# Yale School of Medicine has an expanding clinical research program with hundreds of clinical trials across a wide variety of disease areas.

Our robust infrastructure affords several ways for you to get involved in clinical research. Whether you want to simply refer patients to research studies or be a Principal Investigator (PI) of your own study, we have the resources to guide you every step of the way with support provided at no cost.

#### Do I need special training?

If you are a referring physician, you have already received the training you need to carry out this role. If you would like to serve as a screening and recruitment site, sub-investigator and trial site, or PI, YCCI provides online and face-to-face training opportunities for human subjects protection and Good Clinical Practice. These online or in-person training sessions are designed to conveniently meet your needs and are provided at no cost.



Cardiologist Alexandra Lansky, MD, conducts research on treatments to improve cardiac care that includes TAVR, a mitral clip for heart failure, and a biodegradable scaffold to open blocked cardiac vessels.

"The high-quality training provided by YCCI for faculty and research staff has been timely and extremely valuable in allowing us to move our research forward."

- Alexandra Lansky, MD, FACC, FAHA, FSCAI, FESC

### HELP US DISCOVER

## Be Part of Clinical Research at Yale

If you are interested in incorporating clinical research into your practice, we are here to help.

#### CONTACT

Kelly Anastasio Associate Director of Clinical Trial Resources (203) 737-6845 or kelly.anastasio@yale.edu

To view a full listing of available studies and learn more about clinical research at Yale, visit yalestudies.org



#### **Yale Center for Clinical Investigation**

2 Church Street South, Suite 114 New Haven, Connecticut 06519 ycci.yale.edu, yalestudies.org

Yale Center for Clinical Investigation In Partnership with Yale Medicine Engaging
Physicians in
Clinical Research
Opportunities

Paul Taheri, MD, MBA
Deputy Dean for Clinical Affairs
and CEO, Yale Medicine

# As a community physician you have full access to the Yale Center for Clinical Investigation's (YCCI's) comprehensive services and expertise to facilitate clinical research.

YCCI supports all aspects of clinical research including:

- **Study Initiation** Study design, grants, and contracts; IRB approval
- **Conducting Research** Protocol development, support staff, study marketing and recruitment, biospecimen management
- Finance Budget preparation, invoicing, payment of research subjects
- **Regulatory Support** Data and safety monitoring, preparation for FDA audits

## YCCI also ovesees OnCore, Yale's electronic clinical research management system.

OnCore reduces the administrative burden on investigators by providing seamless integration of all components of clinical research, including subject administration, calendar and financials functionality, quality assurance monitoring, pre-screening of subjects, and case report forms.

OnCore is integrated with Epic to allow investigators to access clinical data to support their research.

## Yale has a long and renowned history of groundbreaking research on understanding, preventing, and treating diabetes.

In 1979, Yale clinician scientists devised an improved method of delivering insulin to children with type 1 diabetes that led to the development of the insulin pump. More recently, Yale researchers tested an artificial pancreas in teens outside the hospital setting.

On the type 2 diabetes front, Yale scientists are unraveling the molecular mechanisms that lead to juvenile and adult type 2 diabetes in their quest to develop novel therapeutics and treatment strategies to safely and effectively treat patients.

#### What Role Can I Assume In Clinical Research?

#### PROJECT ROLE: REFERRING PHYSICIAN

#### STUDY ACTIVITY:

• Call YCCI recruitment line (1-877-Y-STUDIES)

#### SUPPORT PROVIDED:

Active studies listed at yalestudies.org

#### PROJECT ROLE: SCREENING AND RECRUITMENT SITE

#### STUDY ACTIVITIES:

- Identify YCCI on your protocol
- Screen patients
- Obtain informed consent
- Refer to the trial site for study participation

#### SUPPORT PROVIDED:

- Sponsor approval (usually)
- Study PI approval and collaboration
- Good Clinical Practice training
- Internal Review Board training
- Some coordinator support
- Data entry support

#### **PROJECT ROLE: SUB-INVESTIGATOR**

#### **STUDY ACTIVITIES:**

- Considered an Investigator on the study
- Identify YCCI on your protocol
- Screen patients
- Obtain informed consent
- Conduct study visits
- Complete all data entry
- Handle study drug/device
- Support monitoring visits

#### SUPPORT PROVIDED:

- Sponsor approval
- Study PI approval and collaboration
- Good Clinical Practice training
- Internal Review Board training
- Full-time coordinator support
- Data entry support

#### PROJECT ROLE: STUDY PRINCIPAL INVESTIGATOR

#### STUDY ACTIVITIES:

- Responsible for all aspects of operation and implementation
- · Identify YCCI on your protocol
- Screen patients
- Obtain informed consent
- Conduct study visits
- Complete all data entry
- Handle study drug/device
- Support monitoring visits
- Solely responsible to the conduct of the study

#### SUPPORT PROVIDED:

- Sponsor approval
- Site visit by sponsor (usually)
- Good Clinical Practice training
- Internal Review Board training
- Full-time coordinator support
- Data entry support
- Regulatory support

For most of her life, Claire Wirt, shown here with her mother and grandmother, has participated in a study that aims to prevent, delay, and reverse the progression of type 1 diabetes.

"I wanted to participate in a study because I wanted to help prevent other children and me from getting diabetes and maybe find a cure as well."

- Claire Wirt, Age 9



# STRONG COMMITMENT

LOW COMMITMENT