

DCRI ARRHYTHMIA CORE LAB

Efficient.
Innovative.
Reliable.

At the DCRI, the Arrhythmia Core Laboratory (ACL) is dedicated to providing high-quality evaluation, adjudication, and validation of electrocardiographic and electrogram review. Led by Jonathan Piccini, MD, MHS, and Associate Director Sean Pokorney, MD, MBA, the ACL has extensive experience in heart rhythm monitoring, 12-lead electrocardiogram and device-based electrogram event adjudication, arrhythmia science, clinical trials design and execution, and outcomes research.

The DCRI ACL has the largest group of HRS board-certified clinical cardiac electrophysiology adjudicators across the globe. We have enrolled more patients in heart rhythm-related trials than any other academic research organization. Our thought leadership, experience, and collaboration with the other trial support units at the DCRI set us apart.

Our ACL is an integral part of the DCRI Clinical Events Classification (CEC) group. The CEC group is committed to providing the highest-quality adjudicated endpoint data with scientific rigor, efficiency, and innovation by coordinating and conducting systematic, comprehensive, unbiased, blinded, and independent clinical events adjudication. With more than 170,000 projects adjudicated, more than 100 trials completed, more than 50 trials ongoing, and more than 32,000 reviews per year, CEC brings discipline to every project—from start to finish.

Select DCRI Electrophysiology Clinical Trials and Core Lab Projects

Trial	Intervention
Mode Selection Trial in Sinus Node Dysfunction (MOST)*	DDDR vs. VVIR
SCD-HeFT*	Primary prevention ICD
Home Automated External Defibrillator Trial (HAT)*	Home AED after MI
ROCKET*	Rivaroxaban vs. warfarin
ARISTOTLE*	Apixaban vs. warfarin
CAT HF Arrhythmia Study*	OSA in HF patients with devices
CABANA	AF ablation vs. medical Rx
GENETIC AF	Genetic-guided BB dosing in AF
APPRAISE ATP ICD Core	Largest randomized ICD trial: ATP vs. no ATP

**Trial completed*

OUR CAPABILITIES AND EXPERTISE

The ACL provides heart rhythm evaluation and adjudication across several modalities and multiple study designs and settings. Our services include:

- Evaluation and adjudication of 12-lead electrocardiograms
- Evaluation and adjudication of ambulatory monitoring tracings and results
- Evaluation and adjudication of device-based diagnostics and electrograms (including but not limited to pacemaker, implantable cardioverter defibrillator, and cardiac resynchronization therapy recordings)
- Design and implementation of core laboratory protocols, study manuals, and procedures

- Quality assurance evaluations and validation for the blinded adjudication process
- Publication and dissemination of study results
- Pre-clinical, phase I, II, and III clinical trials, post-marketing, and observational studies
- Clinical trial design, support, and execution

Plus, our IBM Clinical Development Endpoint Adjudication Module (EAM)[™] allows reviewers to adjudicate electronically with an Internet connection; track the workflow process, providing a full audit trail (21 CFR part 11-compliant); produce reports from executive summary to detailed information; and provide electronic dossiers.



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Find out more about
the DCRI Arrhythmia
Core Lab.

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OUR HISTORY

The DCRI and Duke ACL have participated in numerous studies of heart rhythm therapies over the past 15–20 years. Notable projects include the Mode Selection Trial in Sinus Node Dysfunction (MOST) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). The ACL also served as the core laboratory for the first study of noninvasive ventilation in patients with heart failure and sleep apnea (CAT-HF) and the first pharmacogenetic-guided trial of beta-blocker therapy for the prevention of recurrent AF in patients with heart failure (GENETIC AF).

ACL LEADERSHIP



Jonathan P. Piccini, MD, MHS, FHRS, is the director of the Arrhythmia Core Laboratory. He is a clinical cardiac electrophysiologist and associate professor of medicine at Duke University Medical Center and the Duke Clinical Research Institute. Dr. Piccini is also the director of the Duke Center for Atrial Fibrillation and the Duke Center for Arrhythmia Research and Treatment Innovation at Duke University.

His focus is on the care of patients with atrial fibrillation and complex arrhythmias, with particular emphasis on catheter ablation, left atrial appendage occlusion, and lead extraction. His research interests include the conduct of clinical trials and the assessment of innovative cardiovascular therapeutics for the care of patients with heart rhythm disorders. Dr. Piccini has more than 250 publications in the field of heart rhythm medicine. To search publications, go to dcri.org/publications.



Sean D. Pokorney, MD, MBA, is the associate director of the Arrhythmia Core Laboratory. He is a clinical cardiac electrophysiologist and assistant professor of medicine at Duke University Medical Center and the Duke Clinical Research Institute. His focus is on the care of patients with heart rhythm disorders, particularly those with atrial fibrillation; complex arrhythmias; and lead and device management, with a focus on lead extraction. Dr. Pokorney serves on the Council of Clinical Cardiology Electrocardiography and Arrhythmias Committee for the American Heart Association. He has published extensive research in heart rhythm medicine, including several notable publications in *JAMA*, *Lancet*, *Circulation*, *Journal of the American College of Cardiology*, *Heart Rhythm*, *JACC Electrophysiology*, and *Circulation Arrhythmia and Electrophysiology*.

Dr. Pokorney serves on the Council of Clinical Cardiology Electrocardiography and Arrhythmias Committee for the American Heart Association. He has published extensive research in heart rhythm medicine, including several notable publications in *JAMA*, *Lancet*, *Circulation*, *Journal of the American College of Cardiology*, *Heart Rhythm*, *JACC Electrophysiology*, and *Circulation Arrhythmia and Electrophysiology*.



Tracy Gentry is the project leader for the Duke Arrhythmia Core Laboratory. She is an experienced, PMP-certified manager and scientist with over 20 years of experience in project management, research, pre-clinical and clinical development, quality assurance and regulatory compliance, bench to bedside translation, GMP manufacturing for cellular therapy, staff supervision, and clinical trial support.



Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE