinical research: *observational studies* and *clinical trials*.

Clinical Trials

Are studies that test a medical, surgical (device or drug), or behavioral intervention which aims to:

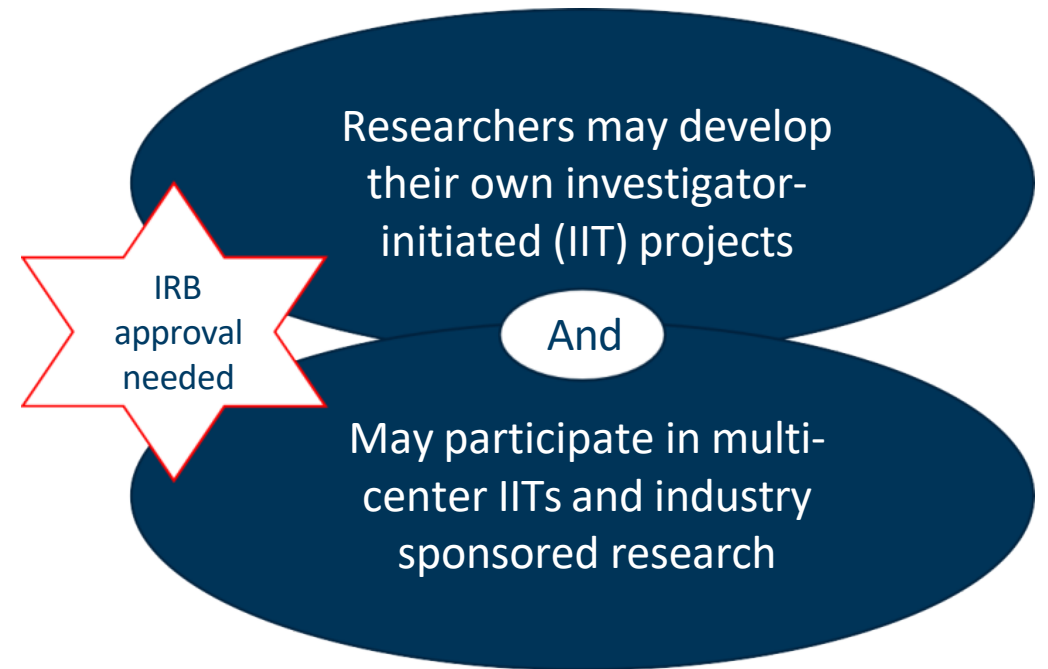
- Evaluate and develop early treatments or diagnosis, new treatments or prevention.
- Learn if new treatments are safe and effective compared to existing treatments.
- Prevent those at risk of developing disease.
- Improve quality of life

Observational Studies

- Do not test medical devices or drugs
- May assist in identifying novel treatments and prevention strategies

What is NOT Research?

- Some quality improvement projects (only an IRB can make this determination)
- Some Scholarly Activity



OHRI oversees Non-Research Activities too!



Examples that require **immediate** support or guidance from OHRI

1. Humanitarian Use Devices

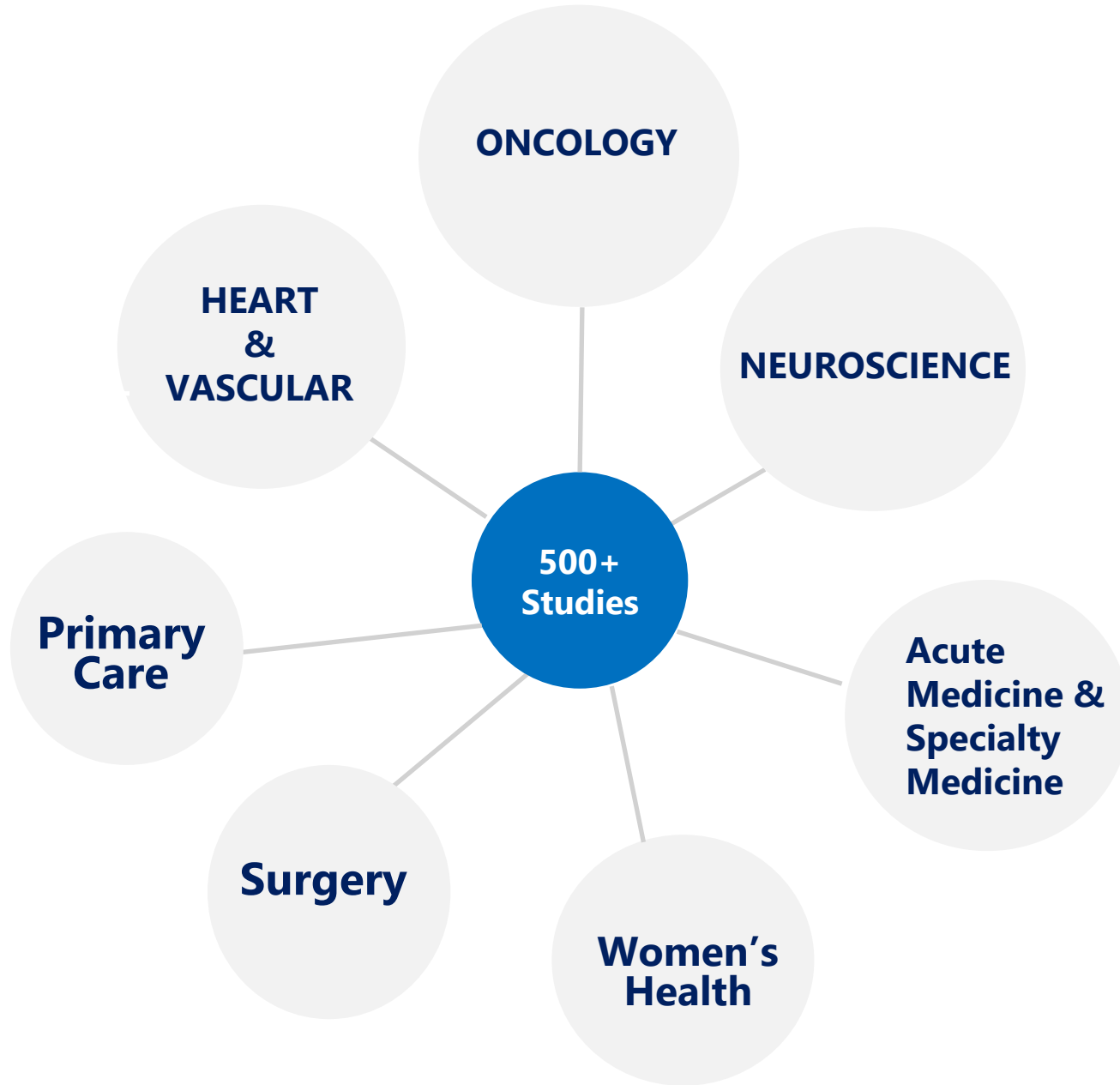
- A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in **not more than 8,000 individuals** in the United States per year (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255))

2. Expanded Access Programs

- Sometimes called “compassionate use”, expanded access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

Please contact ResearchAffairs@ohiohealth.com for assistance.

OHRI Supports All **7** Service Lines



STUDY TYPES

- Investigator Initiated Trials
 - Retrospective
 - Prospective
 - Observational
 - Quality Improvement
 - Interventional
 - Phase 1-4 Clinical Trials
 - Post-market
- = 200+ Actively Enrolling Trials

2023 By the Numbers

OhioHealth Research by the numbers



2023 Top Highlights



Led by **Anish Amin, MD**, OHRI participated in a study (NCT04060680) designed to demonstrate safety and efficacy of the Extravascular Implantable Cardioverter Defibrillator (EV ICD™) System. The device sponsored by Medtronic was **FDA approved** on October 23, 2023. The study involved 356 patients internationally, and of those, 24 were from OhioHealth. Pivotal trial results showing the system's safety and effectiveness were published in *The New England Journal of Medicine*. PMID: 36036522



The NEW ENGLAND
JOURNAL of MEDICINE



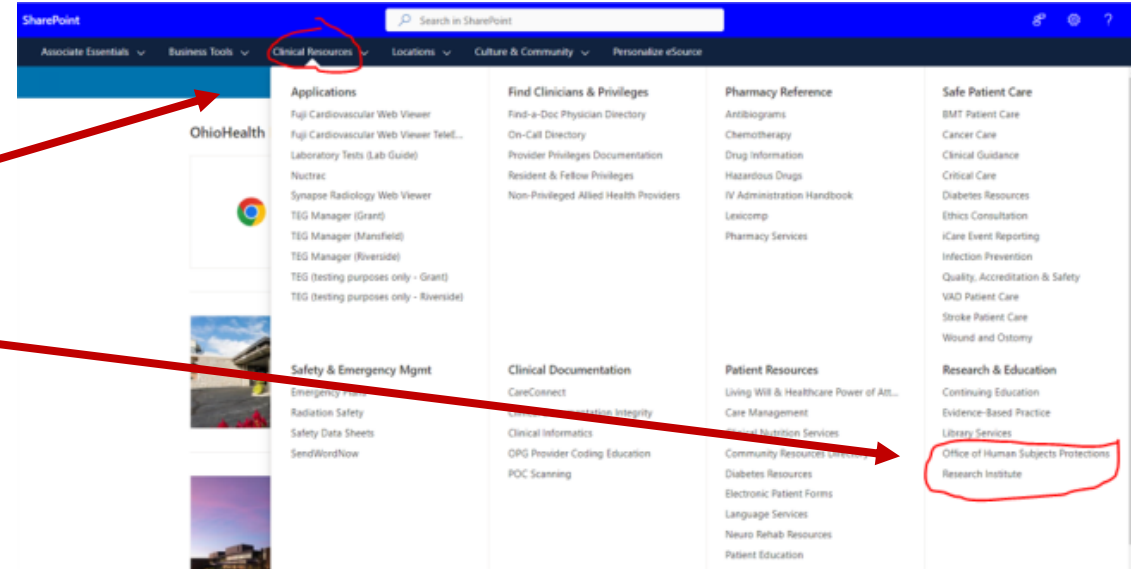
Last year we reported outcomes from our leading clinical trial, MS-PATHS. This was a nationwide, multi-center data-sharing study, with each site collecting standard information on MS patients through the Multiple Sclerosis Performance Test (MSPT), standardized imaging sequences, and data pulled from the electronic medical record. Led by **Jacqueline Nicholas, MD**, Chief of Neuroimmunology and Multiple Sclerosis (MS) and director of MS research, OhioHealth provided invaluable data that would advance new therapies. Nationwide, over 18,000 patients were included in this study that spanned 5 years. OHRI assisted with consenting **5,836 patients** to the study (32%).

Are You Considering a Research Project?

Option
1

Access the OHRI website on eSource for guidance.

- Clinical Resources
- “Research Institute”



Option
2

Ask OHRI using the QR code and OHRI will contact you!
(it's also in our eSource page)





We are more than a health system
We are a belief system
***WE* are OhioHealth**

